IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEWRON PHARMACEUTICALS S.p.A., ZAMBON S.p.A., MDD US OPERATIONS, LLC, Plaintiffs, v. AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA INC., MSN LABORATORIES PRIVATE LIMITED, OPTIMUS PHARMA PVT LTD, PRINSTON PHARMACEUTICAL, INC., RK PHARMA INC., ZENARA PHARMA PRIVATE LIMITED, Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Newron Pharmaceuticals S.p.A. ("Newron"), Zambon S.p.A. ("Zambon"), and MDD US Operations, LLC ("MDD", collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 8,076,515 ("the '515 patent"), 8,278,485 (the "'485 patent"), and 8,283,380 (the "'380 patent") (collectively, the Asserted Patents") under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., including §§ 271(e)(2), 271(a)-(c), and for a declaratory judgment of infringement of the '515, '485, and '380 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271(a)-(c). Plaintiffs institute this action to enforce their patent rights covering FDA-approved XADAGO® (safinamide) tablets.

THE PARTIES

A. Plaintiffs

2. Plaintiff Newron Pharmaceuticals S.p.A. is a joint stock company organized under the laws of the Republic of Italy with its principal place of business at Via Antonio Meucci 3, 20091 Bresso (MI) Italy.

3. Plaintiff Zambon S.p.A. is a company organized under the laws of Italy with its principal place of business at Via Lillo del Duca 10, 20091 Bresso (MI) Italy.

4. Plaintiff MDD US Operations, LLC is a company organized under the laws of Delaware with its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

B. Aurobindo

5. On information and belief, Defendant Aurobindo Pharma Limited ("Aurobindo Pharma") is a corporation organized and existing under the laws of India with its principal place of business at Plot No. 11, Water Mark Building, Hightech City Rd, Whitefields, Kondapur, Hyderabad, Telangana 500084, India. On information and belief, Defendant Aurobindo Pharma USA Inc. ("Aurobindo Pharma USA", collectively, "Aurobindo") is a corporation organized and existing under the laws of Delaware with its principal place of business at 279 Princeton-Hightstown Rd, East Windsor, NJ 08520-1401.

C. MSN

6. On information and belief, Defendant MSN Laboratories Private Limited ("MSN") is a corporation organized and existing under the laws of India with its principal place of business

at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad 500018 Telangana, India.

D. Optimus

7. On information and belief, Defendant Optimus Pharma Pvt Ltd ("Optimus") is a corporation organized and existing under the laws of India with its principal place of business at 2nd Floor, Sy No. 37/A & 37/P, Plot No.6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500084, Telangana, India.

E. Prinston

8. On information and belief, Defendant Prinston Pharmaceutical, Inc. ("Prinston") is a corporation organized and existing under the laws of Delaware with its principal place of business at 700 Atrium Drive, Somerset, NJ 08873.

F. RK Pharma

9. On information and belief, Defendant RK Pharma, Inc. ("RK Pharma") is a corporation organized and existing under the laws of Delaware with its principal place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, NY 10965.

G. Zenara

10. On information and belief, Defendant Zenara Pharma Private Limited ("Zenara") is a corporation organized and existing under the laws of India with its principal place of business at Plot 87-95, Phase III, Industrial Development Area, Cherlapalli, Hyderabad, Telangana 500051, India.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) because the action concerns a federal question arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

A. Aurobindo

12. This Court has personal jurisdiction over Aurobindo Pharma USA because, on information and belief, Aurobindo Pharma USA is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Aurobindo Pharma USA has purposefully availed itself to the privileges of conducting business in Delaware and consented to general jurisdiction in Delaware.

13. This Court has personal jurisdiction over Defendant Aurobindo Pharma because, *inter alia*, Aurobindo Pharma, itself and through its subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma, itself and through its subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

14. In addition, this Court has personal jurisdiction over Aurobindo Pharma and Aurobindo Pharma USA because, among other things, on information and belief: (1) Aurobindo Pharma and its subsidiary Aurobindo Pharma USA, collectively and/or in concert with each other, developed Aurobindo's ANDA Product that is the subject of ANDA No. 215902 and filed Aurobindo's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale or offer for sale of Aurobindo's ANDA Product in the United States, including in Delaware; (2) upon approval of Aurobindo's ANDA, Aurobindo Pharma and its subsidiary

Aurobindo Pharma USA, collectively and/or in concert with each other, intend to market, distribute, offer for sale, sell, and/or import Aurobindo's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Product in Delaware; and (3) also upon approval of Aurobindo's ANDA, Aurobindo's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing Aurobindo's ANDA, Aurobindo Pharma and Aurobindo Pharma USA have made clear that they intend to use their distribution channels to direct sales of Aurobindo's ANDA Product into Delaware.

15. In addition, upon information and belief, this Court has personal jurisdiction over Aurobindo Pharma USA and Aurobindo Pharma because both regularly engage in patent litigation concerning Aurobindo's ANDA products in this District, have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and have filed counterclaims in such cases. *See, e.g.*, *UCB Inc. et al. v. Annora Pharma Pvt. Ltd. et al.*, C.A. No. 20-0987-CFC, D.I. 37 (D. Del. July 24, 2020) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-0985-RGA, D.I. 10 (D. Del. Dec. 20, 2020) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *Taiho Pharm. Co. v. Eugia Pharma Specialities Ltd.*, C.A. No. 19-2309-CFC (D. Del. Mar. 23, 2020) (Aurobindo Pharma USA, Inc.); *Millennium Pharm. v. Aurobindo Pharma USA, Inc.*, C.A. No. 19-0471-CFC (D. Del. Dec. 26, 2019) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.); *Pfizer Inc. v. Aurobindo Pharma, Ltd.*, C.A. No. 19-0748-CFC (D. Del. July 8, 2019) (Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc.).

16. In the alternative, this Court may exercise personal jurisdiction over Aurobindo Pharma pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Aurobindo Pharma is a foreign company not subject to personal jurisdiction in the courts in any state, and (c) Aurobindo Pharma has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Pharma satisfies due process.

17. Venue is proper in this District with respect to Aurobindo Pharma pursuant to 28 U.S.C. § 1391(c)(3) because Aurobindo Pharma is a foreign corporation and may be sued in any judicial district.

18. Venue is proper in this Court with respect to Aurobindo Pharma USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Aurobindo Pharma USA is a corporation organized and existing under the laws of the State of Delaware.

B. MSN

19. This Court has personal jurisdiction over Defendant MSN because, *inter alia*, MSN, either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, MSN, either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

20. Upon information and belief, Defendant MSN is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

21. In addition, this Court has personal jurisdiction over MSN because, among other things, on information and belief: (1) MSN developed MSN's ANDA product that is the subject of ANDA No. 215978 and filed MSN's ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of MSN's ANDA Product in the United States, including in Delaware; (2) upon approval of MSN's ANDA, MSN intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import MSN's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of MSN's ANDA Product in Delaware; and (3) also upon approval of MSN's ANDA, MSN's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing its ANDA, MSN has made clear that it intends to use its distribution channel to direct sales of MSN's ANDA Product into Delaware.

22. In addition, this Court has personal jurisdiction over MSN because it regularly engages in patent litigation concerning MSN's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Acadia Pharms.*

Inc. v. Aurobindo Pharma Ltd. et al., C.A. No. 20-0985-RGA, D.I. 77 (D. Del. Dec. 20, 2020); *Genentech, Inc. v. MSN Labs. Pvt. Ltd. et al.*, C.A. No. 19-0205-RGA, D.I. 9 (D. Del. Jan. 31, 2019); *Onyx Therapeutics, Inc. v. MSN Pharms. Inc. et al.*, C.A. No. 17-1833-LPS, D.I. 8 (D. Del. Dec. 20, 2017).

23. In the alternative, this Court may exercise personal jurisdiction over MSN pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) MSN Laboratories Private Limited is a foreign company not subject to personal jurisdiction in the courts in any state, and (c) MSN has sufficient contacts with the United States as a whole, including but not limited to participating in the preparation and submission of MSN's ANDA to the FDA, and/or marketing and/or manufacturing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over MSN satisfies due process.

24. Venue is proper in this District with respect to MSN pursuant to 28 U.S.C. § 1391(c)(3) because MSN is a foreign corporation and may be sued in any judicial district.

C. Optimus

25. This Court has personal jurisdiction over Defendant Optimus because, *inter alia*, Optimus, either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Optimus, either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

26. Upon information and belief, Defendant Optimus is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

27. In addition, this Court has personal jurisdiction over Optimus because, among other things, on information and belief: (1) Optimus developed Optimus' ANDA Product that is the subject of ANDA No. 216020 and filed Optimus' ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of Optimus' ANDA Product in the United States, including in Delaware; (2) upon approval of Optimus' ANDA, Optimus intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import Optimus' ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Optimus' ANDA Product in Delaware; and (3) also upon approval of Optimus' ANDA, Optimus' ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing its ANDA, Optimus has made clear that it intends to use its distribution channel to direct sales of Optimus' ANDA Product into Delaware.

28. In addition, this Court has personal jurisdiction over Optimus because it regularly engages in patent litigation concerning Optimus' ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Otsuka Pharm.*

Co., Ltd. et al. v. Optimus Pharma Pvt Ltd, C.A. No. 19-2008-LPS (D. Del. Jan. 10, 2020); *Intercept Pharms., Inc. et al. v. Optimus Pharma Pvt Ltd et al.*, C.A. No. 20-1215-MN, D.I. 14 (D. Del. Sept. 10, 2020).

29. In the alternative, this Court may exercise personal jurisdiction over Optimus pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Optimus is a foreign company not subject to personal jurisdiction in the courts in any state, and (c) Optimus has sufficient contacts with the United States as a whole, including but not limited to participating in the preparation and submission of Optimus' ANDA to the FDA, and/or marketing and/or manufacturing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Optimus satisfies due process.

30. Venue is proper in this District with respect to Optimus pursuant to 28 U.S.C. § 1391(c)(3) because Optimus is a foreign corporation and may be sued in any judicial district.

D. Prinston

31. This Court has personal jurisdiction over Prinston because, on information and belief, Prinston is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Prinston has purposefully availed itself to the privileges of conducting business in Delaware and consented to general jurisdiction in Delaware.

32. In addition, this Court has personal jurisdiction over Defendant Prinston because, *inter alia*, Prinston, either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Prinston, either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports,

markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

33. Upon information and belief, Defendant Prinston is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

34. In addition, this Court has personal jurisdiction over Prinston because, among other things, on information and belief: (1) Prinston developed Prinston's ANDA Product that is the subject of ANDA No. 215739 and filed Prinston's ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of Prinston's ANDA Product in the United States, including in Delaware; (2) upon approval of Prinston's ANDA, Prinston intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import Prinston's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Prinston's ANDA Product in Delaware; and (3) also upon approval of Prinston's ANDA, Prinston's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing its ANDA, Prinston has made clear that it intends to use its distribution channel to direct sales of Prinston's ANDA Product into Delaware.

35. In addition, this Court has personal jurisdiction over Prinston because it regularly engages in patent litigation concerning Prinston's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Novartis Pharms. Corp. v. Apotex Inc. et al.*, C.A. No. 20-0133-LPS, D.I. 38 (D. Del. Jan. 28, 2020); *Boehringer Ingelheim Pharm. Inc. et al. v. Prinston Pharm. Inc. et al.*, C.A. No. 19-1499-CFC, D.I. 10 (D. Del. Aug. 9, 2019).

36. Venue is proper in this Court with respect to Prinston pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Prinston is a corporation organized and existing under the laws of the State of Delaware.

E. RK Pharma

37. This Court has personal jurisdiction over RK Pharma because, on information and belief, RK Pharma is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, RK Pharma has purposefully availed itself to the privileges of conducting business in Delaware and consented to general jurisdiction in Delaware.

38. This Court has personal jurisdiction over Defendant RK Pharma because, *inter alia*, RK Pharma either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, RK Pharma, either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to

Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

39. Upon information and belief, Defendant RK Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

40. In addition, this Court has personal jurisdiction over RK Pharma because, among other things, on information and belief: (1) RK Pharma developed RK Pharma's ANDA Product that is the subject of ANDA No. 215945 and filed RK Pharma's ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of RK Pharma's ANDA Product in the United States, including in Delaware; (2) upon approval of RK Pharma's ANDA, RK Pharma intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or import RK Pharma's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of RK Pharma's ANDA Product in Delaware; and (3) also upon approval of RK Pharma's ANDA, RK Pharma's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing its ANDA, RK Pharma has made clear that it intends to use its distribution channel to direct sales of RK Pharma's ANDA Product into Delaware.

