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AstraZeneca Pharmaceuticals LP and
AstraZeneca UK Limited

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

BIOVAIL LABORATORIES INTERNATIONAL SRL, BIOVAIL CORPORATION and BTA PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendants Biovail Laboratories International SRL ("Biovail SRL"), Biovail Corporation ("Biovail Corp."), and BTA

Pharmaceuticals, Inc. ("BTA") (collectively "Biovail" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

2. Plaintiff AstraZeneca UK Limited is a company incorporated under the Laws of England and Wales, having a registered office at 15 Stanhope Gate, W1K 1LN, London, England.

3. Upon information and belief, 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. Upon information and belief, Biovail SRL is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products in the U.S. On information and belief, Biovail SRL is a wholly-owned subsidiary of Biovail Corp.

4. Upon information and belief, 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. Upon 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. Upon information and belief, Biovail Corp. has at all times relevant to this Complaint directed, encouraged, controlled, authorized, and/or participated in the actions of Biovail SRL at issue in this case.

5. Upon information and belief, BTA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 700 U.S. Highway 202/206, Bridgewater, New Jersey 08807. Upon information and belief, BTA is in the business of, among other things, U.S. product distribution and regulatory affairs relating to generic copies of branded pharmaceutical products in the U.S. On information and belief, BTA is a wholly-owned subsidiary of Biovail Corp.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

7. Upon information and belief, this Court has personal jurisdiction over Biovail SRL including because Biovail SRL has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, upon 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, purposefully availing itself of the laws of this jurisdiction, Biovail SRL filed a patent infringement lawsuit in this judicial district against Sun Pharmaceutical Industries, Ltd., India, in Civil Action No. 2:08-cv-04005-WJM-MF, which is currently pending.

9. Upon information and belief, this Court has personal jurisdiction over Biovail Corp. including because Biovail Corp. has purposely availed itself of the benefits and

protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, upon 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, purposefully availing itself of the laws of New Jersey, Biovail Corp. filed a lawsuit in New Jersey Superior Court. The suit was removed to this Court as Civil Action No. 2:06-cv-01625-SRC-CCC.

11. Upon information and belief, Biovail Corp. encouraged, directed, and/or participated in the submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 90-882, the ANDA at issue in this case.

12. Upon 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." (*See* Exhibit A attached). Upon further information and belief, Biovail Corp. includes within its U.S. regulatory filings the activities of Biovail SRL, including, for example, 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 (in the "About Biovail Section"), states that Biovail SRL "develops, manufactures, and sells Biovail's pharmaceutical products." (*See* Exhibit B attached).

14. On December 1, 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/lnvestor%20Relations/Latest%20News/default.asp?s=l&state=showrelease&releaseid=1230930 (attached as Exhibit C). Biovail Corp. attributed the infringing acts at issue in this Complaint not to Biovail SRL, but to itself.

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

16. Upon information and belief, this Court has personal jurisdiction over BTA including because BTA has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. Upon information and belief, BTA has a principal place of business in Bridgewater, New Jersey.

17. Biovail Corp.'s website further identifies BTA as Biovail Corp.'s wholly owned subsidiary in charge of U.S. product distribution and having regulatory affairs functions. (*See* Exhibit B).

18. Four related lawsuits are currently pending in this Court. On July 28, 2008, AstraZeneca filed suit in this Court against Handa Pharmaceuticals, LLC and John Doe Entity ("Handa") seeking a judgment that its U.S. Patent Nos. 4,879,288 (the "'288 patent," a copy of which is attached hereto as Exhibit D) and 5,948,437 (the "'437 patent," a copy of which is attached hereto as Exhibit E) are infringed by Handa's filing of its ANDA No. 90-482. *See AstraZeneca Pharma LP and AstraZeneca UK Ltd. v. Handa Pharma, LP and John Doe Entity,* Case No. 08-3773 (D.N.J.). On September 26, 2008, AstraZeneca filed suit in this Court against Accord Healthcare, Inc., Accord Health Care, Inc., Accord Healthcare Ltd., and Intas

Pharmaceuticals, Ltd. ("Accord") seeking a judgment that the '437 patent is infringed by Accord's filing of its ANDA No. 90-681. *See AstraZeneca Pharma LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharma, Ltd,* Case No. 08-4804 (D.N.J.). On October 28, 2008, AstraZeneca filed another suit in this court against Handa seeking a judgment that both the '288 and '437 patents are infringed by Handa's amendments to its ANDA No. 90-482. *See AstraZeneca Pharma LP and AstraZeneca UK Ltd. v. Handa Pharma, LP and John Doe Entity,* Case No. 08-5328 (D.N.J.). On December 8, 2008, AstraZeneca filed another suit in this court against Handa seeking a judgment that both the '288 and '437 patents are infringed by another Handa amendment to its ANDA No. 90-482. *See AstraZeneca Pharma LP and AstraZeneca UK Ltd. v. Handa Pharma, LP and John Doe Entity,* Case No. 08-5997 (D.N.J.). Each of these actions is assigned to the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni and are all proceeding concurrently. AstraZeneca believes this action should proceed concurrently with these pending actions.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Biovail

19. AstraZeneca realleges paragraphs 1-18 above as if set forth specifically herein.

20. Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 22-047, by which the FDA first granted approval for 50 mg, 150 mg, 200 mg, 300 mg and 400 mg extended release tablets containing the active ingredient quetiapine (11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f][1,4] thiazepine) fumarate. The quetiapine fumarate extended release tablets described in NDA No. 22-047 are sold by AstraZeneca in the United States under the trademark SEROQUEL® XR.

