IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For its complaint herein, Plaintiff alleges as follows:

1. 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.

2. Upon information and belief, defendant Andrx Pharmaceuticals, LLC ("Andrx LLC") is a limited liability company organized under the laws of Delaware, and maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

3. Upon information and belief, Andrx LLC is a wholly-owned subsidiary of Andrx Corporation ("Andrx Corp."), a corporation organized under the laws of Delaware that maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

4. Upon information and belief, Andrx LLC and Andrx Corp. have common officers and directors; the acts of Andrx LLC complained of herein were done at

the direction of, with the authorization of, and with the cooperation, participation and assistance of Andrx Corp.

5. Andrx LLC and Andrx Corp. are referred to hereinafter collectively as "Andrx."

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America and specifically under 35 U.S.C. §271(e) and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

7. Upon information and belief, Andrx, including through subsidiaries, sells various products and does business throughout the United States including this District, and both Defendants are organized under the laws of Delaware.

8. Upon information and belief, Andrx manufactures bulk pharmaceuticals and pharmaceutical products that are sold and used, including through subsidiaries, throughout the United States, including this District.

CLAIM FOR RELIEF

9. Biovail incorporates paragraphs 1-8 by reference herein.

10. United States Patent No. 5,529,791 (hereinafter "the '791 patent") was lawfully granted on June 25, 1996 to Galephar P.R., Inc., Ltd. ("Galephar"), the assignee of the named inventors, Arthur M. Deboeck and Philippe R. Baudier.

11. A copy of the '791 patent is attached as Exhibit A.

12. Biovail is the exclusive licensee of the '791 patent under a September, 1995 Agreement, which remains in full force and effect, and has the exclusive right to sublicense others and to sue for infringement.

13. Biovail is the holder of New Drug Application ("NDA"), No. 21-392, by which the United States Food & Drug Administration ("FDA") first granted approval for 120, 180, 240, 300, 360 and 420 mg extended release tablets including the active ingredient diltiazem hydrochloride. These tablets are marketed in the United States under the tradename Cardizem® LA, and are indicated for the treatment of hypertension, and the management of chronic stable angina.

14. Upon information and belief, Andrx filed in the FDA an Abbreviated New Drug Application ("ANDA") No. 77-686 including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell a generic version of Cardizem® LA 420 mg tablets prior to the expiration of that patent.

15. Upon information and belief, on or about June 22, 2005, Andrx sent a notice letter to Biovail, Galephar, and to Bank of Nova Scotia in which Andrx represented that it had filed an ANDA for Cardizem® LA 420 mg tablets, and that it sought approval of its ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about June 27, 2005.

16. Upon information and belief, the Andrx product that is the subject of its ANDA No. 77-686 will contain beads that will be compressed with other excipients into tablets. On further information and belief, by virtue of the tableting process, beads

of the Andrx product will contain an effective amount of a wetting agent in admixture with one or more Diltiazem salts.

17. Because Andrx seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '791 patent before its expiration, Andrx has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

18. Biovail is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Andrx's ANDA be a date that is not earlier than the expiration date for the '791 patent, or any later expiration of exclusivity for the '791 patent to which Biovail is or becomes entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter a Judgment that:

a. Andrx infringed one or more claims of the '791 patent by submitting the aforesaid ANDA;

b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Andrx, its affiliates and subsidiaries, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, and their successors or assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions as claimed in the '791 patent;

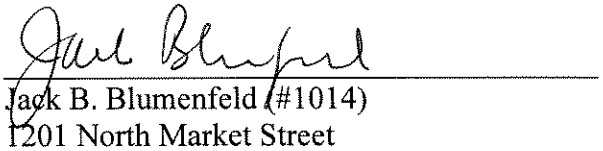
c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Andrx's ANDA No. 77-686 be a date that is not

earlier than the expiration date for the '791 patent, or any later date of exclusivity to which Plaintiffs are or become entitled;

d. To the extent Andrx has committed any acts with respect to the compositions claimed in the '791 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiffs be awarded damages for such acts; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL



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