41. Venue is proper in this Court with respect to RK Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) because RK Pharma is a corporation organized and existing under the laws of the State of Delaware.

F. Zenara

42. This Court has personal jurisdiction over Defendant Zenara because, *inter alia*, Zenara, either directly or through its subsidiaries, agents, and/or affiliates, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Zenara, either directly or through its subsidiaries, agents, and/or affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

43. Upon information and belief, Defendant Zenara is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, either directly or through various operating subsidiaries, agents, and/or affiliates throughout the United States, including in Delaware.

44. In addition, this Court has personal jurisdiction over Zenara because, among other things, on information and belief: (1) Zenara developed Zenara's ANDA Product that is the subject of ANDA No. 215913 and filed Zenara's ANDA for the purpose of seeking approval to engage in, either directly or through subsidiaries, agents, affiliates, and/or alter egos, the commercial manufacture, use, sale or offer for sale of Zenara's ANDA Product in the United States, including in Delaware; (2) upon approval of Zenara's ANDA, Zenara intends to, either directly or through subsidiaries, agents, affiliates, and/or alter egos, market, distribute, offer for sale, sell, and/or

import Zenara's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Zenara's ANDA Product in Delaware; and (3) also upon approval of Zenara's ANDA, Zenara's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By filing its ANDA, Zenara has made clear that it intends to use its distribution channel to direct sales of Zenara's ANDA Product into Delaware.

45. In addition, this Court has personal jurisdiction over Zenara because it regularly engages in patent litigation concerning Zenara's ANDA products in this District, does not contest personal jurisdiction in this District, and/or has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Genzyme Corp. et al. v. Zenara Pharma Pvt. Ltd.*, C.A. No. 19-0264-CFC, D.I. 7 (D. Del. Feb. 7, 2019); *Otsuka Pharm. Co., Ltd. v. Zenara Pharma Pvt. Ltd. et al.*, C.A. No. 20-1599-LPS (D. Del. Nov. 24, 2020).

46. In the alternative, this Court may exercise personal jurisdiction over Zenara pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Zenara is a foreign company not subject to personal jurisdiction in the courts in any state, and (c) Zenara has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Zenara satisfies due process.

47. Venue is proper in this District with respect to Zenara pursuant to 28 U.S.C. § 1391(c)(3) because Zenara is a foreign corporation and may be sued in any judicial district.

48. Joinder of the defendants is proper pursuant to 35 U.S.C. § 299.

FACTUAL BACKGROUND

G. XADAGO® (safinamide) Tablets

49. Newron is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system.

50. Parkinson's disease (PD) is the second most common chronic progressive neurodegenerative disorder in the elderly after Alzheimer's disease, affecting 1-2% of individuals aged ≥ 65 years worldwide. [Ex. 1 (March 21, 2017 Newron Press Release).]

51. Idiopathic PD, meaning PD with an unknown cause, is the most common form of Parkinsonism. Idiopathic PD is often referred to as "Parkinson's Disease."

52. The diagnosis of PD is mainly based on observational criteria of muscular rigidity, resting tremor, or postural instability in combination with bradykinesia (i.e., slowness of movement). As the disease progresses, symptoms become more severe. [*Id.*]

53. Levodopa ("L-dopa") remains the most effective treatment for PD, and over 75% of patients with PD receive L-dopa. However, long-term treatment with L-dopa leads to seriously debilitating motor fluctuations, i.e., phases of normal functioning (ON-time) and decreased functioning (OFF-time). Therefore, as the disease progresses, additional medications are added on to L-dopa to help with management of these motor fluctuations. [*See id.*]

54. In March of 2017, after extensive effort, research, and development, Newron, through its U.S. subsidiary, secured FDA approval for NDA No. 207145 for XADAGO® (safinamide) tablets, indicated as adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes. [Ex. 2 (3/21/2017 FDA Letter).]

55. The active ingredient in XADAGO® (safinamide) tablets is the mesylate salt of safinamide, or safinamide mesylate, which is a pharmaceutically acceptable acid salt of safinamide. [Ex. 3 (XADAGO® Label), § 11.]

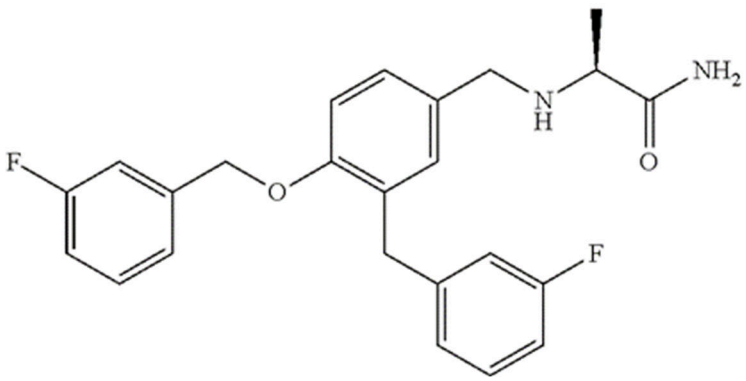
56. FDA's approval of XADAGO® (safinamide) tablets constituted the first New Chemical Entity approved for PD patients with motor fluctuations in the United States in over a decade. [Ex. 1 (March 21, 2017 Newron Press Release).]

57. A true, correct, and complete copy of the current FDA-approved Full Prescribing Information for XADAGO® (safinamide) tablets is attached as Exhibit 3.

58. "XADAGO is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing 'off' episodes." [Ex. 3 (XADAGO® Label), § 1.]

59. XADAGO® (safinamide) tablets contain highly pure safinamide mesylate, including less than 0.03% (by weight) of the impurity (S)-2-[3-(3-fluorobenzyl)-4-(3-fluorobenzyloxy)-benzylamino]propanamide ("Compound IIa"):

(IIa)



or a pharmaceutically acceptable acid salt thereof ("Compound IIc").

60. "XADAGO is available as 50 mg and 100 mg film-coated tablets for oral administration. Each tablet contains 65.88 mg or 131.76 mg of safinamide mesylate, equivalent to 50 mg or 100 mg, respectively, of safinamide free base." [*Id.* § 11.]

61. The FDA-approved labeling for XADAGO® (safinamide) tablets instructs healthcare providers that "XADAGO has been shown to be effective only in combination with levodopa/carbidopa *[see Indications and Usage (1)]*." [*Id.* § 2.1]

62. The FDA-approved labeling for XADAGO® (safinamide) tablets includes clinical study information regarding XADAGO® (safinamide) tablets' efficacy as an "Adjunctive Treatment in Patients with PD Experiencing OFF Time on a Stable Dose of Levodopa" in Section 14.1. [*Id.* § 14.1.] It instructs, encourages and teaches long-term concurrent administration of XADAGO® (safinamide) tablets, stable doses of levodopa, and stable doses of other PD treatments. [*See id.* § 14.1.] Section 14.1 states that "[t]wo double-blind, placebo-controlled, multi-national, 24-week studies (Study 1 and Study 2) were conducted in PD patients experiencing 'OFF' Time during treatment with carbidopa/levodopa and other PDF medications . . . ." [*Id.*]

63. Section 14.1 sets forth "[t]he percentages of patients taking stable doses of other classes of PD medications, in addition to levodopa/decarboxylase inhibitor" in Study 1, and identifies "[t]he average daily dose of levodopa was 630 mg." [*Id.*] Section 14.1 instructs that "[i]n Study 1, XADAGO 50 mg/day and 100 mg/day significantly increased "ON" Time compared to placebo (Table 2). The increase in "ON" Time without troublesome dyskinesia was accompanied by a similar significant reduction in "OFF" Time and a reduction in Unified PD Rating Scale Part III (UPDRS III) scores assessed during "ON" Time (Table 3). Improvement in "ON" Time occurred without an increase in troublesome dyskinesia." [*Id.*]

64. Section 14.1 also sets forth the percentages of "patients taking stable doses of other classes of PD medications, in addition to levodopa/decarboxylase inhibitor" in Study 2, and identifies "[t]he average daily dose of levodopa was 777 mg." [*Id.*] Section 14.1 instructs that:

> In Study 2, XADAGO was significantly better than placebo for increasing "ON" Time (Table 4). The observed increase in "ON" Time without troublesome dyskinesia was

> accompanied by a reduction in "OFF" Time of similar magnitude and a reduction in UPDRS III score (assessed during "ON" Time). The time course of effect was similar to that showed in the above figure for Study 1. As in Study 1, the increase in "ON" Time without troublesome dyskinesia was accompanied by a similar significant reduction in "OFF" Time and a reduction in Unified PD Rating Scale Part III (UPDRS III) scores assessed during "ON" Time (Table 5).

[*Id.*]

65. The information in Section 14.1 of the XADAGO® label further demonstrates that XADAGO® (safinamide) tablets 50 mg and 100 mg contain an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof. [*Id.*]

66. Section 2.1 of the XADAGO® label instructs healthcare providers "[t]he recommended starting dosage of XADAGO is 50 mg administered orally once daily (at the same time of day), without regard to meals. After two weeks, the dosage may be increased to 100 mg once daily, based on individual need and tolerability." [*Id.* § 2.1.]

67. Based on that instruction, in the XADAGO® label, the oral dosage schedule for a person of X kg, where X may range from 10kg to 100kg, will be about 0.5 mg/kg/day to about 5 mg/kg/day. For example, a healthcare provider administering XADAGO® (safinamide) tablets to a 70kg person according to the instructions in the XADAGO® label, will follow an oral dosage schedule of about 0.7 mg/kg/day to about 1.4 mg/kg/day, corresponding to a dosage of 50 mg and 100 mg, respectively.

H. The Asserted '515 Patent

68. On December 13, 2011, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '515 patent, titled "Process for the Production of 2-[4-(3- and 2-Fluorobenzyloxy) Benzylamino] Propanamides," and naming Elena Barbanti, Carla Caccia, Patricia Salvati, Francesco Velardi, Tiziano Ruffilli, and Luigi Bogogna as inventors. A true and correct copy of the '515 patent is attached to this complaint as Exhibit 4.

69. The ’515 patent is assigned to Newron.

70. Zambon holds an exclusive license to the ’515 patent.

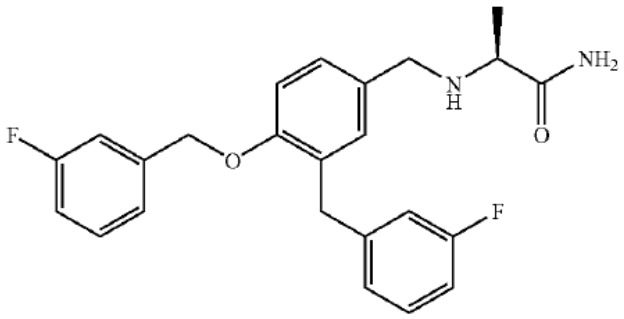
71. MDD holds an exclusive sublicense to the ’515 patent.

72. The ’515 patent is listed in association with XADAGO® (safinamide) tablets in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book,” which provides notice concerning patents covering FDA-approved drugs.

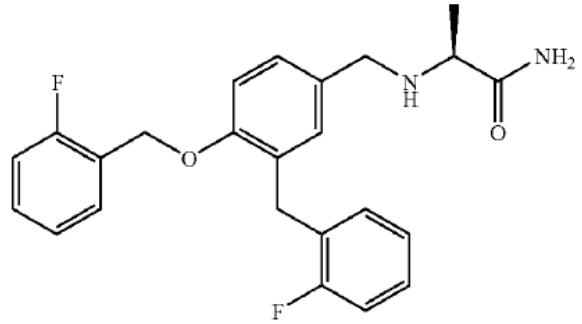
73. Claim 32 of the ’515 patent reads as follows:

> High purity safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof with a content of the respective impurity (S)-2-[3-(3-fluorobenzyl)-4-(3-fluorobenzyloxy)-benzylamino]propanamide (IIa) or (S)-2-[3-(2-fluorobenzyl)-4-(2-fluorobenzyloxy)-benzylamino]propanamide (IIb)

(IIa)



(IIb)



> or their pharmaceutically acceptable acid salts, which is lower than 0.03% (by weight).