21. Plaintiff AstraZeneca Pharmaceuticals LP is the owner of the '288 patent, entitled "Novel Dibenzothiazepine Antipsychotic," which was duly and legally issued by the United States Patent and Trademark Office on November 7, 1989 upon assignment from the inventors Edward J. Warawa and Bernard M. Migler. The '288 patent claims, *inter alia*, quetiapine fumarate, the active ingredient of SEROQUEL® XR, and methods of using that compound.

22. The '288 patent will expire on September 26, 2011.

23. Plaintiff AstraZeneca UK Limited is the owner of the '437 patent, entitled "Pharmaceutical Compositions Using Thiazepine," which was duly and legally issued by the United States Patent and Trademark Office on September 7, 1999 upon assignment from the inventors Bhavnish V. Parikh, Robert J. Timko and William J. Addicks. The '437 patent claims, *inter alia*, sustained release formulations of quetiapine fumarate, including SEROQUEL® XR extended release tablets, and processes for preparing and using such formulations.

24. The '437 patent will expire on May 28, 2017.

25. By letter dated December 23, 2008 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Biovail notified AstraZeneca that it had submitted ANDA No. 90-882 to the FDA seeking the approval of the FDA to commercially manufacture, use and sell, prior to the expiration of the '288 and '437 patents, quetiapine fumarate extended release tablets in 200, 300 and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL® XR 200, 300 and 400 mg extended release tablets.

26. In the Notice Letter, Biovail alleged that both the '288 and '437 patents are invalid. Apart from its allegations of patent invalidity, Biovail did not allege in the Notice

Letter that its proposed generic quetiapine fumarate extended release tablets do not infringe the '288 and '437 patents.

27. Biovail has infringed the '288 patent and the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-882 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '288 and '437 patents, or the use of which is claimed in the '288 and '437 patents, prior to the expiration of those patents.

28. AstraZeneca is entitled to full relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 90-882 be a date that is not earlier than the later of September 26, 2011, the expiration date of the '288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

29. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 90-882 be a date that is not earlier than the later of May 28, 2017, the expiration date of the '437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

Count 2: Inducement of Infringement By Biovail Corp.

30. AstraZeneca realleges paragraphs 1-29 as if set forth specifically herein.

31. Biovail SRL has directly infringed the '288 patent and the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-882 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '288 and '437 patents, or the use of which is claimed in the '288 and '437 patents, prior to the expiration of those patents.

32. Upon information and belief, Biovail Corp. knowingly and intentionally induced and/or aided and abetted Biovail SRL in the preparation and filing of ANDA No. 90-882.

33. Upon information and belief, Biovail Corp. knowingly and intentionally induced and/or aided and abetted Biovail SRL in providing information and materials to the FDA in connection with ANDA No. 90-882.

34. Upon information and belief, Biovail Corp. knowingly and intentionally induced and/or aided and abetted Biovail SRL in the development of the quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-882, and that will infringe the '288 and '437 patents under 35 U.S.C. § 271(a).

35. Upon information and belief, Biovail Corp. has infringed the '288 and '437 patents under 35 U.S.C. § 271(b) by knowingly and intentionally inducing and/or aiding and abetting Biovail SRL's preparation and filing of ANDA No. 90-882.

Count 3: Inducement of Infringement By BTA

36. AstraZeneca realleges paragraphs 1-35 as if set forth specifically herein.

37. Biovail SRL has directly infringed the '288 patent and the '437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-882 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the '288 and '437 patents, or the use of which is claimed in the '288 and '437 patents, prior to the expiration of those patents.

38. Upon information and belief, BTA knowingly and intentionally induced and/or aided and abetted Biovail SRL in the preparation and filing of ANDA No. 90-882.

39. Upon information and belief, BTA knowingly and intentionally induced and/or aided and abetted Biovail SRL in providing information and materials to the FDA in connection with ANDA No. 90-882.

40. Upon information and belief, BTA has infringed the '288 and '437 patents under 35 U.S.C. § 271(b) by knowingly and intentionally inducing and/or aiding and abetting Biovail SRL's preparation and filing of ANDA No. 90-882.

Count 4: Exceptional Case

41. AstraZeneca realleges paragraphs 1-40 as if set forth specifically herein.

42. Prior to filing ANDA No. 90-882, Defendants were aware of the existence of the '288 and '437 patents, and, upon information and belief, were aware that the filing of ANDA No. 90-882, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '288 and '437 patents, infringed those patents.

43. Upon information and belief, prior to sending the Notice Letter, Defendants were aware of the prior actions pending in this Court involving the '288 patent: *AstraZeneca Pharma LP et al. v. Teva Pharma USA, Inc.*, Civil Action Nos. 05-CV-5333, 06-CV-1528 and 07-CV-3001 ("Teva Actions") and in *AstraZeneca Pharma LP et al. v. Sandoz, Inc.*, Civil Action No. 07-CV-1632 ("Sandoz Action").

44. The opinions set forth in the Notice Letter that the '288 and '437 patents are invalid are devoid of an objective, good faith basis in either the facts or the law.

45. This case is an exceptional one, and AstraZeneca is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the ‘288 and ‘437 patents remain valid and enforceable, and that these patents have been infringed by Defendants;

(b) A judgment declaring that the effective date of any approval of ANDA No. 90-882 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(j)) be a date that is not earlier than the later of September 26, 2011, the expiration date of the ‘288 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled;

(c) A judgment declaring that the effective date of any approval of ANDA No. 90-882 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the later of May 28, 2017, the expiration date of the ‘437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled;

(d) A permanent injunction against any infringement of the ‘288 and ‘437 patents by Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them;

(e) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of its reasonable attorney fees pursuant to 35 U.S.C. § 285;

(f) To the extent that Defendants have committed any acts with respect to the subject matter claimed in the ‘288 patent or the ‘437 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem proper.

Respectfully submitted,

Dated: January 9, 2009

By: s/ Andrew T. Berry

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