IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC and FOREST LABORATORIES HOLDINGS, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
BRECKENRIDGE PHARMACEUTICAL, INC.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) and Forest Laboratories Holdings, Ltd. (collectively, "Forest") file this Complaint for patent infringement against Defendant Breckenridge Pharmaceutical, Inc. under 35 U.S.C. §§ 271(e)(2), (a), (b), and (c). This patent action concerns the pharmaceutical drug product Saphris®. Forest hereby alleges as follows:

JURISDICTION AND PARTIES

1. Plaintiff Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda.

3. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a Florida corporation, having its principal place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida 33487.

4. 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.

5. 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 Forest Laboratories, LLC, which is a Delaware limited liability company.

6. 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.

7. 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.*, *Novartis v. Breckenridge*, 1:14-cv-01043 (D. Del. Aug. 13, 2014); *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.).

8. 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. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

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

9. Plaintiffs reallege and incorporate by reference paragraphs 1-8.

10. 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 Forest Laboratories Holdings, Ltd. 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.

11. Forest Laboratories, Inc. (n/k/a Forest Laboratories, 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. The '476 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for NDA No. 22117.

12. Plaintiff Forest Laboratories Holdings, Ltd. is the assignee of the '476 patent. Plaintiffs manufacture and sell 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®.

13. 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 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.

14. 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, unenforceable, and/or will not be infringed by Breckenridge's Generic Asenapine Product.

15. Breckenridge sent, or caused to be sent, to Plaintiffs a letter dated November 13, 2014 ("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)(ii). Breckenridge's Notice Letter alleges invalidity and noninfringement of certain claims of the '476 patent. Breckenridge's Notice Letter does not raise a noninfringement defense with regard to claims 1, 2, 5, and 6 of the '476 patent.

16. 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, if approved, would infringe one or more claims of the '476 patent.

17. 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.

18. 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.

19. On information and belief, Breckenridge has knowledge of the ’476 patent and has 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.

20. 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.

21. 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.

22. 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.

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))

23. Plaintiffs reallege and incorporate by reference paragraphs 1-22.

24. 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.

25. On information and belief, if the FDA approves Breckenridge's Generic Asenapine Product for use and 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.

26. On information and belief, Breckenridge has knowledge of the '476 patent and has 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.

27. 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.

28. 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).

29. 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).

30. 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.

COUNT III FOR PATENT INFRINGEMENT
(Infringement of the '358 Patent Under 35 U.S.C. § 271(e)(2))

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

32. United States Patent No. 7,741,358 ("the '358 patent"), titled "Crystal Form of Asenapine Maleate," was duly and legally issued to inventor Gerhardus Johannes Heeres by the PTO on June 22, 2010. The '358 patent is currently assigned to Plaintiff Forest Laboratories Holdings, Ltd. and expires on April 6, 2026. A true and correct copy of the '358 patent is attached as Exhibit C.

33. The '358 patent is listed in the Orange Book for NDA No. 22117.

34. 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 authorization to commercially manufacture, use, offer for sale, and sell Breckenridge's Generic Asenapine Product in the United States before the expiration of the '358 patent.

35. On information and belief, ANDA No. 205960 contains a Paragraph IV certification alleging that the claims of the '358 patent are invalid, unenforceable, and/or will not be infringed by Breckenridge's Generic Asenapine Product.

36. Breckenridge sent, or caused to be sent, to Plaintiffs 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)(ii). Breckenridge's Notice Letter alleges noninfringement of claims 1-11 of the '358 patent. Breckenridge's Notice Letter does not allege invalidity of the '358 patent.

37. 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, if approved, would infringe one or more claims of the '358 patent.

38. On information and belief, Breckenridge seeks approval of at least one indication for Breckenridge's Generic Asenapine Product that is claimed in the '358 patent.

39. Under 35 U.S.C. § 271(e)(2)(A), Breckenridge infringed one or more claims of the '358 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 '358 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 '358 patent. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States Breckenridge's Generic Asenapine Product would contribute to or induce the direct infringement of one or more of claims of the '358 patent by users of Breckenridge's Generic Asenapine Product.

40. On information and belief, Breckenridge has knowledge of the '358 patent and has 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 '358 patent.

41. 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 '358 patent, with the requisite intent.

42. 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 '358 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 instruction and/or label provided by Breckenridge in practicing one or more claims of the '358 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 '358 patent.

43. 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.

COUNT IV FOR PATENT INFRINGEMENT
(Infringement of the '228 Patent Under 35 U.S.C. § 271(e)(2))

44. Plaintiffs reallege and incorporate by reference paragraphs 1-43.

45. United States Patent No. 8,022,228 ("the '228 patent"), titled "Crystal Form of Asenapine Maleate," was duly and legally issued to inventor Gerhardus Johannes Heeres by the PTO on September 20, 2011. The '228 patent is currently assigned to Plaintiff Forest Laboratories Holdings, Ltd. and expires on April 6, 2026. A true and correct copy of the '228 patent is attached as Exhibit D.

46. The ’228 patent is listed in the Orange Book for NDA No. 22117.

47. 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 authorization to commercially manufacture, use, offer for sale, and sell Breckenridge’s Generic Asenapine Product in the United States before the expiration of the ’228 patent.

48. On information and belief, ANDA No. 205960 contains a Paragraph IV certification alleging that the claims of the ’228 patent are invalid, unenforceable, and/or will not be infringed by Breckenridge’s Generic Asenapine Product.

49. Breckenridge sent, or caused to be sent, to Plaintiffs 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)(ii). Breckenridge’s Notice Letter alleges noninfringement of claims 1-7 of the ’228 patent. Breckenridge’s Notice Letter does not allege invalidity of the ’228 patent.

50. 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, if approved, would infringe one or more claims of the ’228 patent.

51. Under 35 U.S.C. § 271(e)(2)(A), Breckenridge infringed one or more claims of the ’228 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 ’228 patent—Breckenridge’s Generic Asenapine Product. On information and belief, if approved by the FDA, Breckenridge’s Generic Asenapine Product for use and sale in the United States would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the ’228 patent.

52. 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.

PRAYER FOR RELIEF

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

a) declare that United States Patent Nos. 5,763,476; 7,741,358; and 8,022,228 are valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Breckenridge infringed United States Patent Nos. 5,763,476; 7,741,358; and 8,022,228 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 patents;

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 Nos. 5,763,476; 7,741,358; and 8,022,228, 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 Nos. 5,763,476; 7,741,358; and 8,022,228, 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 Nos. 5,763,476; 7,741,358; and 8,022,228, 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/ Maryellen Noreika

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