74. Claim 34 of the ’515 patent reads as follows:

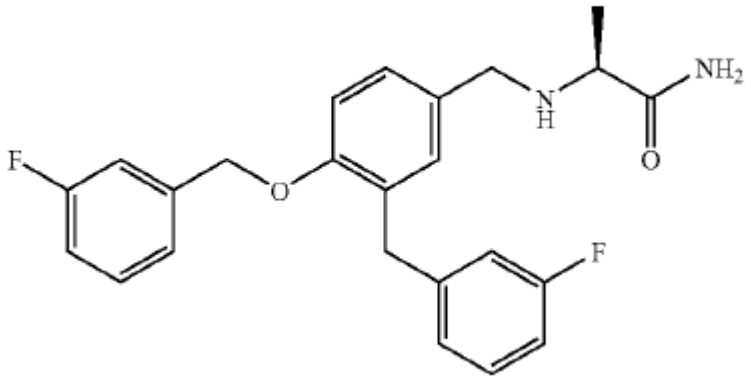
> A pharmaceutical formulation containing high purity safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof wherein the content of the

respective impurity of formula (IIa) or (IIb) of claim 32 or a pharmaceutically acceptable acid salt thereof is lower than 0.03% (by weight).

75. Claim 40 of the '515 patent reads as follows:

A method for treating CNS disorders, selected from the group consisting of epilepsy, Parkinson disease, Alzheimer disease, depression, restless leg syndrome and migraine comprising administering to a patient in need thereof an effective amount of high purity safinamide or a pharmaceutically acceptable acid salt thereof wherein the content of the impurity (S)-2-[3-(3-fluorobenzyloxy)-4-(3-flurobenzyl)-benzylamino]propanamide of formula (IIa)

(IIa)



or a pharmaceutically acceptable acid salt thereof is lower than 0.03% (by weight).

76. XADAGO® (safinamide) tablets, and their use according to the directions and instructions on the FDA-approved label, are covered by at least claims 34 and 40 of the '515 patent.

I. The Asserted '485 Patent

77. On October 2, 2012, the USPTO duly and legally issued the '485, titled "Process for the Production of 2-[4-(3- and 2-Fluorobenzyloxy) Benzylamino] Propanamides," and naming Elena Barbanti, Carla Caccia, Patricia Salvati, Francesco Velardi, Tiziano Ruffilli, and Luigi Bogogna as inventors. A true and correct copy of the '485 patent is attached to this complaint as Exhibit 5.

78. The '485 patent is assigned to Newron.

79. Zambon holds an exclusive license to the '485 patent.

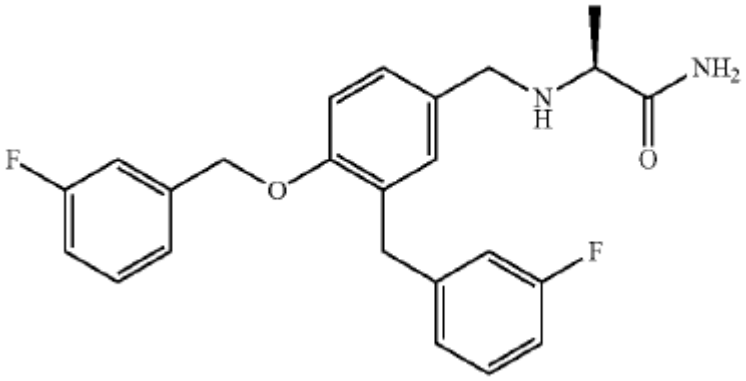
80. MDD holds an exclusive sublicense to the ’485 patent.

81. The ’485 patent is listed in association with XADAGO® (safinamide) tablets in the Orange Book which provides notice concerning patents covering FDA-approved drugs.

82. Claim of 37 the ’485 patent reads as follows:

> A method for treating Parkinson’s disease comprising administering to a patient in need thereof an effective amount of high purity safinamide or a pharmaceutically acceptable acid salt thereof wherein the content of the impurity (S)-2-[3-(3-fluorobenzyl)-4-(3-flurobenzyloxy)-benzylamino]propanamide of formula (IIa)

(IIa)



> or a pharmaceutically acceptable acid salt thereof is lower than 0.03% (by weight).

83. XADAGO® (safinamide) tablets, and their use according to the directions and instructions on the FDA-approved label, are covered by at least claim 37 of the ’485 patent.

J. The Asserted ’380 Patent

84. On October 9, 2012, the USPTO duly and legally issued the ’380 patent, titled “Methods for Treatment of Parkinson’s Disease,” and naming Ruggero Fariello, Carlo Cattaneo, Patricia Salvati, and Luca Benatti as inventors. A true and correct copy of the ’380 patent is attached to this complaint as Exhibit 6.

85. The ’380 patent is assigned to Newron.

86. Zambon holds an exclusive license to the ’380 patent.

87. MDD holds an exclusive sublicense to the '380 patent.

88. The '380 patent is listed in association with XADAGO® (safinamide) tablets in the Orange Book which provides notice concerning patents covering FDA-approved drugs.

89. Claim 1 of the '380 patent reads as follows:

> In a method of treating idiopathic Parkinson's disease in a patient receiving a stable dose of levodopa, the improvement comprising:
> concurrently administering safinamide, or a pharmaceutically acceptable salt thereof, on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day,
> while maintaining the patient on a stable dose of levodopa.

90. XADAGO® (safinamide) tablets, and their use according to the directions and instructions on the FDA-approved label, are covered by at least claim 1 of the '380 patent.

ACTS GIVING RISE TO THIS ACTION FOR DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

K. Aurobindo

91. On or about April 30, 2021, Plaintiffs received a letter, dated April 29, 2021, signed on behalf of Aurobindo by Steven J. Moore of the law firm Withers Bergman ("Aurobindo's Paragraph IV Letter").

92. This action is being commenced before the expiration of 45 days from the date Plaintiffs received Aurobindo's Paragraph IV Letter, which triggers a stay of FDA approval of Aurobindo's ANDA No. 215902 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

93. Aurobindo's Paragraph IV Letter states that Aurobindo had filed Abbreviated New Drug Application ("ANDA") No. 215902 with the FDA seeking approval for safinamide mesylate tablets, 50 mg and 100 mg drug tablet product ("Aurobindo's ANDA Product"), which are a generic version of Plaintiffs' XADAGO® (safinamide) tablets.

94. Aurobindo's Paragraph IV Letter also states that ANDA No. 215902 contains any required bioavailability and/or bioequivalence data and a Paragraph IV certification for the '515, '485, and '380 patents.

95. Aurobindo submitted to the FDA ANDA No. 215902 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Aurobindo's ANDA Product before the expiration of the '515, '485, '380 patents.

96. Attached to Aurobindo's Paragraph IV Letter is a statement of the factual and legal bases for Aurobindo's position that the '515, '485, and '380 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Aurobindo's ANDA Product described in ANDA No. 215902.

97. In particular, Aurobindo's Paragraph IV letter alleges that claims 32-38 and 40-44 of the '515 patent are invalid and Aurobindo's ANDA Product would not infringe claims 1-31, 39 and 45-58 of the '515 patent.

98. Aurobindo's Paragraph IV Letter does not allege invalidity of claims 1-31, 39 and 45-58 of the '515 patent or non-infringement of claims 32-38 and 40-44 of the '515 patent.

99. Aurobindo's Paragraph IV letter also alleges that claims 36-41 of the '485 patent are invalid and Aurobindo's ANDA Product would not infringe claims 1-35 and 42-50 of the '485 patent.

100. Aurobindo's Paragraph IV Letter does not allege invalidity of claims 1-35 and 42-50 of the '485 patent or non-infringement of claims 36-41 of the '485 patent.

101. Aurobindo's Paragraph IV letter further alleges that claims 1-7 of the '380 patent are invalid and Aurobindo's ANDA Product would not infringe claims 8-10 of the '380 patent.

102. Aurobindo's Paragraph IV Letter does not allege invalidity of claims 8-10 of the '380 patent or non-infringement of claims 1-7 of the '380 patent.

103. In filing and maintaining ANDA No. 215902, Aurobindo has requested and continues to request FDA approval to market a generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

104. On information and belief, following FDA approval of ANDA No. 215902, Aurobindo will offer for sale and sell its approved generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

105. Aurobindo's effort to seek FDA approval to market a generic version of XADAGO® (safinamide) tablets prior to the expiration of the '515, '485, and '380 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 215902, the '515 patent, the '485 patent, and the '380 patent as further evidenced by Aurobindo's Paragraph IV Letter.

106. Aurobindo's ANDA Product, both the 50 mg and 100 mg strengths, contains an effective amount of highly pure safinamide or a pharmaceutically acceptable acid salt thereof, including because those amounts of active ingredient copy the amounts of active ingredient in XADAGO® (safinamide) tablets, which have been deemed effective amounts by FDA.

107. Aurobindo's ANDA Product will be sold and distributed with labeling that will be substantially the same as the labeling for XADAGO® (safinamide) tablets, and thus will contain substantially the same instructions for use as those in the label for XADAGO® (safinamide) tablets, including instructions that are substantially the same as those described above in paragraphs 61-67.

108. For example, on information and belief, the labeling for Aurobindo's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers that the product is indicated for use as adjunctive treatment to levodopa/carbidopa in patients with idiopathic Parkinson's disease (PD) experiencing "off" episodes and teaches once daily dosing of either 50 mg or 100 mg tablets, and thus promotes and encourages use of Aurobindo's ANDA Product to treat Parkinson's disease by administering an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof to Parkinson's disease patients.

109. In addition, on information and belief, the clinical studies section of the labeling for Aurobindo's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers to concurrently administer, to idiopathic Parkinson's Disease patients, safinamide on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day while maintaining the patients on stable doses of levodopa, and thus promotes and encourages use of the product on that dosage schedule to Parkinson's disease patients on stable doses of levodopa. Healthcare providers would understand the labeling for Aurobindo's ANDA Product to promote and encourage use of an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day because, for example a healthcare provider administering Aurobindo's ANDA Product to a 70kg Parkinson's disease patient according to the instructions on Aurobindo's labeling, would be administering safinamide or a pharmaceutically acid acceptable salt thereof an oral dosage schedule of either about 0.7 mg/kg/day (50 mg once daily) to about 1.4 mg/kg/day (100 mg once daily).

110. On information and belief, Aurobindo's ANDA Product contains highly pure safinamide mesylate and has a content of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc), which is lower than 0.03% (by weight). Indeed Aurobindo did not

allege non-infringement of claims 32-38 and 40-44 of the '515 patent and claims 36-41 of the '485 patent, including on the basis that its product does not contain highly pure safinamide mesylate nor less than 0.03% (by weight) of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc).

111. For the reasons above, on information and belief, Aurobindo is seeking approval for products, used according to proposed labeling that is substantially similar to the labeling for XADAGO® (safinamide) tablets, that meet all the limitations of at least claims 34 and 40 of the '515 patent, claim 37 of the '485 patent, and claim 1 of the '380 patent, either literally or under the doctrine of equivalents; therefore, the products Aurobindo is likely to sell will infringe the '515, '485, and '380 patents.

L. MSN

112. On or about May 17, 2021, Plaintiffs received a letter, dated May 14, 2021, signed on behalf of MSN by Gurpreet Singh Walia of the law firm FisherBroyles, LLP ("MSN's Paragraph IV Letter").

113. This action is being commenced before the expiration of 45 days from the date Plaintiffs received MSN's Paragraph IV Letter, which triggers a stay of FDA approval of MSN's ANDA No. 215978 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

114. MSN's Paragraph IV Letter states that MSN had filed Abbreviated New Drug Application ("ANDA") No. 215978 with the FDA seeking approval for safinamide mesylate tablets, 50 mg and 100 mg ("MSN's ANDA Product"), which are a generic version of Plaintiffs' XADAGO® (safinamide) tablets.

115. MSN's Paragraph IV Letter also states that ANDA No. 215978 contains any required bioavailability or bioequivalence data and a Paragraph IV certification for the '515, '485, and '380 patents.

116. MSN submitted to the FDA ANDA No. 215978 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of MSN's ANDA Product before the expiration of the '515, '485, '380 patents.

117. Attached to MSN's Paragraph IV Letter is a statement of the factual and legal bases for MSN's position that the '515, '485, and '380 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of MSN's ANDA Product described in ANDA No. 215978.

