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

ELAN PHARMA INTERNATIONAL LTD. and FOURNIER LABORATORIES IRELAND LTD.,	)	
Plaintiffs,	)	**Civil Action No. _____**
v.	)	
BIOVAIL LABORATORIES INTERNATIONAL SRL and BIOVAIL CORPORATION,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Elan Pharma International Ltd. ("Elan") and Fournier Laboratories Ireland Ltd. ("Fournier") for their Complaint against Biovail Laboratories International SRL ("Biovail SRL") and Biovail Corporation ("Biovail Corp.") (collectively "Biovail") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 5,145,684 ("the '684 patent"), 7,276,249 ("the '249 patent"), and 7,320,802 ("the '802 patent"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of the highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents, and is based on the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

THE PARTIES

2. Elan Pharma International Ltd. is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

3. Fournier Laboratories Ireland Ltd. is an Irish corporation having a principal place of business at Anngrove Carrigtwohill, Co. Cork, Ireland.

4. Biovail SRL is an International Society with Restricted Liability formed under the Societies with Restricted Liability Act of Barbados, having its principal place of business at Chelston Park, Building 2, Collymore Rock, St. Michael, Barbados. On information and belief, Biovail SRL is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Biovail SRL is a wholly-owned subsidiary of Biovail Corp.

5. Biovail Corp. is a corporation organized and existing under the laws of Canada, having its principal place of business at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada. On information and belief, Biovail Corp. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Biovail SRL. On information and belief, Biovail Corp.

has at all times relevant to this Complaint directed, encouraged, controlled, authorized, and participated in the actions of Biovail SRL at issue in this case.

JURISDICTION AND VENUE

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

7. On information and belief, this Court has personal jurisdiction over Biovail SRL because Biovail SRL has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Biovail SRL has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

8. On August 8, 2008, Biovail SRL filed a patent infringement lawsuit in this judicial district against Sun Pharmaceutical Industries, Ltd., India, in Case No. 2:08-cv-04005-WJM-MF, which is currently pending.

9. On information and belief, this Court has personal jurisdiction over Biovail Corp. because Biovail Corp. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Biovail Corp. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

10. On February 22, 2006, Biovail Corp. purposely availed itself of the laws of New Jersey by filing a lawsuit in New Jersey Superior Court. The suit was removed to this Court in Case No. 2:06-cv-01625-SRC-CCC.

11. On information and belief, Biovail Corp. encouraged, directed, and/or participated in the submission to the United States Food and Drug Administration ("FDA") of the ANDA at issue in this case.

12. On information and belief, Biovail Corp. and Biovail SRL operate as an integrated, unitary business. For example, Biovail Corp. states in its regulatory filings that references to "the 'Company,' 'Biovail,' 'we,' 'us,' 'our,' or similar words or phrases are to Biovail Corporation and its subsidiaries taken together." On further information and belief, Biovail Corp. includes within its U.S. regulatory filings the activities of Biovail SRL, including revenue earned.

13. Biovail Corp. maintains a website at the URL www.biovail.com. Biovail Corp.'s website serves as the website for all of Biovail Corp.'s subsidiaries, including Biovail SRL, with the sole exception of Biovail's Contract Research Division, which according to the Biovail website, "operates as an independent business unit." On the Biovail website, the activities of Biovail SRL are attributed to Biovail Corp. For example, Biovail Corp.'s website, www.biovail.com (About Biovail Section), states that Biovail SRL "develops, manufactures, and sells Biovail's pharmaceutical products."

14. On September 3, 2008, Biovail Corp. announced the filing of the ANDA at issue in this Complaint. *See* Biovail Corp. Announcement, *available at* http://www.biovail.com/english/Investor%20Relations/Latest%20News/default.asp?s=1&state=showrelease&releaseid=1193368 (attached as Ex. A). Biovail Corp. attributed the infringing acts at issue in this Complaint not to Biovail SRL, but to itself.

