IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN SALES, LLC, ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED, and ALLERGAN USA, INC.,	)	C.A. No.:
Plaintiffs,	)	
v.	)	
BRECKENRIDGE PHARMACEUTICAL, INC.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan Sales, LLC, Allergan Pharmaceuticals International Limited, and Allergan USA, Inc. (collectively, "Plaintiffs") file this Complaint for patent infringement against Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") under 35 U.S.C. §§ 271(e)(2), (a), (b), and (c). This patent action concerns the pharmaceutical drug product Saphris® and Breckenridge's infringement of United States Patent No. 5,763,476 ("the '476 patent"). Plaintiffs hereby allege as follows:

JURISDICTION AND PARTIES

1. Plaintiff Allergan Sales, LLC is a Delaware limited liability company having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

2. Plaintiff Allergan Pharmaceuticals International Limited is a private company limited by shares under the laws of Ireland and having a registered office at Clonshaugh Business and Technology Park, Coolock, Dublin 17 Ireland.

3. Plaintiff Allergan USA, Inc. is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

4. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. is a Florida corporation, having its principal place of business at 15 Massirio Drive, Suite 201, Berlin, CT 06037.

5. On information and belief, Breckenridge is a generic pharmaceutical company in the business of marketing, researching, and developing generic drug products. On information and belief, Breckenridge directly and through its affiliates markets and sells drug products in the State of Delaware and throughout the United States.

6. This action is related to *Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. v. Breckenridge Pharmaceutical, Inc.*, 1:14-cv-1504 (consolidated with 1:14-cv-1119) (D. Del.) and *Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. v. Breckenridge Pharmaceutical, Inc.*, 1:17-cv-1287 (D. Del).

7. Breckenridge is subject to personal jurisdiction in this district because, *inter alia*, Breckenridge has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement against Plaintiffs, including Plaintiff Allergan Sales, LLC and Plaintiff Allergan USA, Inc., which are a Delaware limited liability company and a Delaware corporation, respectively.

8. This Court also has personal jurisdiction over Breckenridge because Breckenridge has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Breckenridge regularly and continuously transacts business within the State of Delaware.

9. This Court also has personal jurisdiction over Breckenridge because Breckenridge has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See,*

e.g., *Onyx Therapeutics, Inc. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 19-71-LPS (D. Del.); *Pfizer Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al.*, C.A. No. 17-cv-1532-LPS (D. Del.); *Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. v. Breckenridge Pharmaceutical, Inc.*, 1:14-cv-1504 (consolidated with 1:14-cv-1119) (D. Del.); *Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. v. Breckenridge Pharmaceutical, Inc.*, 1:17-cv-1287 (D. Del); *Novartis Pharmaceuticals Corp., et al. v. Breckenridge Pharmaceutical, Inc.*, 1:14-cv-01043 (D. Del.); *Pfizer Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al*., 1:12-cv-00810 (consolidated with 1:12-cv-00808) (D. Del.); *Par Pharmaceutical, Inc., et al. v. Breckenridge Pharmaceutical, Inc.*, 1:13-cv-01114 (D. Del.); *UCB, Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al*., 1:13-cv-01211 (D. Del.); *Cephalon, Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al.*, 1:11-cv-01070 (D. Del.).

10. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Upon information and belief, venue is proper in this judicial district as Breckenridge previously litigated the issues of infringement and validity of U.S. Patent No. 5,763,476 in the related case *Forest Laboratories, LLC v. Breckenridge Pharmaceutical, Inc.*, 1:14-cv-1504 (consolidated with 1:14-cv-1119) (D. Del) and did not challenge venue.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the ’476 Patent Under 35 U.S.C. § 271(e)(2))

11. Plaintiffs reallege and incorporate by reference paragraphs 1-10.

12. United States Patent No. 5,763,476 (“the ’476 patent”), titled “Sublingual or Buccal Pharmaceutical Composition,” was duly and legally issued to inventors Leonardus Petrus Carla Delbressine and Johannes Hubertus Wieringa by the United States Patent and Trademark

Office ("PTO") on June 9, 1998. The PTO issued a certificate of correction for the '476 patent on November 24, 1998. The '476 patent is currently assigned to Plaintiff Allergan Pharmaceuticals International Limited and expires on June 9, 2020. This expiration date includes a 5-year patent term extension granted by the PTO pursuant to 35 U.S.C. § 156. A true and correct copy of the '476 patent, including its certificate of correction, is attached as Exhibit A. A true and correct copy of the Certificate Extending Patent Term is attached as Exhibit B.