118. In filing and maintaining ANDA No. 215978, MSN has requested and continues to request FDA approval to market a generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

119. On information and belief, following FDA approval of ANDA No. 215978, MSN will offer for sale and sell its approved generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

120. MSN's effort to seek FDA approval to market a generic version of XADAGO® (safinamide) tablets prior to the expiration of the '515, '485, and '380 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 215978, the '515 patent, the '485 patent, and the '380 patent as further evidenced by MSN's Paragraph IV Letter.

121. MSN's ANDA Product, both the 50 mg and 100 mg strengths, contains an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof, including because those amounts of active ingredient copy the amounts of active ingredient in XADAGO® (safinamide) tablets, which have been deemed effective amounts by FDA.

122. MSN's ANDA Product will be sold and distributed with labeling that will be substantially the same as the labeling for XADAGO® (safinamide) tablets, and thus will contain substantially the same instructions for use as those in the label for XADAGO® (safinamide) tablets, including instructions that are substantially the same as those described above in paragraphs 61-67.

123. For example, on information and belief, the labeling for MSN's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers that the product is indicated for use as adjunctive treatment to levodopa/carbidopa in patients with idiopathic Parkinson's disease (PD) experiencing "off" episodes and teaches once daily dosing of either 50 mg or 100 mg tablets, and thus promotes and encourages use of MSN's ANDA Product to treat Parkinson's disease by administering an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof to Parkinson's disease patients.

124. In addition, on information and belief, the clinical studies section of the labeling for MSN's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers to concurrently administer, to idiopathic Parkinson's Disease patients, safinamide on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day while maintaining the patients on stable doses of levodopa, and thus promotes and encourages use of the product on that dosage schedule to Parkinson's disease patients on stable doses of levodopa. Healthcare providers would understand the labeling for MSN's ANDA Product to promote and encourage use of an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day because, for example a healthcare provider administering MSN's ANDA Product to a 70kg Parkinson's disease patient according to the instructions on MSN's labeling, would be administering

safinamide or a pharmaceutically acid acceptable salt thereof an oral dosage schedule of either about 0.7 mg/kg/day (50 mg once daily) to about 1.4 mg/kg/day (100 mg once daily).

125. Since receiving MSN's Paragraph IV Letter, Plaintiffs have attempted to procure a copy of ANDA No. 215978 and the underlying DMF from MSN. Because the terms of the proposed Offer of Confidential Access would not allow Plaintiffs to meaningfully process the information in the ANDA, or receive the DMF, including, for example, by not allowing Plaintiffs' in-house counsel or in-house scientists to review those materials, Plaintiffs could not agree to the terms of the original Offer. On June 1, 2021, counsel for Plaintiffs sent MSN's counsel a letter in an attempt to negotiate access to ANDA No. 215978 and the underlying DMF. As of the filing of this Complaint, MSN has not responded.

126. Plaintiffs are not aware of any other means for obtaining information regarding the purity of safinamide mesylate or the amount of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc) in MSN's ANDA Product. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm their allegations of infringement and to present the Court evidence that MSN's ANDA Product fall within the scope of one or more claims of the '515 and '485 patents.

127. For the reasons above, on information and belief, MSN is seeking approval for products, used according to proposed labeling that is substantially similar to the labeling for XADAGO® (safinamide) tablets, that meet all the limitations of at least claims 34 and 40 of the '515 patent, claim 37 of the '485 patent, and claim 1 of the '380 patent, either literally or under the doctrine of equivalents; therefore, the products MSN is likely to sell will infringe the '515, '485, and '380 patents.

M. Optimus

128. On or about May 17, 2021, Plaintiffs received a letter, dated May 15, 2021, signed on behalf of Optimus by Parithosh K. Tungaturthi of the law firm IP Pundit LLC ("Optimus' Paragraph IV Letter").

129. Optimus' Paragraph IV Letter states that Optimus had filed Abbreviated New Drug Application ("ANDA") No. 216020 with the FDA seeking approval for safinamide mesylate tablets, 50 mg and 100 mg drug tablet product ("Optimus' ANDA Product"), which are a generic version of Plaintiffs' XADAGO® (safinamide) tablets.

130. This action is being commenced before the expiration of 45 days from the date Plaintiffs received Optimus' Paragraph IV Letter, which triggers a stay of FDA approval of Optimus' ANDA No. 216020 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

131. Optimus' Paragraph IV Letter also states that ANDA No. 216020 contains any required bioavailability and/or bioequivalence data and/or bioequivalence waiver and a Paragraph IV certification for the '515, '485, and '380 patents.

132. Optimus submitted to the FDA ANDA No. 216020 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Optimus' ANDA Product before the expiration of the '515, '485, '380 patents.

133. Attached to Optimus' Paragraph IV Letter is a statement of the factual and legal bases for Optimus' position that the '515, '485, and '380 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Optimus' ANDA Product described in ANDA No. 216020.

134. In particular, Optimus' Paragraph IV letter alleges that claims 1-58 of the '515 patent are invalid and Optimus' ANDA Product would not infringe claims 1-31 and 45 of the '515 patent.

135. Optimus' Paragraph IV Letter does not allege non-infringement of claims 32-44 and 46-58 of the '515 patent.

136. Optimus' Paragraph IV letter also alleges that claims 1-50 of the '485 patent are invalid and Optimus' ANDA Product would not infringe claims 1-35 and 38-50 of the '485 patent.

137. Optimus' Paragraph IV Letter does not allege non-infringement of claims 36-37 of the '485 patent.

138. Optimus' Paragraph IV letter further alleges that claims 1-10 of the '380 patent are invalid.

139. Optimus' Paragraph IV Letter does not allege non-infringement of claims 1-10 of the '380 patent.

140. In filing and maintaining ANDA No. 216020, Optimus has requested and continues to request FDA approval to market a generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

141. On information and belief, following FDA approval of ANDA No. 216020, Optimus will offer for sale and sell its approved generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

142. Optimus' effort to seek FDA approval to market a generic version of XADAGO® (safinamide) tablets prior to the expiration of the '515, '485, and '380 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between

the parties with respect to the subject matter of ANDA No. 216020, the '515 patent, the '485 patent, and the '380 patent as further evidenced by Optimus' Paragraph IV Letter.

143. Optimus' ANDA Product, both the 50 mg and 100 mg strengths, contains an effective amount of highly pure safinamide or a pharmaceutically acceptable acid salt thereof, including because those amounts of active ingredient copy the amounts of active ingredient in XADAGO® (safinamide) tablets, which have been deemed effective amounts by FDA.

144. Optimus' ANDA Product will be sold and distributed with labeling that will be substantially the same as the labeling for XADAGO® (safinamide) tablets, and thus will contain substantially the same instructions for use as those in the label for XADAGO® (safinamide) tablets, including instructions that are substantially the same as those described above in paragraphs 61-67.

145. For example, on information and belief, the labeling for Optimus' ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers that the product is indicated for use as adjunctive treatment to levodopa/carbidopa in patients with idiopathic Parkinson's disease (PD) experiencing "off" episodes and teaches once daily dosing of either 50 mg or 100 mg tablets, and thus promotes and encourages use of Optimus' ANDA Product to treat Parkinson's disease by administering an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof to Parkinson's disease patients.

146. In addition, on information and belief, the clinical studies section of the labeling for Optimus' ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers to concurrently administer, to idiopathic Parkinson's Disease patients, safinamide on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day while maintaining the patients on stable doses of levodopa, and thus promotes and encourages use of the

product on that dosage schedule to Parkinson's disease patients on stable doses of levodopa. Healthcare providers would understand the labeling for Optimus' ANDA Product to promote and encourage use of an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day because, for example a healthcare provider administering Optimus' ANDA Product to a 70kg Parkinson's disease patient according to the instructions on Optimus' labeling, would be administering safinamide or a pharmaceutically acid acceptable salt thereof an oral dosage schedule of either about 0.7 mg/kg/day (50 mg once daily) to about 1.4 mg/kg/day (100 mg once daily).

147. On information and belief, Optimus' ANDA Product contains highly pure safinamide mesylate and has a content of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc), which is lower than 0.03% (by weight). Indeed Optimus did not allege non-infringement of claims 32-44 and 46-58 of the '515 patent, claims 36-37 of the '485 patent, and claims 1-10 of the '380 patent, including on the basis that its product does not contain highly pure safinamide mesylate nor less than 0.03% (by weight) of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc).

148. For the reasons above, on information and belief, Optimus is seeking approval for products, used according to proposed labeling that is substantially similar to the labeling for XADAGO® (safinamide) tablets, that meet all the limitations of at least claims 34 and 40 of the '515 patent, claim 37 of the '485 patent, and claim 1 of the '380 patent, either literally or under the doctrine of equivalents; therefore, the products Optimus is likely to sell will infringe the '515, '485, and '380 patents.

N. Prinston

149. On or about May 17, 2021, Plaintiffs received a letter, dated May 12, 2021, signed on behalf of Prinston by Shashank Upadhye of the law firm Upadhye Tang LLP ("Prinston's Paragraph IV Letter").

150. This action is being commenced before the expiration of 45 days from the date Plaintiffs received Prinston's Paragraph IV Letter, which triggers a stay of FDA approval of Prinston's ANDA No. 215739 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

151. Prinston's Paragraph IV Letter states that Prinston had filed Abbreviated New Drug Application ("ANDA") No. 215739 with the FDA seeking approval for safinamide mesylate tablets, 50 mg and 100 mg drug tablet product ("Prinston's ANDA Product"), which are a generic version of Plaintiffs' XADAGO® (safinamide) tablets.

152. Prinston's Paragraph IV Letter also states that ANDA No. 215739 contains any required bioavailability and/or bioequivalence data and a Paragraph IV certification for the '515, '485, and '380 patents.

153. Prinston submitted to the FDA ANDA No. 215739 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Prinston's ANDA Product before the expiration of the '515, '485, '380 patents.

154. Attached to Prinston's Paragraph IV Letter is a statement of the factual and legal bases for Prinston's position that the '515, '485, and '380 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Prinston's ANDA Product described in ANDA No. 215739.

155. In filing and maintaining ANDA No. 215739, Prinston has requested and continues to request FDA approval to market a generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

156. On information and belief, following FDA approval of ANDA No. 215739, Prinston will offer for sale and sell its approved generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

157. Prinston's effort to seek FDA approval to market a generic version of XADAGO® (safinamide) tablets prior to the expiration of the '515, '485, and '380 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 215739, the '515 patent, the '485 patent, and the '380 patent as further evidenced by Prinston's Paragraph IV Letter.

158. Prinston's ANDA Product, both the 50 mg and 100 mg strengths, contains an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof, including because those amounts of active ingredient copy the amounts of active ingredient in XADAGO® (safinamide) tablets, which have been deemed effective amounts by FDA.

159. Prinston's ANDA Product will be sold and distributed with labeling that will be substantially the same as the labeling for XADAGO® (safinamide) tablets, and thus will contain substantially the same instructions for use as those in the label for XADAGO® (safinamide) tablets, including instructions that are substantially the same as those described above in paragraphs 61-67.

160. For example, on information and belief, the labeling for Prinston's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers that the product is indicated for use as adjunctive treatment to levodopa/carbidopa in patients with idiopathic Parkinson's disease (PD) experiencing "off" episodes and teaches once daily dosing of either 50 mg or 100 mg tablets, and thus promotes and encourages use of Prinston's ANDA

Product to treat Parkinson's disease by administering an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof to Parkinson's disease patients.

161. In addition, on information and belief, the clinical studies section of the labeling for Prinston's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers to concurrently administer, to idiopathic Parkinson's Disease patients, safinamide on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day while maintaining the patients on stable doses of levodopa, and thus promotes and encourages use of the product on that dosage schedule to Parkinson's disease patients on stable doses of levodopa. Healthcare providers would understand the labeling for Prinston's ANDA Product to promote and encourage use of an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day because, for example a healthcare provider administering Prinston's ANDA Product to a 70kg Parkinson's disease patient according to the instructions on Prinston's labeling, would be administering safinamide or a pharmaceutically acid acceptable salt thereof an oral dosage schedule of either about 0.7 mg/kg/day (50 mg once daily) to about 1.4 mg/kg/day (100 mg once daily).

