IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC and FOREST LABORATORIES HOLDINGS, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HIKMA PHARMACEUTICALS, LLC, HIKMA PHARMACEUTICALS, PLC, and WEST-WARD PHARMACEUTICAL CORP.,	)	
Defendants.	)	

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 Hikma Pharmaceuticals, LLC, Hikma Pharmaceuticals, PLC, and West-Ward Pharmaceutical Corp. under 35 U.S.C. §§ 271(e)(2) and (a), (b), and (c). This patent action concerns the pharmaceutical drug product Saphris®. Plaintiffs hereby allege 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 Hikma Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the country of Jordan, having its principal place of business at P.O. Box 182400, Amman 11118, Jordan.

4. On information and belief, Defendant Hikma Pharmaceuticals, PLC is a public limited company organized and existing under the laws of the United Kingdom, having its principal place of business at 13 Hanover Square, London W1S 1HL, United Kingdom. On information and belief, Defendant Hikma Pharmaceuticals, PLC is a principal shareholder of Defendant Hikma Pharmaceuticals, LLC. On information and belief, Defendant Hikma Pharmaceuticals, LLC is a subsidiary of its parent Hikma Pharmaceuticals PLC.

5. On information and belief, Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC are in the business of developing and manufacturing generic drugs throughout the world. Hikma Pharmaceuticals, PLC's website states that its generic business in the United States "operates as West-Ward Pharmaceuticals, a domestic marketer and manufacturer of generic pharmaceutical products."

6. Upon information and belief, Defendant West-Ward Pharmaceutical Corp. ("West-Ward") is a company organized and existing under the laws of the State of Delaware, having a place of business at 401 Industrial Way West, Eatontown, NJ 07724. Upon information and belief, West-Ward acts as a domestic marketer, manufacturer, and distributor of drug products for sale and use throughout the United States of entities affiliated with Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC. West-Ward's website states the following: "West-Ward Pharmaceuticals is one of the top 20 generic prescription medication providers in the US, providing pharmaceuticals to a growing number of chain stores, wholesalers, distributors, health systems and government agencies. We are the US agent and

subsidiary of Hikma PLC." West-Ward's website indicates that it has a sales representative for the State of Delaware. Upon information and belief, West-Ward has active pharmacy wholesaler and controlled substance distributor and manufacturer licenses in Delaware. Upon information and belief, West-Ward is a wholly-owned subsidiary of its parent Hikma Pharmaceuticals PLC.

7. Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC are subject to personal jurisdiction in this district because, inter alia, alone and/or together with their agent West-Ward, Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC have 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.

8. This Court also has personal jurisdiction over Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC because, alone and/or together with their agent West-Ward (a Delaware corporation), Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC have, inter alia, purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC, together with West-Ward, regularly and continuously transact business within the State of Delaware.

9. In the alternative, and to the extent either Defendants Hikma Pharmaceuticals, PLC or Hikma Pharmaceuticals, LLC contest jurisdiction in this forum, this Court has personal jurisdiction over Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC under Fed. R. Civ. P. 4(k)(2).

10. West-Ward is subject to personal jurisdiction in this district because it is a Delaware corporation and, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the regular sale of pharmaceutical products within the State of Delaware.

11. On information and belief, West-Ward is further subject to jurisdiction in this Court because it is the agent, affiliate, representative, and/or alter ego of and/or acts in concert with Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC for purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware. On information and belief, the acts of Defendants Hikma Pharmaceuticals, PLC and Hikma Pharmaceuticals, LLC complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and/or assistance of, and, in part, for the benefit of West-Ward.

12. 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 ’358 Patent Under 35 U.S.C. § 271(e)(2))

13. Plaintiffs reallege and incorporate by reference paragraphs 1-12.

14. 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 A.

15. 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 '358 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 22117.

16. Plaintiff Forest Laboratories Holdings, Ltd. is the assignee of the '358 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®.

17. On information and belief, Defendants Hikma Pharmaceuticals, PLC, Hikma Pharmaceuticals, LLC, and West-Ward (collectively referred to hereafter as "Hikma") filed, or caused to be filed, ANDA No. 206117 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of 5 mg and 10 mg sublingual asenapine maleate tablets ("Hikma's Generic Asenapine Product") in the United States before the expiration of the '358 patent.

18. On information and belief, ANDA No. 206117 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 '358 patent will not be infringed by Hikma's Generic Asenapine Product.

19. Hikma sent, or caused to be sent, to Plaintiffs a letter dated August 22, 2014 ("Hikma's Notice Letter") notifying Plaintiffs that "Hikma Pharmaceuticals LLC…has submitted" ANDA No. 206117, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Hikma's Notice Letter alleges noninfringement of claim 1 of the '358 patent. Hikma's Notice Letter does not allege that the '358 patent is invalid or unenforceable.

20. On information and belief, Hikma seeks approval for the commercial manufacture, use, and sale of at least one formulation for Hikma's Generic Asenapine Product that is claimed in the '358 patent.

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

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

23. On information and belief, Hikma has knowledge of the '358 patent and has filed ANDA No. 206117 seeking authorization to commercially manufacture, use, offer for sale, and sell Hikma's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 206117, physicians, health care providers, and/or patients will use Hikma's Generic Asenapine Product in accordance with the instructions and/or label provided by Hikma and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '358 patent.

