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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

Biovail Laboratories  
International, SRL,

Plaintiff,

v.

Sun Pharmaceutical Industries,  
Ltd., India,

Defendant.

Civil Action No.:

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Biovail Laboratories International, SRL, for its Complaint against Defendant Sun Pharmaceutical Industries, Ltd., India, hereby states as follows:

**THE PARTIES**

1. Plaintiff Biovail Laboratories International, SRL (“Biovail”) is a limited liability entity organized and existing under the laws of the nation of Barbados, having a principal place of business at Collymore Rock in St. Michael, Barbados, West Indies.

2. On information and belief, defendant Sun Pharmaceutical Industries, Ltd., India (“Sun India”) is an alien corporation having a principal place of business in Mumbai, India.

**NATURE OF THE ACTION**

3. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*

**JURISDICTION AND VENUE**

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has jurisdiction over the person of Sun India due to, *inter alia*, Sun India's consent to jurisdiction in conformance with 21 C.F.R. § 314.95(c)(7) and its systematic and continuous contacts with New Jersey. Upon information and belief, Sun India manufactures drugs that are purposefully distributed throughout the United States, including in this Judicial District, either directly or through its wholly-owned subsidiaries or agents, and Sun India therefore is subject to the jurisdiction of this Court. In addition, upon information and belief, this Court has personal jurisdiction over Sun India by virtue of the presence of its wholly-owned subsidiaries and agents in this Judicial District which, among other things, own real property, lease real property, and maintain a registered agent in New Jersey.

6. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) & (d) and 1400(b).

**THE PATENTS**

7. Biovail is the assignee of U.S. Patent No. 5,286,497 ("the '497 patent"), duly and legally issued on February 15, 1994, to inventors Dennis L. Hendrickson *et al.* The '497 patent is entitled "Diltiazem Formulation." A true and correct copy of the '497 patent is attached hereto as Exhibit 1.

8. Biovail is the assignee of U.S. Patent No. 5,439,689 ("the '689 patent"), duly and legally issued on August 8, 1995, to inventors Dennis L. Hendrickson *et al.* The '689 patent is entitled "Diltiazem Formulation." A true and correct copy of the '689 patent is attached hereto as Exhibit 2.

9. Biovail is the assignee of U.S. Patent No. 5,470,584 ("the '584 patent"), duly and legally issued on November 28, 1995, to inventors Dennis L. Hendrickson *et al.* The '584 patent is entitled "Diltiazem Formulation." A true and correct copy of the '584 patent is attached hereto as Exhibit 3.

**ACTS GIVING RISE TO THIS ACTION**

10. Biovail is the holder of approved New Drug Application No. 020062 for Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules. Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules are distributed and used throughout the United States,

including in this Judicial District, for the treatment of cardiovascular disorders, including hypertension and angina.

11. Through its U.S. agent, Sun India submitted Abbreviated New Drug Application No. 90-492 (“Sun India’s ANDA”) to the United States Food and Drug Administration (“FDA”) under 21 U.S.C. § 355(j). Sun India’s ANDA seeks approval to market diltiazem hydrochloride extended release capsules in 120, 180, 240, 300, and 360 mg strengths as generic equivalents to Biovail’s Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules.

12. By letters dated June 25, 2008 (“Notification Letters”), Sun India notified Biovail that it had submitted Sun India’s ANDA. Sun India’s Notification Letters also indicated that Sun India intends to market diltiazem hydrochloride extended release capsules prior to the stated expiration dates of the ‘497, ‘689, and ‘584 patents.

13. In its Notification Letters, Sun India also notified Biovail that Sun India’s ANDA indicates that to the best of Sun India’s knowledge, the manufacture, use, or sale of Sun India’s diltiazem hydrochloride extended release capsules would not infringe the ‘497, ‘689, and ‘584 patents.

**COUNT I: INFRINGEMENT OF  
UNITED STATES PATENT NO. 5,286,497  
UNDER 35 U.S.C. § 271(e)(2)**

14. Biovail incorporates by reference paragraphs 1-13 of this Complaint as if fully set forth herein.

15. Sun India’s submission of Sun India’s ANDA to obtain approval for the commercial manufacture, sale, or use of Sun India’s diltiazem hydrochloride extended release capsules before the expiration of the ‘497 patent constitutes infringement of one or more of the claims of the ‘497 patent pursuant to 35 U.S.C. § 271(e)(2).