162. Since receiving Prinston's Paragraph IV Letter, Plaintiffs have attempted to procure a copy of ANDA No. 215739 and the underlying DMF from Prinston. Because the terms of the proposed Offer of Confidential Access would not allow Plaintiffs to meaningfully process the information in the ANDA, or receive the DMF, including, for example, by not allowing Plaintiffs' in-house counsel or in-house scientists to review those materials, Plaintiffs could not agree to the terms of the original Offer. On June 1, 2021, counsel for Plaintiffs sent Prinston's counsel a letter in an attempt to negotiate access to ANDA No. 215739 and the underlying DMF. On June 3, 2021, counsel for Prinston responded to Plaintiffs' positions, confirming certain conditions of access

were non-negotiable, and thus confirming the parties had reached an impasse on the terms of access.

163. Plaintiffs are not aware of any other means for obtaining information regarding the purity of safinamide mesylate or the amount of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc) in Prinston's ANDA Product. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm their allegations of infringement and to present the Court evidence that Prinston's ANDA Product fall within the scope of one or more claims of the '515 and '485 patents.

164. For the reasons above, on information and belief, Prinston is seeking approval for products, used according to proposed labeling that is substantially similar to the labeling for XADAGO® (safinamide) tablets, that meet all the limitations of at least claims 34 and 40 of the '515 patent, claim 37 of the '485 patent, and claim 1 of the '380 patent, either literally or under the doctrine of equivalents; therefore, the products Prinston is likely to sell will infringe the '515, '485, and '380 patents.

O. RK Pharma

165. On or about May 17, 2021, Plaintiffs received a letter, dated May 14, 2021, signed on behalf of RK Pharma by Sri K. Sankaran of the law firm PADDA Law Group PLLC ("RK Pharma's Paragraph IV Letter").

166. This action is being commenced before the expiration of 45 days from the date Plaintiffs received RK Pharma's Paragraph IV Letter, which triggers a stay of FDA approval of RK Pharma's ANDA No. 215945 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

167. RK Pharma's Paragraph IV Letter states that RK Pharma had filed Abbreviated New Drug Application ("ANDA") No. 215945 with the FDA seeking approval for safinamide

mesylate tablets, 50 mg and 100 mg ("RK Pharma's ANDA Product"), which are a generic version of Plaintiffs' XADAGO® (safinamide) tablets.

168. RK Pharma's Paragraph IV Letter also states that ANDA No. 215945 contains any required bioavailability and/or bioequivalence data and a Paragraph IV certification for the '515, '485, and '380 patents.

169. RK Pharma submitted to the FDA ANDA No. 215945 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of RK Pharma's ANDA Product before the expiration of the '515, '485, '380 patents.

170. Attached to RK Pharma's Paragraph IV Letter is a statement of the factual and legal bases for RK Pharma's position that the '515, '485, and '380 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of RK Pharma's ANDA Product described in ANDA No. 215945.

171. In particular, RK Pharma's Paragraph IV letter alleges that claims 32-35 and 40-44 of the '515 patent are invalid and RK Pharma's ANDA Product would not infringe claims 1-31, 36-39 and 45-58 of the '515 patent.

172. RK Pharma's Paragraph IV Letter does not allege invalidity of claims 1-31, 36-39 and 45-58 of the '515 patent or non-infringement of claims 32-35 and 40-44 of the '515 patent.

173. RK Pharma's Paragraph IV letter also alleges that claim 37 of the '485 patent is invalid and RK Pharma's ANDA Product would not infringe claims 1-36 and 38-50 of the '485 patent.

174. RK Pharma's Paragraph IV Letter does not allege invalidity of claims 1-36 and 38-50 of the '485 patent or non-infringement of claim 37 of the '485 patent.

175. In filing and maintaining ANDA No. 215945, RK Pharma has requested and continues to request FDA approval to market a generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

176. On information and belief, following FDA approval of ANDA No. 215945, RK Pharma will offer for sale and sell its approved generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

177. RK Pharma's effort to seek FDA approval to market a generic version of XADAGO® (safinamide) tablets prior to the expiration of the '515, '485, and '380 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 215945, the '515 patent, the '485 patent, and the '380 patent as further evidenced by RK Pharma's Paragraph IV Letter.

178. RK Pharma's ANDA Product, both the 50 mg and 100 mg strengths, contains an effective amount of highly pure safinamide or a pharmaceutically acceptable acid salt thereof, including because those amounts of active ingredient copy the amounts of active ingredient in XADAGO® (safinamide) tablets, which have been deemed effective amounts by FDA.

179. RK Pharma's ANDA Product will be sold and distributed with labeling that will be substantially the same as the labeling for XADAGO® (safinamide) tablets, and thus will contain substantially the same instructions for use as those in the label for XADAGO® (safinamide) tablets, including instructions that are substantially the same as those described above in paragraphs 61-67.

180. For example, on information and belief, the labeling for RK Pharma's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers that

the product is indicated for use as adjunctive treatment to levodopa/carbidopa in patients with idiopathic Parkinson's disease (PD) experiencing "off" episodes and teaches once daily dosing of either 50 mg or 100 mg tablets, and thus promotes and encourages use of RK Pharma's ANDA Product to treat Parkinson's disease by administering an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof to Parkinson's disease patients.

181. In addition, on information and belief, the clinical studies section of the labeling for RK Pharma's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers to concurrently administer, to idiopathic Parkinson's Disease patients, safinamide on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day while maintaining the patients on stable doses of levodopa, and thus promotes and encourages use of the product on that dosage schedule to Parkinson's disease patients on stable doses of levodopa. Healthcare providers would understand the labeling for RK Pharma's ANDA Product to promote and encourage use of an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day because, for example a healthcare provider administering RK Pharma's ANDA Product to a 70kg Parkinson's disease patient according to the instructions on RK Pharma's labeling, would be administering safinamide or a pharmaceutically acid acceptable salt thereof an oral dosage schedule of either about 0.7 mg/kg/day (50 mg once daily) to about 1.4 mg/kg/day (100 mg once daily).

182. On information and belief, RK Pharma's ANDA Product contains highly pure safinamide mesylate and has a content of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc), which is lower than 0.03% (by weight). Indeed RK Pharma did not allege non-infringement of claims 32-35 and 40-44 of the '515 patent and claim 37 of the '485 patent, including on the basis that its product does not contain highly pure safinamide mesylate

nor less than 0.03% (by weight) of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc).

183. For the reasons above, on information and belief, RK Pharma is seeking approval for products, used according to proposed labeling that is substantially similar to the labeling for XADAGO® (safinamide) tablets, that meet all the limitations of at least claims 34 and 40 of the '515 patent, claim 37 of the '485 patent, and claim 1 of the '380 patent, either literally or under the doctrine of equivalents; therefore, the products RK Pharma is likely to sell will infringe the '515, '485, and '380 patents.

P. Zenara

184. On or about May 18, 2021, Plaintiffs received a letter, dated May 17, 2021, signed on behalf of Zenara by Dr. Jagadeesh Rangisetty, Chief Executive Officer of Zenara ("Zenara's Paragraph IV Letter").

185. This action is being commenced before the expiration of 45 days from the date Plaintiffs received Zenara's Paragraph IV Letter, which triggers a stay of FDA approval of Zenara's ANDA No. 215913 pursuant to 21 U.S.C § 355(j)(5)(B)(iii).

186. Zenara's Paragraph IV Letter states that Zenara had filed Abbreviated New Drug Application ("ANDA") No. 215913 with the FDA seeking approval for safinamide tablets, 50 mg and 100 mg ("Zenara's ANDA Product"), which are a generic version of Plaintiffs' XADAGO® (safinamide) tablets.

187. Zenara's Paragraph IV Letter also states that ANDA No. 215913 contains any required bioavailability or bioequivalence data and a Paragraph IV certification for the '515, '485, and '380 patents.

188. Zenara submitted to the FDA ANDA No. 215913 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA's approval to engage in

the commercial manufacture, use, importation, offer for sale, and/or sale of Zenara's ANDA Product before the expiration of the '515, '485, '380 patents.

189. Attached to Zenara's Paragraph IV Letter is a statement of the factual and legal bases for Zenara's position that the '515, '485, and '380 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Zenara's ANDA Product described in ANDA No. 215913.

190. In particular, Zenara's Paragraph IV letter alleges that claims 1-10 of the '380 patent are invalid and Zenara's ANDA Product would not infringe claims 9-10 of the '380 patent.

191. Zenara's Paragraph IV Letter does not allege non-infringement of claims 1-8 of the '380 patent.

192. In filing and maintaining ANDA No. 215913, Zenara has requested and continues to request FDA approval to market a generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

193. On information and belief, following FDA approval of ANDA No. 215913, Zenara will offer for sale and sell its approved generic version of XADAGO® (safinamide) tablets throughout the United States, including in Delaware.

194. Zenara's effort to seek FDA approval to market a generic version of XADAGO® (safinamide) tablets prior to the expiration of the '515, '485, and '380 patents constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 215913, the '515 patent, the '485 patent, and the '380 patent as further evidenced by Zenara's Paragraph IV Letter.

195. Zenara's ANDA Product, both the 50 mg and 100 mg strengths, contains an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof, including

because those amounts of active ingredient copy the amounts of active ingredient in XADAGO® (safinamide) tablets, which have been deemed effective amounts by FDA.

196. Zenara's ANDA Product will be sold and distributed with labeling that will be substantially the same as the labeling for XADAGO® (safinamide) tablets, and thus will contain substantially the same instructions for use as those in the label for XADAGO® (safinamide) tablets, including instructions that are substantially the same as those described above in paragraphs 61-67.

197. For example, on information and belief, the labeling for Zenara's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers that the product is indicated for use as adjunctive treatment to levodopa/carbidopa in patients with idiopathic Parkinson's disease (PD) experiencing "off" episodes and teaches once daily dosing of either 50 mg or 100 mg tablets, and thus promotes and encourages use of Zenara's ANDA Product to treat Parkinson's disease by administering an effective amount of safinamide or a pharmaceutically acceptable acid salt thereof to Parkinson's disease patients.

198. In addition, on information and belief, the clinical studies section of the labeling for Zenara's ANDA Product, like the labeling for XADAGO® (safinamide) tablets, instructs healthcare providers to concurrently administer, to idiopathic Parkinson's Disease patients, safinamide on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day while maintaining the patients on stable doses of levodopa, and thus promotes and encourages use of the product on that dosage schedule to Parkinson's disease patients on stable doses of levodopa. Healthcare providers would understand the labeling for Zenara's ANDA Product to promote and encourage use of an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day because, for example a healthcare provider administering Zenara's ANDA Product to a 70kg Parkinson's

disease patient according to the instructions on Zenara's labeling, would be administering safinamide or a pharmaceutically acid acceptable salt thereof an oral dosage schedule of either about 0.7 mg/kg/day (50 mg once daily) to about 1.4 mg/kg/day (100 mg once daily).

199. Since receiving Zenara's Paragraph IV Letter, Plaintiffs have attempted to procure a copy of ANDA No. 215913 and the underlying DMF from Zenara. Because the terms of the proposed Offer of Confidential Access would not allow Plaintiffs to meaningfully process the information in the ANDA, or receive the DMF, including, for example, by not allowing Plaintiffs' in-house counsel or in-house scientists to review those materials, Plaintiffs could not agree to the terms of the original Offer. On June 1, 2021, counsel for Plaintiffs sent Zenara's counsel a letter in an attempt to negotiate access to ANDA No. 215913 and the underlying DMF. On June 3, 2021, Zenara's counsel contacted Plaintiffs' counsel, but did not address the proffered terms of accessing Zenara's confidential information. As of the filing of this Complaint, Zenara still has not addressed those proffered terms of access.

200. Plaintiffs are not aware of any other means for obtaining information regarding the purity of safinamide mesylate or the amount of Compound IIa or a pharmaceutically acceptable acid salt thereof (e.g., Compound IIc) in Zenara's ANDA Product. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm their allegations of infringement and to present the Court evidence that Zenara's ANDA Product fall within the scope of one or more claims of the '515 and '485 patents.

201. For the reasons above, on information and belief, Zenara is seeking approval for products, used according to proposed labeling that is substantially similar to the labeling for XADAGO® (safinamide) tablets, that meet all the limitations of at least claims 34 and 40 of the

'515 patent, claim 37 of the '485 patent, and claim 1 of the '380 patent, either literally or under the doctrine of equivalents; therefore, the products Zenara is likely to sell will infringe the '515, '485, and '380 patents.