13. Plaintiff Allergan Sales, LLC holds New Drug Application ("NDA") No. 22117, which is directed to the use of Saphris® in the treatment of schizophrenia and bipolar disorder. The FDA approved NDA No. 22117 on August 13, 2009 and was granted pediatric exclusivity on March 3, 2015, thereby awarding an additional 6-months of market exclusivity after expiration of the patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Saphris®. The '476 patent is listed in the Orange Book for NDA No. 22117.

14. Plaintiff Allergan Pharmaceuticals International Limited is the assignee of the '476 patent. Plaintiffs manufacture and sell 2.5 mg, 5 mg, and 10 mg dosage strengths of sublingual tablets containing the active ingredient asenapine maleate in the United States under the brand name Saphris®. Plaintiff Allergan USA, Inc. is a distributor of Saphris® in the United States.

15. On information and belief, Breckenridge filed, or caused to be filed, ANDA No. 205960 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of asenapine maleate tablets (equiv. to 2.5 mg base, equiv. to 5 mg base, and equiv. to 10 mg base) ("Breckenridge's Generic Asenapine Product") in the United States before the expiration of the '476 patent.

16. On information and belief, ANDA No. 205960 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the claims of the '476 patent are invalid and/or will not be infringed by Breckenridge's Generic Asenapine Product.

17. Breckenridge sent, or caused to be sent, to Plaintiffs a letter dated December 27, 2019 ("Breckenridge's Notice Letter") notifying Plaintiffs that Breckenridge had submitted ANDA No. 205960, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Breckenridge's Notice Letter alleges that the claimed subject matter of the '476 patent is invalid, unenforceable, and/or will not be infringed, but does not set forth the factual and legal bases of this allegation with respect to any claim of the '476 patent. However, Breckenridge's Notice Letter incorporates by reference its previous Notice Letters dated November 13, 2014 (with respect to sublingual tablets, equiv. to 5 mg base and equiv. to 10 mg base) and July 27, 2017 (with respect to sublingual tablets, equiv. to 2.5 mg base) as well as all defenses raised in litigation C.A. No. 14-1119-MSG (D. Del.).

18. Plaintiffs received Breckenridge's Notice Letter no earlier than December 30, 2019. Plaintiffs filed this complaint within 45 days of receipt of Breckenridge's Notice Letter and, as a result, accounting for the date of expiration of the '476 patent and the FDA's award of an additional 6-months of pediatric exclusivity with respect to NDA No. 22117, the 30-month stay under 21 C.F.R. § 314.107(b)(3) with respect to ANDA No. 205960 expires no earlier than December 10, 2020.

19. On information and belief, Breckenridge seeks approval for the commercial manufacture, use, and sale of at least one formulation for Breckenridge's Generic Asenapine Product that is claimed in the '476 patent.

20. On information and belief, Breckenridge seeks approval of at least one indication for Breckenridge's Generic Asenapine Product that is claimed in the '476 patent.

21. Under 35 U.S.C. § 271(e)(2)(A), Breckenridge infringed one or more claims of the '476 patent, in violation of Plaintiffs' patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '476 patent—Breckenridge's Generic Asenapine Product. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Breckenridge's Generic Asenapine Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Breckenridge's Generic Asenapine Product would contribute to or induce the direct infringement of one or more claims of the '476 patent by users of Breckenridge's Generic Asenapine Product.

22. On information and belief, Breckenridge has knowledge of the '476 patent and filed ANDA No. 205960 seeking authorization to commercially manufacture, use, offer for sale, and sell Breckenridge's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 205960, physicians, health care providers, and/or patients will use Breckenridge's Generic Asenapine Product in accordance with the instructions and/or label provided by Breckenridge and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent.

23. On information and belief, Breckenridge knows and intends that physicians, health care providers, and/or patients will use Breckenridge's Generic Asenapine Product in accordance with the instructions and/or label provided by Breckenridge, and will therefore induce infringement of one or more claims of the '476 patent, with the requisite intent.

24. On information and belief, if the FDA approves ANDA No. 205960, Breckenridge will sell or offer to sell its Generic Asenapine Product specifically labeled for use in practicing one or more claims of the '476 patent, wherein Breckenridge's Generic Asenapine Product is a material part of the claimed invention, wherein Breckenridge knows that physicians will prescribe and patients will use Breckenridge's Generic Asenapine Product in accordance with the instructions and/or label provided by Breckenridge in practicing one or more claims of the '476 patent, and wherein asenapine is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Breckenridge will thus contribute to the infringement of one or more claims of the '476 patent.