16. On information and belief, Sun India’s submission of its ANDA constitutes intentional and willful infringement of the ‘497 patent.

17. Biovail will be substantially and irreparably harmed by Sun India’s infringing activities unless those activities are enjoined by this Court. Biovail has no adequate remedy at law.

**COUNT II: DECLARATION OF INFRINGEMENT OF  
UNITED STATES PATENT NO. 5,286,497**

18. Biovail incorporates by reference paragraphs 1-17 of this Complaint as if fully set forth herein.

19. On information and belief, Sun India's ANDA alleges that all dosage strengths of its diltiazem hydrochloride extended release capsules are bioequivalent to the corresponding dosage strengths of the Reference Listed Drug (RLD), that is, Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules.

20. All dosage strengths of Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules are covered by one or more claims of the '497 patent.

21. On information and belief, all dosage strengths of Sun India's ANDA threaten to infringe, directly, contributorily, and/or by way of inducement, one or more claims of the '497 patent.

22. On information and belief, Sun India intends to engage in the commercial manufacture, use, and sale of diltiazem hydrochloride extended release capsules promptly upon receiving FDA approval to do so.

23. Based on Sun India's allegations of bioequivalence of its diltiazem hydrochloride extended release capsules to Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules, the '497 patent's coverage of Sun India's product and Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules, and Sun India's intent to engage in the commercial manufacture, use, and sale of diltiazem hydrochloride extended release capsules promptly upon receiving FDA approval to do so, there exists an actual controversy between the parties.

24. Biovail requests a declaratory judgment in its favor of infringement of the '497 patent.

25. Biovail will be substantially and irreparably harmed by Sun India's infringing activities unless those activities are enjoined by this Court. Biovail has no adequate remedy at law.

**COUNT III: INFRINGEMENT OF  
UNITED STATES PATENT NO. 5,439,689  
UNDER 35 U.S.C. § 271(e)(2)**

26. Biovail incorporates by reference paragraphs 1-25 of this Complaint as if fully set forth herein.

27. Sun India's submission of Sun India's ANDA to obtain approval for the commercial manufacture, sale, or use of Sun India's diltiazem hydrochloride extended release capsules before the expiration of the '689 patent constitutes infringement of one or more of the claims of the '689 patent pursuant to 35 U.S.C. § 271(e)(2).

28. On information and belief, Sun India's submission of its ANDA constitutes intentional and willful infringement of the '689 patent.

29. Biovail will be substantially and irreparably harmed by Sun India's infringing activities unless those activities are enjoined by this Court. Biovail has no adequate remedy at law.

**COUNT IV: DECLARATION OF INFRINGEMENT OF  
UNITED STATES PATENT NO. 5,439,689**

30. Biovail incorporates by reference paragraphs 1-29 of this Complaint as if fully set forth herein.

31. On information and belief, Sun India's ANDA alleges that all dosage strengths of its diltiazem hydrochloride extended release capsules are bioequivalent to the corresponding dosage strengths of the Reference Listed Drug (RLD), that is, Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules.

32. All dosage strengths of Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules are covered by one or more claims of the '689 patent.

33. On information and belief, all dosage strengths of Sun India's ANDA threaten to infringe, directly, contributorily, and/or by way of inducement, one or more claims of the '689 patent.

34. On information and belief, Sun India intends to engage in the commercial manufacture, use, and sale of diltiazem hydrochloride extended release capsules promptly upon receiving FDA approval to do so.

35. Based on Sun India's allegations of bioequivalence of its diltiazem hydrochloride extended release capsules to Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release

capsules, the '689 patent's coverage of Sun India's product and Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules, and Sun India's intent to engage in the commercial manufacture, use, and sale of diltiazem hydrochloride extended release capsules promptly upon receiving FDA approval to do so, there exists an actual controversy between the parties.

36. Biovail requests a declaratory judgment in its favor of infringement of the '689 patent.

37. Biovail will be substantially and irreparably harmed by Sun India's infringing activities unless those activities are enjoined by this Court. Biovail has no adequate remedy at law.