COUNTS I-VI AGAINST AUROBINDO

COUNT I

(Infringement of the '515 Patent Under 35 U.S.C. § 271(e)(2) by Aurobindo)

202. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

203. Aurobindo submitted ANDA No. 215902 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product throughout the United States. By submitting the application, Aurobindo has committed an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

204. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product will constitute an act of direct infringement of the '515 patent, either literally or under the doctrine of equivalents.

205. On information and belief, Aurobindo will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

206. Healthcare providers administering Aurobindo's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

207. On information and belief, Aurobindo became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '515 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

208. On information and belief, Aurobindo knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Aurobindo's ANDA Product, with its labeling, will actively induce the direct infringement of the '515 patent.

209. On information and belief, Aurobindo knew or should have known that Aurobindo's ANDA Product will be especially made or especially adapted for use in an infringement of the '515 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Aurobindo knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Aurobindo's ANDA Product will actively contribute to the direct infringement of the '515 patent.

210. Unless and until Aurobindo is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

211. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Aurobindo's ANDA No. 215902 be a date that is not earlier than the expiration date of the '515 patent.

COUNT II

(Declaratory Judgment of Infringement of the '515 Patent Under 35 U.S.C. § 271(a)/(b) or (c) by Aurobindo)

212. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

213. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

214. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

215. On information and belief, Aurobindo will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215902.

216. Aurobindo's actions, including but not limited to, the development of Aurobindo's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Aurobindo has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Aurobindo's ANDA Product.

217. Aurobindo has actual knowledge of the '515 patent.

218. On information and belief, Aurobindo became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '515 patent as one of the patents covering XADAGO® (safinamide) tablets.

219. On information and belief, Aurobindo's ANDA practices all limitations of at least claim 34 of the '515 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Aurobindo's ANDA Product will constitute an act of direct infringement of the '515 patent.

220. On information and belief, Aurobindo will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

221. On information and belief, healthcare providers administering Aurobindo's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

222. On information and belief, Aurobindo possesses specific intent to encourage direct infringement of at least claim 40 of the '515 patent, including because Aurobindo's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Aurobindo's ANDA Product have no substantial non-infringing uses, Aurobindo intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 40 the '515 patent.

223. On information and belief, upon awareness of the '515 patent, Aurobindo either actually knew of the potential for infringement of at least claim 40 of the '515 patent, or was willfully blind as to the potential for that infringement at least because Aurobindo provides instructions for infringement of at least claim 40 of the '515 patent in its proposed product labeling.

224. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 40 of the '515 patent.

225. Aurobindo's Paragraph IV letter makes no allegations of non-infringement for claims 34 and 40 of the '515 patent.

226. On information and belief, Aurobindo knows that its ANDA Product is a material part of the method of at least claim 40 of the '515 patent, including as evidenced in the contents of its proposed label. On information and belief, Aurobindo's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 40 of the '515 patent, as evidenced in the contents of its proposed labeling. On information and belief, Aurobindo's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

227. Thus, on information and belief, Aurobindo will contribute to the infringement of at least claim 40 of the '515 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Aurobindo's ANDA Product, which is a material for use in practicing the method of at least claim 40 of the '515 patent.

228. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product will constitute an act of contributory infringement of the '515 patent.

229. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

230. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product before patent expiration

will constitute direct infringement of at least claim 34 of the '515 patent, and active inducement of infringement and contributory infringement of at least claim 40 of the '515 patent.

231. Unless and until Aurobindo is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT III

(Infringement of the '485 Patent Under 35 U.S.C. § 271(e)(2) by Aurobindo)

232. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

233. Aurobindo submitted ANDA No. 215902 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product throughout the United States. By submitting the application, Aurobindo has committed an act of infringement of the '485 patent under 35 U.S.C. § 271(e)(2)(A).

234. On information and belief, Aurobindo will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

235. Healthcare providers administering Aurobindo's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

236. On information and belief, Aurobindo became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV

certification to the FDA regarding ANDA No. 215902, in which it identified the '485 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

237. On information and belief, Aurobindo knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Aurobindo's ANDA Product, with its labeling, will actively induce the direct infringement of the '485 patent.

238. On information and belief, Aurobindo knew or should have known that Aurobindo's ANDA Product will be especially made or especially adapted for use in an infringement of the '485 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Aurobindo knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Aurobindo's ANDA Product will actively contribute to the direct infringement of the '485 patent.

239. Unless and until Aurobindo is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

240. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Aurobindo's ANDA No. 215902 be a date that is not earlier than the expiration date of the '485 patent.

COUNT IV

(Declaratory Judgment of Infringement of the '485 Patent Under 35 U.S.C. § 271(b) or (c) by Aurobindo)

241. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

242. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

243. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

244. Aurobindo has actual knowledge of the '485 patent.

245. On information and belief, Aurobindo became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '485 patent as one of the patents covering XADAGO® (safinamide) tablets.

246. On information and belief, Aurobindo will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215902.

247. Aurobindo's actions, including but not limited to, the development of Aurobindo's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Aurobindo has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Aurobindo's ANDA Product.

248. On information and belief, Aurobindo will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

249. On information and belief, healthcare providers administering Aurobindo's ANDA Product within the United States and according to the instructions in the product's labeling will

directly infringe at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

250. On information and belief, Aurobindo possesses specific intent to encourage direct infringement of at least claim 37 of the '485 patent, including because Aurobindo's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Aurobindo's ANDA Product have no substantial non-infringing uses, Aurobindo intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 37 the '485 patent.

251. On information and belief, upon awareness of the '485 patent, Aurobindo either actually knew of the potential for infringement of at least claim 37 of the '485 patent, or was willfully blind as to the potential for that infringement at least because Aurobindo provides instructions for infringement of at least claim 37 of the '485 patent in its proposed product labeling.

252. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 37 of the '485 patent.

253. On information and belief, Aurobindo knows that its ANDA Product is a material part of the method of at least claim 37 of the '485 patent, including as evidenced in the contents of its proposed label. On information and belief, Aurobindo's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 37 of the '485 patent, as evidenced in the contents of its proposed labeling. On information and belief, Aurobindo's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks

FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

254. Thus, on information and belief, Aurobindo will contribute to the infringement of at least claim 37 of the '485 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Aurobindo's ANDA Product, which is a material for use in practicing the method of at least claim 37 of the '485 patent.

255. Aurobindo's Paragraph IV letter makes no allegations of non-infringement for claim 37 of the '485 patent.

256. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Aurobindo's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

257. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Aurobindo's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 37 of the '485 patent.

258. Unless and until Aurobindo is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT V

(Infringement of the '380 Patent Under 35 U.S.C. § 271(e)(2) by Aurobindo)

259. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

260. Aurobindo submitted ANDA No. 215902 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product throughout the United States. By submitting the

application, Aurobindo has committed an act of infringement of the '380 patent under 35 U.S.C. § 271(e)(2)(A).

261. On information and belief, Aurobindo will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

262. Healthcare providers administering Aurobindo's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

263. On information and belief, Aurobindo became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '380 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

264. On information and belief, Aurobindo knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Aurobindo's ANDA Product, with its labeling, will actively induce the direct infringement of the '380 patent.

265. On information and belief, Aurobindo knew or should have known that Aurobindo's ANDA Product will be especially made or especially adapted for use in an infringement of the '380 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling.

And, on information and belief, Aurobindo knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Aurobindo's ANDA Product will actively contribute to the direct infringement of the '380 patent.

266. Unless and until Aurobindo is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

267. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Aurobindo's ANDA No. 215902 be a date that is not earlier than the expiration date of the '380 patent.

COUNT VI

(Declaratory Judgment of Infringement of the '380 Patent Under 35 U.S.C. § 271(b) or (c) by Aurobindo)

268. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

269. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

270. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

271. Aurobindo has actual knowledge of the '380 patent.

272. On information and belief, Aurobindo became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '380 patent as one of the patents covering XADAGO® (safinamide) tablets.

273. On information and belief, Aurobindo will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215902.

274. Aurobindo's actions, including but not limited to, the development of Aurobindo's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Aurobindo has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Aurobindo's ANDA Product.

275. On information and belief, Aurobindo will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

276. On information and belief, healthcare providers administering Aurobindo's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

277. On information and belief, Aurobindo possesses specific intent to encourage direct infringement of at least claim 1 of the '380 patent, including because Aurobindo's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Aurobindo's ANDA Product have no substantial non-infringing uses, Aurobindo intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 1 the '380 patent.

278. On information and belief, upon awareness of the '380 patent, Aurobindo either actually knew of the potential for infringement of at least claim 1 of the '380 patent, or was willfully blind as to the potential for that infringement at least because Aurobindo provides instructions for infringement of at least claim 1 of the '380 patent in its proposed product labeling.

279. The commercial manufacture, importation, use, sale, or offer for sale of Aurobindo's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 1 of the '380 patent.

280. On information and belief, Aurobindo knows that its ANDA Product is a material part of the method of at least claim 1 of the '380 patent, including as evidenced in the contents of its proposed label. On information and belief, Aurobindo's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 1 of the '380 patent, as evidenced in the contents of its proposed labeling. On information and belief, Aurobindo's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

281. Thus, on information and belief, Aurobindo will contribute to the infringement of at least claim 1 of the '380 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Aurobindo's ANDA Product, which is a material for use in practicing the method of at least claim 1 of the '380 patent.

282. Aurobindo's Paragraph IV letter makes no allegations of non-infringement for claim 1 of the '380 patent.

283. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Aurobindo's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

284. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Aurobindo's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 1 of the '380 patent.

285. Unless and until Aurobindo is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNTS VII-XII AGAINST MSN

COUNT VII

(Infringement of the '515 Patent Under 35 U.S.C. § 271(e)(2) by MSN)

286. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

287. MSN submitted ANDA No. 215978 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product throughout the United States. By submitting the application, Aurobindo has committed an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

288. The commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product will constitute an act of direct infringement of the '515 patent, either literally or under the doctrine of equivalents.

289. On information and belief, MSN will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval,

labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

290. Healthcare providers administering MSN's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

291. On information and belief, MSN became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215978, in which it identified the '515 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

292. On information and belief, MSN knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of MSN's ANDA Product, with its labeling, will actively induce the direct infringement of the '515 patent.

293. On information and belief, MSN knew or should have known that MSN's ANDA Product will be especially made or especially adapted for use in an infringement of the '515 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, MSN knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of MSN's ANDA Product will actively contribute to the direct infringement of the '515 patent.

294. Unless and until MSN is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

295. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of MSN's ANDA No. 215978 be a date that is not earlier than the expiration date of the '515 patent.

COUNT VIII

(Declaratory Judgment of Infringement of the '515 Patent Under 35 U.S.C. § 271(a)/(b) or (c) by MSN)

296. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

297. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

298. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

299. On information and belief, MSN will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215978.

300. MSN's actions, including but not limited to, the development of MSN's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that MSN has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute MSN's ANDA Product.

301. MSN has actual knowledge of the '515 patent.

302. On information and belief, MSN became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of

using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215978, in which it identified the '515 patent as one of the patents covering XADAGO® (safinamide) tablets.

303. On information and belief, MSN's ANDA practices all limitations of at least claim 34 of the '515 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of MSN's ANDA Product will constitute an act of direct infringement of the '515 patent.

304. On information and belief, MSN will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

305. On information and belief, healthcare providers administering MSN's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

306. On information and belief, MSN possesses specific intent to encourage direct infringement of at least claim 40 of the '515 patent, including because MSN's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and MSN's ANDA Product have no substantial non-infringing uses, MSN intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 40 the '515 patent.

307. On information and belief, upon awareness of the '515 patent, MSN either actually knew of the potential for infringement of at least claim 40 of the '515 patent, or was willfully blind as to the potential for that infringement at least because MSN provides instructions for infringement of at least claim 40 of the '515 patent in its proposed product labeling.

308. The commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 40 of the '515 patent.

309. On information and belief, MSN knows that its ANDA Product is a material part of the method of at least claim 40 of the '515 patent, including as evidenced in the contents of its proposed label. On information and belief, MSN's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 40 of the '515 patent, as evidenced in the contents of its proposed labeling. On information and belief, MSN's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

310. Thus, on information and belief, MSN will contribute to the infringement of at least claim 40 of the '515 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing MSN's ANDA Product, which is a material for use in practicing the method of at least claim 40 of the '515 patent.