15. Biovail Corp.'s website further identifies BTA Pharmaceuticals, Inc. as Biovail Corp.'s wholly owned subsidiary in charge of U.S. product distribution and regulatory

affairs. On information and belief, BTA Pharmaceuticals, Inc. has a principal place of business in Bridgewater, New Jersey.

16. On information and belief, Biovail Pharmaceuticals, Inc., Biovail Distribution Corporation, Biovail Americas Corporation, Biovail Technologies, Ltd., and BTA Pharmaceuticals, Inc. are wholly-owned U.S. subsidiaries of Biovail Corp. registered to do business in New Jersey.

17. A related lawsuit is currently pending in this Court. On February 29, 2008, Elan and Fournier filed suit in this Court against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the '684, '249, and '802 patents is infringed by Teva's filing of its ANDA No. 90-069. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-1085 (D.N.J.).

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

19. On September 8, 1992, the '684 patent, entitled "Surface Modified Drug Nanoparticles," was duly and legally issued. A true and correct copy of the '684 patent is attached as Exhibit B. Elan is the current assignee of the '684 patent.

20. On October 2, 2007, the '249 patent, entitled "Nanoparticulate Fibrate Formulations," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '249 patent is attached as Exhibit C.

21. On January 22, 2008, the '802 patent, entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '802 patent is attached as Exhibit D.

22. On November 5, 2004, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-656 for TRICOR® tablets, which contain fenofibrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia and to reduce elevaled LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia, or mixed dyslipidemia.

23. The '684, '249, and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

24. On information and belief, Biovail submitted ANDA No. 90-715 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages ("Biovail's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145mg tablets.

25. By letter dated September 19, 2008, Biovail advised Elan and Fournier that it had submitted ANDA No. 90-715 seeking approval to manufacture, use, or sell Biovail's Tablets, 48 mg and 145 mg, prior to the expiration of the '684, '249, and '802 patents.

26. The September 19, 2008 letter also advised Elan and Fournier that Biovail's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Biovail's opinion, the '684, '249, and '802 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Biovail's Tablets, 48 mg and 145 mg.

COUNT I

27. Plaintiffs incorporate each of the preceding paragraphs 1-26 as if fully set forth herein.

28. By filing ANDA No. 90-715 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Biovail's Tablets, 48 mg and 145 mg, prior to the expiration of the '684 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '684 patent under 35 U.S.C. § 271(e)(2).

29. The commercial manufacture, use, offer to sell, sale, or importation of Biovail's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '684 patent under 35 U.S.C. § 271.

30. On information and belief, Biovail was aware of the existence of the '684 patent and was aware that the filing of its ANDA and certification with respect to the '684 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

31. Plaintiffs incorporate each of the preceding paragraphs 1-26 as if fully set forth herein.

32. By filing ANDA No. 90-715 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Biovail's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '249 patent under 35 U.S.C. § 271(e)(2).

33. The commercial manufacture, use, offer to sell, sale, or importation of Biovail's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '249 patent under 35 U.S.C. § 271.

34. On information and belief, Biovail was aware of the existence of the '249 patent and was aware that the filing of its ANDA and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

COUNT III

35. Plaintiffs incorporate each of the preceding paragraphs 1-26 as if fully set forth herein.

36. By filing ANDA No. 90-715 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Biovail's Tablets, 48 mg and 145 mg, prior to the expiration of the '802 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '802 patent under 35 U.S.C. § 271(e)(2).

37. The commercial manufacture, use, offer to sell, sale, or importation of Biovail's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '802 patent under 35 U.S.C. § 271.

38. On information and belief, Biovail was aware of the existence of the '802 patent and was aware that the filing of its ANDA and certification with respect to the '802 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Biovail has infringed the '684, '249, and '802 patents;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Biovail's ANDA No. 90-715 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '684, '249, and '802 patents;

C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Biovail and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '684, '249, and '802 patents for the full terms

thereof;

D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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