

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK**

**ABBOTT LABORATORIES and** )  
**LABORATOIRES FOURNIER S.A.,** )  
 )  
**Plaintiffs,** )  
 )  
**v.** )  
 )  
**BIOVAIL LABORATORIES** )  
**INTERNATIONAL SRL and** )  
**BIOVAIL CORPORATION,** )  
 )  
**Defendants.** )  
 )

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR  
PATENT INFRINGEMENT**

Abbott Laboratories ("Abbott") and Laboratoires Fournier S.A. ("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. 6,277,405 ("the '405 patent"), 7,037,529 ("the '529 patent"), and 7,041,319 ("the '319 patent"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell a generic copy of Plaintiffs' highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

**THE PARTIES**

2. Plaintiff Abbott Laboratories is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Plaintiff Laboratoires Fournier S.A. is a French corporation having its principal place of business at 28 Boulevard Clemenceau, 21000 Dijon, France.

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 Corporation 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. By letter dated September 30, 2008, Biovail SRL's counsel indicated that his firm was designated as the agent for service of process at an address in Rochester, New York pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. As a result, this Court has personal jurisdiction over Biovail SRL.

8. 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.

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 York'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. The Biovail Corp. website, located at the URL [www.biovail.com](http://www.biovail.com), also regularly and routinely solicits commercial activity in this district and in New York State, by:

- a. Permitting New York residents to solicit Biovail product information and comment on Biovail products (*see* <http://www.biovail.com/english/products/default.asp?s=1>, <http://www.biovail.com/english/Products/default.asp?s=1&state=productlist&country=USA&viewer=patient> and <http://www.biovail.com/english/Products/default.asp?s=1&state=productlist&country=USA&viewer=doctor>);
- b. Inviting New York residents to receive e-mail alerts from Biovail on its SEC filings, its news releases and its upcoming events (*see* <http://www.biovail.com/english/investor%20relations/default.asp?s=1> and <http://www.biovail.com/english/contact%20us/default.asp?s=1>);

- c. Offering employment opportunities to New York residents (*see* <http://www.biovail.com/english/careers/default.asp?s=1>); and
- d. Soliciting interest from New Yorkers in investing in Biovail, and in communicating directly with Biovail's investor relations group (*see* <http://www.biovail.com/english/investor%20relations/default.asp?s=1>).

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."

13. On further information and belief, Biovail Corp. includes within its U.S. regulatory filings the activities of Biovail SRL, including revenue earned.

14. Biovail Corp.'s website, [www.biovail.com](http://www.biovail.com), 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."

15. On the Biovail website, the activities of Biovail SRL are attributed to Biovail Corp. For example, Biovail Corp.'s website, [www.biovail.com](http://www.biovail.com) (About Biovail Section), states that Biovail SRL "develops, manufactures, and sells Biovail's pharmaceutical products."

16. 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=snowrelease&releaseid=1193368> (attached as Ex. A).

17. In its September 3, 2008 announcement, Biovail Corp. attributed the infringing acts at issue in this Complaint not to Biovail SRL, but to itself.

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

### **BACKGROUND**

19. Fournier is the owner by assignment of: (a) the '405 patent (attached hereto as Exhibit B); (b) the '529 patent (attached hereto as Exhibit C); and (c) the '319 patent (attached hereto as Exhibit D). The '405, '529, and '319 patents are collectively referred to herein as the "Patents-in-Suit."

20. The '405 and '529 patents are titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It." The '319 patent is titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability."

21. The Patents-in-Suit each expressly claim priority to and seek the benefit of a French patent application, No. 97 00479, dated January 17, 1997 ("the '479 application").

22. Pawan Seth and André Stamm are the named inventors on the Patents-in-Suit and on the '479 application.

23. Abbott is the exclusive licensee of the Patents-in-Suit.

24. The Patents-in-Suit, which currently expire on January 9, 2018, each claim novel fenofibrate compositions that exhibit a particular dissolution profile.

25. Fenofibrate is useful as a lipid and cholesterol lowering agent for treatment of adults with increased triglyceride levels.
26. Abbott has approval from the FDA to market fenofibrate tablets under the name TRICOR®.
27. TRICOR® (fenofibrate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under provisions of 21 U.S.C. § 355(j).
28. The FDA's "Orange Book" also lists patents associated with approved drugs. The Patents-In-Suit are listed in the "Orange Book" in association with TRICOR® (fenofibrate).
29. 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 a generic version of the TRICOR® 48 mg and 145 mg tablets.
30. By letter dated September 19, 2008, sent from an office located in this judicial district, Biovail advised Abbott 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 Patents-in-Suit.