311. The commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product will constitute an act of contributory infringement of the '515 patent.

312. The commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

313. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product before patent expiration will constitute direct infringement of at least claim 34 of the '515 patent, and active inducement of infringement and contributory infringement of at least claim 40 of the '515 patent.

314. Unless and until MSN is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT IX

(Infringement of the '485 Patent Under 35 U.S.C. § 271(e)(2) by MSN)

315. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

316. MSN submitted ANDA No. 215978 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product throughout the United States. By submitting the application, MSN has committed an act of infringement of the '485 patent under 35 U.S.C. § 271(e)(2)(A).

317. On information and belief, MSN will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

318. Healthcare providers administering MSN's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct

infringement of at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

319. On information and belief, MSN became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215978, in which it identified the '485 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

320. On information and belief, MSN knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of MSN's ANDA Product, with its labeling, will actively induce the direct infringement of the '485 patent.

321. On information and belief, MSN knew or should have known that MSN's ANDA Product will be especially made or especially adapted for use in an infringement of the '485 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, MSN knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of MSN's ANDA Product will actively contribute to the direct infringement of the '485 patent.

322. Unless and until MSN is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

323. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of MSN's ANDA No. 215978 be a date that is not earlier than the expiration date of the '485 patent.

COUNT X

(Declaratory Judgment of Infringement of the '485 Patent Under 35 U.S.C. § 271(b) or (c) by MSN)

324. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

325. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

326. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

327. MSN has actual knowledge of the '485 patent.

328. On information and belief, MSN became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '485 patent as one of the patents covering XADAGO® (safinamide) tablets.

329. On information and belief, MSN will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215978.

330. MSN's actions, including but not limited to, the development of MSN's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that MSN has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute MSN's ANDA Product.

331. On information and belief, MSN will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval,

labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

332. On information and belief, healthcare providers administering MSN's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

333. On information and belief, MSN possesses specific intent to encourage direct infringement of at least claim 37 of the '485 patent, including because MSN's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and MSN's ANDA Product have no substantial non-infringing uses, Aurobindo intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 37 the '485 patent.

334. On information and belief, upon awareness of the '485 patent, MSN either actually knew of the potential for infringement of at least claim 37 of the '485 patent, or was willfully blind as to the potential for that infringement at least because MSN provides instructions for infringement of at least claim 37 of the '485 patent in its proposed product labeling.

335. The commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 37 of the '485 patent.

336. On information and belief, MSN knows that its ANDA Product is a material part of the method of at least claim 37 of the '485 patent, including as evidenced in the contents of its proposed label. On information and belief, MSN's ANDA Product was especially made or

especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 37 of the '485 patent, as evidenced in the contents of its proposed labeling. On information and belief, MSN's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

337. Thus, on information and belief, MSN will contribute to the infringement of at least claim 37 of the '485 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing MSN's ANDA Product, which is a material for use in practicing the method of at least claim 37 of the '485 patent.

338. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of MSN's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

339. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of MSN's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 37 of the '485 patent.

340. Unless and until MSN is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XI

(Infringement of the '380 Patent Under 35 U.S.C. § 271(e)(2) by MSN)

341. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

342. MSN submitted ANDA No. 215978 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product throughout the United States. By submitting the application, MSN has committed an act of infringement of the '380 patent under 35 U.S.C. § 271(e)(2)(A).

343. On information and belief, MSN will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

344. Healthcare providers administering MSN's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

345. On information and belief, Aurobindo became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '380 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

346. On information and belief, MSN knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of MSN's ANDA Product, with its labeling, will actively induce the direct infringement of the '380 patent.

347. On information and belief, MSN knew or should have known that MSN's ANDA Product will be especially made or especially adapted for use in an infringement of the '380 patent,

and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, MSN knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of MSN's ANDA Product will actively contribute to the direct infringement of the '380 patent.

348. Unless and until MSN is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

349. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of MSN's ANDA No. 215978 be a date that is not earlier than the expiration date of the '380 patent.

COUNT XII

(Declaratory Judgment of Infringement of the '380 Patent Under 35 U.S.C. § 271(b) or (c) by MSN)

350. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

351. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

352. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

353. MSN has actual knowledge of the '380 patent.

354. On information and belief, MSN became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215902, in which it identified the '380 patent as one of the patents covering XADAGO® (safinamide) tablets.

355. On information and belief, MSN will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215978.

356. MSN's actions, including but not limited to, the development of MSN's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that MSN has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute MSN's ANDA Product.

357. On information and belief, MSN will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

358. On information and belief, healthcare providers administering MSN's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

359. On information and belief, MSN possesses specific intent to encourage direct infringement of at least claim 1 of the '380 patent, including because MSN's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and MSN's ANDA Product have no substantial non-infringing uses, MSN intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 1 the '380 patent.

360. On information and belief, upon awareness of the '380 patent, MSN either actually knew of the potential for infringement of at least claim 1 of the '380 patent, or was willfully blind as to the potential for that infringement at least because MSN provides instructions for infringement of at least claim 1 of the '380 patent in its proposed product labeling.

361. The commercial manufacture, importation, use, sale, or offer for sale of MSN's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 1 of the '380 patent.

362. On information and belief, MSN knows that its ANDA Product is a material part of the method of at least claim 1 of the '380 patent, including as evidenced in the contents of its proposed label. On information and belief, MSN's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 1 of the '380 patent, as evidenced in the contents of its proposed labeling. On information and belief, MSN's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

363. Thus, on information and belief, MSN will contribute to the infringement of at least claim 1 of the '380 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing MSN's ANDA Product, which is a material for use in practicing the method of at least claim 1 of the '380 patent.

364. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of MSN's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

365. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of MSN's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 1 of the '380 patent.

366. Unless and until MSN is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNTS XIII-XVIII AGAINST OPTIMUS

COUNT XIII

(Infringement of the '515 Patent Under 35 U.S.C. § 271(e)(2) by Optimus)

367. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

368. Optimus submitted ANDA No. 216020 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product throughout the United States. By submitting the application, Optimus has committed an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

369. The commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product will constitute an act of direct infringement of the '515 patent, either literally or under the doctrine of equivalents.

370. On information and belief, Optimus will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

371. Healthcare providers administering Optimus' ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct

infringement of at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

372. On information and belief, Optimus became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215978, in which it identified the '515 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

373. On information and belief, Optimus knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Optimus' ANDA Product, with its labeling, will actively induce the direct infringement of the '515 patent.

374. On information and belief, Optimus knew or should have known that Optimus' ANDA Product will be especially made or especially adapted for use in an infringement of the '515 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Optimus knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Optimus' ANDA Product will actively contribute to the direct infringement of the '515 patent.

375. Unless and until Optimus is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

376. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Optimus' ANDA No. 216020 be a date that is not earlier than the expiration date of the '515 patent.

COUNT XIV

(Declaratory Judgment of Infringement of the '515 Patent Under 35 U.S.C. § 271(a)/(b) or (c) by Optimus)

377. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

378. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

379. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

380. On information and belief, Optimus will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Optimus' ANDA Product immediately and imminently upon FDA approval of ANDA No. 216020.

381. Optimus' actions, including but not limited to, the development of Optimus' ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Optimus has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Optimus' ANDA Product.

382. Optimus has actual knowledge of the '515 patent.

383. On information and belief, Optimus became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 216020, in which it identified the '515 patent as one of the patents covering XADAGO® (safinamide) tablets.

384. On information and belief, Optimus' ANDA practices all limitations of at least claim 34 of the '515 patent, either literally or under the doctrine of equivalents, as detailed above,

and thus the manufacture, importation, use, sale, and/or offer for sale of Optimus' ANDA Product will constitute an act of direct infringement of the '515 patent.

385. On information and belief, Optimus will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

386. On information and belief, healthcare providers administering Optimus' ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

387. On information and belief, Optimus possesses specific intent to encourage direct infringement of at least claim 40 of the '515 patent, including because Optimus' labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Optimus' ANDA Product have no substantial non-infringing uses, Optimus intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 40 the '515 patent.

388. On information and belief, upon awareness of the '515 patent, Optimus either actually knew of the potential for infringement of at least claim 40 of the '515 patent, or was willfully blind as to the potential for that infringement at least because Optimus provides instructions for infringement of at least claim 40 of the '515 patent in its proposed product labeling.

389. The commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 40 of the '515 patent.

390. Optimus' Paragraph IV letter makes no allegations of non-infringement for claims 34 and 40 of the '515 patent.

391. On information and belief, Optimus knows that its ANDA Product is a material part of the method of at least claim 40 of the '515 patent, including as evidenced in the contents of its proposed label. On information and belief, Optimus' ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 40 of the '515 patent, as evidenced in the contents of its proposed labeling. On information and belief, Optimus' ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

392. Thus, on information and belief, Optimus will contribute to the infringement of at least claim 40 of the '515 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Optimus' ANDA Product, which is a material for use in practicing the method of at least claim 40 of the '515 patent.

393. The commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product will constitute an act of contributory infringement of the '515 patent.

394. The commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

395. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of Optimus' ANDA Product before patent expiration will constitute direct infringement of at least claim 34 of the '515 patent, and active inducement of infringement and contributory infringement of at least claim 40 of the '515 patent.

396. Unless and until Optimus is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XV

(Infringement of the '485 Patent Under 35 U.S.C. § 271(e)(2) by Optimus)

397. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

398. Optimus submitted ANDA No. 216020 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product throughout the United States. By submitting the application, Optimus has committed an act of infringement of the '485 patent under 35 U.S.C. § 271(e)(2)(A).

399. On information and belief, Optimus will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

400. Healthcare providers administering Optimus' ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

401. On information and belief, Optimus became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of

using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 216020, in which it identified the '485 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

402. On information and belief, Optimus knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Optimus' ANDA Product, with its labeling, will actively induce the direct infringement of the '485 patent.

403. On information and belief, Optimus knew or should have known that Optimus' ANDA Product will be especially made or especially adapted for use in an infringement of the '485 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Optimus knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Optimus' ANDA Product will actively contribute to the direct infringement of the '485 patent.

404. Unless and until Optimus is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

405. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Optimus' ANDA No. 216020 be a date that is not earlier than the expiration date of the '485 patent.

COUNT XVI

(Declaratory Judgment of Infringement of the '485 Patent Under 35 U.S.C. § 271(b) or (c) by Optimus)

406. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

407. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

408. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

409. Optimus has actual knowledge of the '485 patent.

410. On information and belief, Optimus became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 216020, in which it identified the '485 patent as one of the patents covering XADAGO® (safinamide) tablets.

411. On information and belief, Optimus will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Optimus' ANDA Product immediately and imminently upon FDA approval of ANDA No. 216020.

412. Optimus' actions, including but not limited to, the development of Optimus' ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Optimus has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Optimus' ANDA Product.

413. On information and belief, Optimus will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

414. On information and belief, healthcare providers administering Optimus' ANDA Product within the United States and according to the instructions in the product's labeling will

directly infringe at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

415. On information and belief, Optimus possesses specific intent to encourage direct infringement of at least claim 37 of the '485 patent, including because Optimus' labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Optimus' ANDA Product have no substantial non-infringing uses, Optimus intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 37 the '485 patent.

416. On information and belief, upon awareness of the '485 patent, Optimus either actually knew of the potential for infringement of at least claim 37 of the '485 patent, or was willfully blind as to the potential for that infringement at least because Optimus provides instructions for infringement of at least claim 37 of the '485 patent in its proposed product labeling.

417. The commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 37 of the '485 patent.

418. On information and belief, Optimus knows that its ANDA Product is a material part of the method of at least claim 37 of the '485 patent, including as evidenced in the contents of its proposed label. On information and belief, Optimus' ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 37 of the '485 patent, as evidenced in the contents of its proposed labeling. On information and belief, Optimus' ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks

FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

419. Thus, on information and belief, Optimus will contribute to the infringement of at least claim 37 of the '485 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Optimus' ANDA Product, which is a material for use in practicing the method of at least claim 37 of the '485 patent.

420. Optimus' Paragraph IV letter makes no allegations of non-infringement for claim 37 of the '485 patent.

421. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Optimus' ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

422. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Optimus' ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 37 of the '485 patent.