24. On information and belief, Hikma knows and intends that physicians, health care providers, and/or patients will use Hikma's Generic Asenapine Product in accordance with the instructions and/or label provided by Hikma, and will therefore induce infringement of one or more claims of the '358 patent, with the requisite intent.

25. On information and belief, if the FDA approves ANDA No. 206117, Hikma 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 Hikma's Generic Asenapine Product is a material part of the claimed invention, wherein Hikma knows that physicians will prescribe and patients will use Hikma's Generic Asenapine Product in accordance with the instructions and/or label provided by Hikma 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, Hikma will thus contribute to the infringement of one or more claims of the '358 patent.

26. Plaintiffs will be substantially and irreparably harmed by Hikma'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 '358 Patent Under 35 U.S.C. § 271 (a), (b) and/or (c))

27. Plaintiffs reallege and incorporate by reference paragraphs 1-26.

28. 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), (b), and/or (c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

29. On information and belief, and based on information provided by Hikma, if the FDA approves Hikma's Generic Asenapine Product for sale in the United States, Hikma would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '358 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights, by making, using, offering to sell, selling, and/or importing Hikma's Generic Asenapine Product for use and sale within the United States.

30. On information and belief, Hikma has knowledge of the '358 patent and has filed ANDA No. 206117 seeking authorization to commercially manufacture, use, offer for sale, and sell Hikma's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 206117, physicians, health care providers, and/or patients will use Hikma's Generic Asenapine Product in accordance with the instructions and/or label provided by Hikma and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '358 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

31. On information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Hikma'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 '358 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

32. On information and belief, Hikma knows and intends that physicians, health care providers, and/or patients will use Hikma's Generic Asenapine Product in accordance with the instructions and/or label provided by the '358 patent with the requisite intent under 35 U.S.C. § 271(b).

33. On information and belief, if the FDA approves ANDA No. 206107, Hikma 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 Hikma's Generic Asenapine Product is a material part of the invention claimed in the '358 patent, wherein Hikma knows that physicians will prescribe and patients will use Hikma's Generic Asenapine Product for practicing one or more claims in the '358 patent, and wherein asenapine is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Hikma will thus contribute to the infringement of the '358 patent under 35 U.S.C. § 271(c).

34. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hikma as to liability for the infringement of the '358 patent claims. Hikma's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Hikma's threatened imminent actions.

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

35. Plaintiffs reallege and incorporate by reference paragraphs 1-34.

36. 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 B.

37. The '228 patent is listed in the Orange Book for NDA No. 22117.

38. On information and belief, Hikma filed, or caused to be filed, ANDA No. 206117 with the FDA under 21 U.S.C. § 355(j), seeking authorization to commercially manufacture, use,

offer for sale, and sell Hikma's Generic Asenapine Product in the United States before the expiration of the '228 patent.

39. On information and belief, and based on information provided by Hikma, Hikma infringed one or more claims of the '228 patent under 35 U.S.C. § 271(e)(2)(A), 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—Hikma's Generic Asenapine Product. On information and belief, and based on information provided by Hikma, if approved by the FDA, Hikma'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.

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

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '228 Patent Under 35 U.S.C. § 271(a))

41. Plaintiffs reallege and incorporate by reference paragraphs 1-40.

42. 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), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

43. On information and belief, and based on information provided by Hikma, if the FDA approves Hikma's Generic Asenapine Product for sale in the United States, Hikma would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '228 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights, by making, using,

offering to sell, selling, and/or importing Hikma's Generic Asenapine Product for use and sale within the United States.

44. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hikma as to liability for the infringement of the '228 patent claims. Hikma's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Hikma'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 Nos. 7,741,358 and 8,022,228 are valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Hikma infringed United States Patent Nos. 7,741,358 and 8,022,228 by submitting ANDA No. 206117 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 Hikma's Generic Asenapine Product prior to the expiration of said patents;

c) declare that Hikma's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Hikma's Generic Asenapine Product prior to the expiration of United States Patent No. 7,741,358 constitutes infringement of one or more claims of said patent under 35 U.S.C. §§ 271 (a), (b), and/or (c);

d) declare that Hikma's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Hikma's Generic Asenapine Product prior to the expiration of United States Patent No. 8,022,228 constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271 (a);

e) order that the effective date of any FDA approval of Hikma's Generic Asenapine Product shall be no earlier than the expiration date of United States Patent Nos. 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);

f) enjoin Hikma, and all persons acting in concert with Hikma, from seeking, obtaining, or maintaining final approval of ANDA No. 206117 until the expiration of United States Patent Nos. 7,741,358 and 8,022,228, including any exclusivities or extensions to which Plaintiffs are or become entitled;

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

h) enjoin Hikma, and all persons acting in concert with Hikma, from commercially manufacturing, using, offering for sale, or selling Hikma's Generic Asenapine Product within the United States, or importing Hikma's Generic Asenapine Product into the United States, until the expiration of United States Patent Nos. 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. § 283;

i) 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

j) 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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