31. The September 19, 2008 letter also advised Abbott 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 Patents-in-Suit 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.

32. On November 22, 1996, Pawan Seth, on behalf of Pharma Pass S.A., executed an "Invention Assignment and Cooperation Agreement" ("Assignment") with Fournier. In this Assignment, Pharma Pass S.A. assigned to Fournier the patent right for the '479 application, "Pharmaceutical Composition of Fenofibrate with High Availability and Its Preparation Method" as well as the patent rights for what became the Patents-in-Suit.

33. On information and belief, in December 2002, Biovail Corp. acquired Pharma Pass S.A. and Pharma Pass LLC.

34. On information and belief, Biovail currently receives royalty payments from Fournier as a result of the assignment of the '479 application.

35. Biovail, as the recipient of such royalties and the direct successor-in-interest to Pharma Pass S.A., is in privity with Pharma Pass S.A. and, under the doctrine of assignor estoppel, is estopped from contending that any patent claiming priority to the '479 application, including the Patents-in-Suit, is invalid and/or unenforceable.

36. This complaint is not the first-filed action relating to this dispute. Plaintiffs earlier filed a suit in the United States District Court for the Northern District of Illinois identical to this action. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-CV-6274 (N.D. Ill.) The present action has been filed to protect Plaintiffs' rights pursuant to 21 U.S.C. § 355(j) in the unlikely event that the first-filed action relating to this dispute does not proceed.

37. Plaintiffs filed first in the Northern District of Illinois because there is an existing litigation against a different defendant in that court involving the same patents. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-1243 (N.D. Ill.).

### COUNT I

38. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 37 hereof, as if fully set forth herein.

39. 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Biovail's submission of an ANDA for approval to sell fenofibrate tablets in 48 mg and 145 mg dosages prior to the expiration of the Patents-in-Suit constitutes an act of infringement of one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). In addition, Biovail's Tablets, 48 mg and 145 mg infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

40. On information and belief, Biovail acted without a reasonable basis or a good faith belief that it would not be liable for infringing the Patents-in-Suit.

41. Plaintiffs have no adequate remedy at law to redress Biovail's infringement.

42. Biovail's conduct renders this case "exceptional" as described in 35 U.S.C. § 285, which warrants an award of Plaintiffs' reasonable attorney fees.

43. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the Patents-in-Suit.

## **COUNT II**

44. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 37 hereof, as if fully set forth herein.

45. Through the conduct alleged above, Biovail Corp. has knowingly and actively induced Biovail SRL to infringe, and continue to infringe, one or more claims of each of the Patents-in-Suit.

46. By reason of Biovail Corp.'s inducement of Biovail SRL's direct infringement of the Patents-in-Suit, Biovail Corp. has caused and continues to cause irreparable harm to Plaintiffs.

47. On information and belief, Biovail Corp.'s inducement of Biovail SRL's direct infringement of the Patents-in-Suit will continue unless enjoined by this Court.

48. Plaintiffs have no adequate remedy at law for Biovail Corp.'s inducement of Biovail SRL's direct infringement of the Patents-in-Suit.

49. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants an award of Plaintiffs' reasonable attorney fees.

## **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that each of the Patents-in-Suit is valid and enforceable, and each of the Patents-in-Suit is infringed under 35 U.S.C. § 271(e)(2) by Biovail's filing of its ANDA No. 90-715;

(b) an order that the effective date of the approval of ANDA No. 90-715 be subsequent to the expiration date of each of the Patents-in-Suit;

- (c) a judgment that Biovail is estopped from contending that any of the Patents-in-Suit are invalid or unenforceable;
- (d) an injunction prohibiting Biovail from commercially manufacturing, selling or offering for sale, using, or importing the fenofibrate compositions claimed in the Patents-in-Suit or otherwise infringing one or more claims of the Patents-in-Suit;
- (e) damages and/or other monetary relief pursuant to 35 U.S.C. § 284 in the event of any commercial manufacture, use or sale of fenofibrate compositions falling within the scope of one or more claims of the Patents-in-Suit by Biovail;
- (f) an award of Plaintiffs' interest, costs, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and,
- (g) such other and further relief as the Court may deem just and proper.

DATED: Rochester, New York  
November 4, 2008

Respectfully submitted,

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