

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES INTERNATIONAL SRL)	
a corporation of Barbados,)	
)	
Plaintiff,)	C.A. No. _____
)	
v.)	
)	
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. 7,108,866 (hereinafter "the '866 patent") was lawfully granted on September 19, 2006 to Biovail, the assignee of the named inventors, Kenneth Stephen Albert and Paul José Maes.

11. A copy of the '866 patent is attached as Exhibit A.

12. 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.

13. Upon information and belief, Andrx filed in the FDA an amendment to an Abbreviated New Drug Application ("ANDA") No. 77-686 including a certification with respect to the '866 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 generic versions of Cardizem[®] LA 120, 180, 240, 300, 360 mg, 360 mg and 420 mg tablets prior to the expiration of that patent.

14. Upon information and belief, on or about September 19, 2006, Andrx sent a notice letter to Biovail in which Andrx represented that it had filed an amendment to ANDA No. 77-686 for generic versions of Cardizem[®] LA 120, 180, 240, 300, 360, and 420 mg tablets ("Amended ANDA"), and that it sought approval of its Amended ANDA prior to the expiration of the '866 patent. Biovail received a copy of Andrx's notice letter on or about September 22, 2006.

15. Upon information and belief, the Andrx products that are the subjects of its amendment to ANDA No. 77-686 will contain beads compressed with other excipients into tablets that will infringe the '866 patent.

16. Because Andrx seeks approval of its Amended ANDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '866 patent before its expiration, Andrx has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

17. 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 Amended ANDA be a date that is not earlier than the expiration date for the '866 patent, or any later expiration of exclusivity for the '866 patent to which Biovail is or becomes entitled.

18. Andrx's certification to the FDA that the Andrx products will not infringe any claim of the '866 patent was wholly unjustified, and Andrx's baseless assertions make this case exceptional under 35 U.S.C. § 285. Biovail is entitled to the relief provided by 35 U.S.C. § 285, including attorney fees as a result of Andrx's actions.

PRAYER FOR RELIEF

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

- a. Andrx infringed one or more claims of the '866 patent by submitting the aforesaid Amended 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 compounds claimed in the '866 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 Amended ANDA No. 77-686 be a date that is not earlier than the expiration date for the '866 patent, or any later date of exclusivity to which Plaintiff is or becomes entitled;
- d. To the extent Andrx has committed any acts with respect to the compounds claimed in the '866 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts;

e. This is an exceptional case under 35 U.S.C. § 285, and Biovail is entitled to recover its attorney fees; and

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

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October 4, 2006