**COUNT V: INFRINGEMENT OF  
UNITED STATES PATENT NO. 5,470,584  
UNDER 35 U.S.C. § 271(e)(2)**

38. Biovail incorporates by reference paragraphs 1-37 of this Complaint as if fully set forth herein.

39. Sun India's submission of Sun India's ANDA to obtain approval for the commercial manufacture, sale, or use of Sun India's diltiazem hydrochloride extended release capsules before the expiration of the '584 patent constitutes infringement of one or more of the claims of the '584 patent pursuant to 35 U.S.C. § 271(e)(2).

40. On information and belief, Sun India's submission of its ANDA constitutes intentional and willful infringement of the '584 patent.

41. Biovail will be substantially and irreparably harmed by Sun India's infringing activities unless those activities are enjoined by this Court. Biovail has no adequate remedy at law.

**COUNT VI: DECLARATION OF INFRINGEMENT OF  
UNITED STATES PATENT NO. 5,470,584**

42. Biovail incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

43. On information and belief, Sun India's ANDA alleges that all dosage strengths of its diltiazem hydrochloride extended release capsules are bioequivalent to the corresponding dosage strengths of the Reference Listed Drug (RLD), that is, Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules.

44. All dosage strengths of Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules are covered by one or more claims of the '584 patent.

45. On information and belief, all dosage strengths of Sun India's ANDA threaten to infringe, directly, contributorily, and/or by way of inducement, one or more claims of the '584 patent.

46. On information and belief, Sun India intends to engage in the commercial manufacture, use, and sale of diltiazem hydrochloride extended release capsules promptly upon receiving FDA approval to do so.

47. Based on Sun India's allegations of bioequivalence of its diltiazem hydrochloride extended release capsules to Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules, the '584 patent's coverage of Sun India's product and Biovail's Cardizem<sup>®</sup> CD diltiazem hydrochloride extended release capsules, and Sun India's intent to introduce engage in the commercial manufacture, use, and sale of diltiazem hydrochloride extended release capsules promptly upon receiving FDA approval to do so, there exists an actual controversy between the parties.

48. Biovail requests a declaratory judgment in its favor of infringement of the '584 patent.

49. Biovail will be substantially and irreparably harmed by Sun India's infringing activities unless those activities are enjoined by this Court. Biovail has no adequate remedy at law.

#### **PRAYER FOR RELIEF**

Wherefore, Biovail respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Sun India's submission to the FDA of ANDA No. 90-492 to obtain approval for the commercial manufacture, use, offer for sale, and/or sale in, or importation into, the United States of the Sun India diltiazem hydrochloride extended release capsules before the expiration of the '497, '689, and '584 patents was and is an act of infringement of the '497, '689, and '584 patents;

(2) declaring that Sun India's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun India's diltiazem hydrochloride extended release capsules would constitute infringement of the '497, '689, and '584 patents;

(3) ordering that the effective date of any FDA approval of Sun India's diltiazem hydrochloride extended release capsules shall be no earlier than the expiration dates of the '497, '689, and '584 patents, in accordance with 35 U.S.C. § 271(e)(4)(A);

(4) enjoining Sun India and all persons acting in concert with Sun India from commercially manufacturing, using, offering for sale, or selling Sun India's diltiazem hydrochloride extended release capsules within the United States, or importing Sun India's diltiazem hydrochloride extended release capsules into the United States, until the expiration of the last of the '497, '689, and '584 patents, in accordance with 35 U.S.C. § 271(e)(4)(B);

(5) enjoining Sun India and all persons acting in concert with Sun India from seeking, obtaining, or maintaining approval of ANDA No. 90-492 until the expiration of the '497, '689, and '584 patents;

(6) declaring that the '497, '689, and '584 patents would be directly, contributorily infringed, and/or infringed by inducement, by all dosage strengths of Sun India's diltiazem hydrochloride extended release capsules;

(7) declaring this to be an exception case and awarding Biovail its attorney fees under 35 U.S.C. § 285;

(8) awarding Biovail its costs and expenses in this action; and


(9) awarding Biovail any further and additional relief as this Court deems just and proper.

**DESIGNATION OF TRIAL COUNSEL**

Paul S. Tully, Esq. is hereby designated as trial counsel.

Dated: August 8, 2008

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