25. This Court previously litigated related issues in *Forest Laboratories, LLC and Forest Laboratories Holdings, LTD v. Breckenridge Pharmaceutical, Inc.*, 1:14-cv-1504 (consolidated with 1:14-cv-1119). (*See* D.I. 24-1 in 1:14-cv-1504; D.I. 325 in 1:14-cv-1119.)

26. On April 4, 2016, Breckenridge previously stipulated to infringement of claims 1, 2, and 6 of the '476 Patent. Breckenridge stipulated "that Breckenridge's Proposed ANDA Products infringe claims 1, 2, and 6 of [the '476 Patent], solely to the extent these claims are determined to be valid and enforceable."

27. On October 14, 2016, Breckenridge previously stipulated to infringement of claim 5 of the '476 Patent. Breckenridge stipulated "that Breckenridge's proposed asenapine maleate sublingual tablets, 5 mg and 10 mg, infringe claim 5 of the '476 patent."

28. Plaintiffs will be substantially and irreparably harmed by Breckenridge's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

29.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '476 Patent Under 35 U.S.C. § 271 (a), (b), and/or (c))

30. Plaintiffs reallege and incorporate by reference paragraphs 1-28.

31. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

32. On information and belief, the manufacture, sale, if the FDA approves Breckenridge's Generic Asenapine Product for sale in the United States, Breckenridge would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights by making, using, offering to sell, selling, and/or importing Breckenridge's Generic Asenapine Product for use and sale within the United States.

33. On information and belief, Breckenridge has knowledge of the '476 patent and filed ANDA No. 205960 seeking authorization to commercially manufacture, use, offer for sale, and sell Breckenridge's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 205960, physicians, health care providers, and/or patients will use Breckenridge's Generic Asenapine Product in accordance with the instructions and/or label provided by Breckenridge and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

34. On information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Breckenridge's Generic Asenapine Product so labeled, if approved by the FDA, will induce and contribute to the infringement of

one or more claims of the ’476 patent, including at least claim 4, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs’ patent rights.

35. On information and belief, Breckenridge knows and intends that physicians, health care providers, and/or patients will use Breckenridge’s Generic Asenapine Product in accordance with the instructions and/or label provided by the ’476 patent with the requisite intent under 35 U.S.C. § 271(b).

36. On information and belief, if the FDA approves ANDA No. 205960, Breckenridge will sell or offer to sell its Generic Asenapine Product specifically labeled for use in practicing one or more claims of the ’476 patent, including at least claim 4, wherein Breckenridge’s Generic Asenapine Product is a material part of the invention claimed in the ’476 patent, wherein Breckenridge knows that physicians will prescribe and patients will use Breckenridge’s Generic Asenapine Product for practicing one or more claims in the ’476 patent, and wherein asenapine is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Breckenridge will thus contribute to the infringement of the ’476 patent under 35 U.S.C. § 271(c).

37. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Breckenridge as to liability for the infringement of the ’476 patent claims. Breckenridge’s actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Breckenridge’s threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

a) declare that United States Patent No. 5,763,476 is valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Breckenridge infringed United States Patent No. 5,763,476 by submitting ANDA No. 205960 to the FDA to obtain approval to commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States Breckenridge's Generic Asenapine Product prior to the expiration of said patent;

c) declare that Breckenridge's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Breckenridge's Generic Asenapine Product prior to the expiration of United States Patent No. 5,763,476 constitutes infringement of one or more claims of said patent under 35 U.S.C. §§ 271 (a), (b), and/or (c);

d) order that the effective date of any FDA approval of Breckenridge's Generic Asenapine Product shall be no earlier than the expiration date of United States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Breckenridge, and all persons acting in concert with Breckenridge, from seeking, obtaining, or maintaining final approval of ANDA No. 205960 until the expiration of United States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Breckenridge, and all persons acting in concert with Breckenridge, from commercially manufacturing, using, offering for sale, or selling Breckenridge's Generic Asenapine Product within the United States, or importing Breckenridge's Generic Asenapine Product into the United States, until the expiration of United

States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) enjoin Breckenridge, and all persons acting in concert with Breckenridge, from commercially manufacturing, using, offering for sale, or selling Breckenridge's Generic Asenapine Product within the United States, or importing Breckenridge's Generic Asenapine Product into the United States, until the expiration of United States Patent No. 5,763,476 including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 283;

h) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

i) grant Plaintiffs such further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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