423. Unless and until Optimus is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XVII

(Infringement of the '380 Patent Under 35 U.S.C. § 271(e)(2) by Optimus)

424. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

425. Optimus submitted ANDA No. 216020 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer

for sale of Optimus' ANDA Product throughout the United States. By submitting the application, Optimus has committed an act of infringement of the '380 patent under 35 U.S.C. § 271(e)(2)(A).

426. On information and belief, Optimus will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

427. Healthcare providers administering Optimus' ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

428. On information and belief, Optimus became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 216020, in which it identified the '380 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

429. On information and belief, Optimus knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Optimus' ANDA Product, with its labeling, will actively induce the direct infringement of the '380 patent.

430. On information and belief, Optimus knew or should have known that Optimus' ANDA Product will be especially made or especially adapted for use in an infringement of the '380 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on

information and belief, Optimus knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Optimus' ANDA Product will actively contribute to the direct infringement of the '380 patent.

431. Unless and until Optimus is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

432. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Optimus' ANDA No. 216020 be a date that is not earlier than the expiration date of the '380 patent.

COUNT XVIII

(Declaratory Judgment of Infringement of the '380 Patent Under 35 U.S.C. § 271(b) or (c) by Optimus)

433. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

434. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

435. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

436. Optimus has actual knowledge of the '380 patent.

437. On information and belief, Optimus became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 216020, in which it identified the '380 patent as one of the patents covering XADAGO® (safinamide) tablets.

438. On information and belief, Optimus will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Optimus' ANDA Product immediately and imminently upon FDA approval of ANDA No. 216020.

439. Optimus' actions, including but not limited to, the development of Optimus' ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Optimus has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Optimus' ANDA Product.

440. On information and belief, Optimus will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

441. On information and belief, healthcare providers administering Optimus' ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

442. On information and belief, Optimus possesses specific intent to encourage direct infringement of at least claim 1 of the '380 patent, including because Optimus' labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Optimus' ANDA Product have no substantial non-infringing uses, Optimus intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 1 the '380 patent.

443. On information and belief, upon awareness of the '380 patent, Optimus either actually knew of the potential for infringement of at least claim 1 of the '380 patent, or was willfully blind as to the potential for that infringement at least because Optimus provides instructions for infringement of at least claim 1 of the '380 patent in its proposed product labeling.

444. The commercial manufacture, importation, use, sale, or offer for sale of Optimus' ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 1 of the '380 patent.

445. On information and belief, Optimus knows that its ANDA Product is a material part of the method of at least claim 1 of the '380 patent, including as evidenced in the contents of its proposed label. On information and belief, Optimus' ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 1 of the '380 patent, as evidenced in the contents of its proposed labeling. On information and belief, Optimus' ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

446. Thus, on information and belief, Optimus' will contribute to the infringement of at least claim 1 of the '380 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Optimus' ANDA Product, which is a material for use in practicing the method of at least claim 1 of the '380 patent.

447. Optimus' Paragraph IV letter makes no allegations of non-infringement for claim 1 of the '380 patent.

448. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Optimus' ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

449. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Optimus' ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 1 of the '380 patent.

450. Unless and until Optimus is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNTS XIX-XXIV AGAINST PRINSTON

COUNT XIX

(Infringement of the '515 Patent Under 35 U.S.C. § 271(e)(2) by Prinston)

451. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

452. Prinston submitted ANDA No. 215739 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product throughout the United States. By submitting the application, Prinston has committed an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

453. The commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product will constitute an act of direct infringement of the '515 patent, either literally or under the doctrine of equivalents.

454. On information and belief, Prinston will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval,

labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

455. Healthcare providers administering Prinston's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

456. On information and belief, Prinston became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215739, in which it identified the '515 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

457. On information and belief, Prinston knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Prinston's ANDA Product, with its labeling, will actively induce the direct infringement of the '515 patent.

458. On information and belief, Prinston knew or should have known that Prinston's ANDA Product will be especially made or especially adapted for use in an infringement of the '515 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Prinston knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Prinston's ANDA Product will actively contribute to the direct infringement of the '515 patent.

459. Unless and until Prinston is enjoined from infringing the ’515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

460. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Prinston’s ANDA No. 215739 be a date that is not earlier than the expiration date of the ’515 patent.

COUNT XX

(Declaratory Judgment of Infringement of the ’515 Patent Under 35 U.S.C. § 271(a)/(b) or (c) by Prinston)

461. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

462. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

463. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

464. On information and belief, Prinston will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Prinston’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 215739.

465. Prinston’s actions, including but not limited to, the development of Prinston’s ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Prinston has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Prinston’s ANDA Product.

466. Prinston has actual knowledge of the ’515 patent.

467. On information and belief, Prinston became aware of the ’515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of

using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215739, in which it identified the '515 patent as one of the patents covering XADAGO® (safinamide) tablets.

468. On information and belief, Prinston's ANDA practices all limitations of at least claim 34 of the '515 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Prinston's ANDA Product will constitute an act of direct infringement of the '515 patent.

469. On information and belief, Prinston will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

470. On information and belief, healthcare providers administering Prinston's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

471. On information and belief, Prinston possesses specific intent to encourage direct infringement of at least claim 40 of the '515 patent, including because Prinston's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Prinston's ANDA Product have no substantial non-infringing uses, Prinston intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 40 the '515 patent.

472. On information and belief, upon awareness of the '515 patent, Prinston either actually knew of the potential for infringement of at least claim 40 of the '515 patent, or was willfully blind as to the potential for that infringement at least because Prinston provides instructions for infringement of at least claim 40 of the '515 patent in its proposed product labeling.

473. The commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 40 of the '515 patent.

474. On information and belief, Prinston knows that its ANDA Product is a material part of the method of at least claim 40 of the '515 patent, including as evidenced in the contents of its proposed label. On information and belief, Prinston's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 40 of the '515 patent, as evidenced in the contents of its proposed labeling. On information and belief, Prinston's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

475. Thus, on information and belief, Prinston will contribute to the infringement of at least claim 40 of the '515 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Prinston's ANDA Product, which is a material for use in practicing the method of at least claim 40 of the '515 patent.

476. The commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product will constitute an act of contributory infringement of the '515 patent.

477. The commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

478. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of Prinston's ANDA Product before patent expiration will constitute direct infringement of at least claim 34 of the '515 patent, and active inducement of infringement and contributory infringement of at least claim 40 of the '515 patent.

479. Unless and until Prinston is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XXI

(Infringement of the '485 Patent Under 35 U.S.C. § 271(e)(2) by Prinston)

480. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

481. Prinston submitted ANDA No. 215739 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product throughout the United States. By submitting the application, Prinston has committed an act of infringement of the '485 patent under 35 U.S.C. § 271(e)(2)(A).

482. On information and belief, Prinston will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

483. Healthcare providers administering Prinston's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct

infringement of at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

484. On information and belief, Prinston became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215739, in which it identified the '485 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

485. On information and belief, Prinston knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Prinston's ANDA Product, with its labeling, will actively induce the direct infringement of the '485 patent.

486. On information and belief, Prinston knew or should have known that Prinston's ANDA Product will be especially made or especially adapted for use in an infringement of the '485 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Prinston knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Prinston's ANDA Product will actively contribute to the direct infringement of the '485 patent.

487. Unless and until Prinston is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

488. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Prinston's ANDA No. 215739 be a date that is not earlier than the expiration date of the '485 patent.

COUNT XXII

(Declaratory Judgment of Infringement of the '485 Patent Under 35 U.S.C. § 271(b) or (c) by Prinston)

489. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

490. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

491. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

492. Prinston has actual knowledge of the '485 patent.

493. On information and belief, Prinston became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215739, in which it identified the '485 patent as one of the patents covering XADAGO® (safinamide) tablets.

494. On information and belief, Prinston will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Prinston's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215739.

495. Prinston's actions, including but not limited to, the development of Prinston's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Prinston has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Prinston's ANDA Product.

496. On information and belief, Prinston will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval,

labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

497. On information and belief, healthcare providers administering Prinston's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

498. On information and belief, Prinston possesses specific intent to encourage direct infringement of at least claim 37 of the '485 patent, including because Prinston's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Prinston's ANDA Product have no substantial non-infringing uses, Prinston intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 37 the '485 patent.

499. On information and belief, upon awareness of the '485 patent, Prinston either actually knew of the potential for infringement of at least claim 37 of the '485 patent, or was willfully blind as to the potential for that infringement at least because Prinston provides instructions for infringement of at least claim 37 of the '485 patent in its proposed product labeling.

500. The commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 37 of the '485 patent.

501. On information and belief, Prinston knows that its ANDA Product is a material part of the method of at least claim 37 of the '485 patent, including as evidenced in the contents of its proposed label. On information and belief, Prinston's ANDA Product was especially made or

especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 37 of the '485 patent, as evidenced in the contents of its proposed labeling. On information and belief, Prinston's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

502. Thus, on information and belief, Prinston will contribute to the infringement of at least claim 37 of the '485 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Prinston's ANDA Product, which is a material for use in practicing the method of at least claim 37 of the '485 patent.

503. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Prinston's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

504. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Prinston's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 37 of the '485 patent.

505. Unless and until Prinston is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XXIII

(Infringement of the '380 Patent Under 35 U.S.C. § 271(e)(2) by Prinston)

506. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

507. Prinston submitted ANDA No. 215739 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product throughout the United States. By submitting the application, Prinston has committed an act of infringement of the '380 patent under 35 U.S.C. § 271(e)(2)(A).

508. On information and belief, Prinston will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

509. Healthcare providers administering Prinston's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

510. On information and belief, Prinston became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215739, in which it identified the '380 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

511. On information and belief, Prinston knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Prinston's ANDA Product, with its labeling, will actively induce the direct infringement of the '380 patent.

512. On information and belief, Prinston knew or should have known that Prinston's ANDA Product will be especially made or especially adapted for use in an infringement of the

'380 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Prinston knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Prinston's ANDA Product will actively contribute to the direct infringement of the '380 patent.

513. Unless and until Prinston is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

514. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Prinston's ANDA No. 215739 be a date that is not earlier than the expiration date of the '380 patent.

COUNT XXIV

(Declaratory Judgment of Infringement of the '380 Patent Under 35 U.S.C. § 271(b) or (c) by Prinston)

515. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

516. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

517. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

518. Prinston has actual knowledge of the '380 patent.

519. On information and belief, Prinston became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215739, in which it identified the '380 patent as one of the patents covering XADAGO® (safinamide) tablets.

520. On information and belief, Prinston will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Prinston's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215739.

521. Prinston's actions, including but not limited to, the development of Prinston's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Prinston has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Prinston's ANDA Product.

522. On information and belief, Prinston will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

523. On information and belief, healthcare providers administering Prinston's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

524. On information and belief, Prinston possesses specific intent to encourage direct infringement of at least claim 1 of the '380 patent, including because Prinston's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Prinston's ANDA Product have no substantial non-infringing uses, Prinston intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 1 the '380 patent.

525. On information and belief, upon awareness of the '380 patent, Prinston either actually knew of the potential for infringement of at least claim 1 of the '380 patent, or was willfully blind as to the potential for that infringement at least because Prinston provides instructions for infringement of at least claim 1 of the '380 patent in its proposed product labeling.

526. The commercial manufacture, importation, use, sale, or offer for sale of Prinston's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 1 of the '380 patent.

527. On information and belief, Prinston knows that its ANDA Product is a material part of the method of at least claim 1 of the '380 patent, including as evidenced in the contents of its proposed label. On information and belief, Prinston's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 1 of the '380 patent, as evidenced in the contents of its proposed labeling. On information and belief, Prinston's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

528. Thus, on information and belief, Prinston's will contribute to the infringement of at least claim 1 of the '380 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Prinston's ANDA Product, which is a material for use in practicing the method of at least claim 1 of the '380 patent.

529. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Prinston's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

530. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Prinston's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 1 of the '380 patent.

531. Unless and until Prinston is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNTS XXV-XXX AGAINST RK PHARMA

COUNT XXV

(Infringement of the '515 Patent Under 35 U.S.C. § 271(e)(2) by RK Pharma)

532. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

533. RK Pharma submitted ANDA No. 215945 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product throughout the United States. By submitting the application, RK Pharma has committed an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

534. The commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product will constitute an act of direct infringement of the '515 patent, either literally or under the doctrine of equivalents.

535. On information and belief, RK Pharma will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

536. Healthcare providers administering RK Pharma's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

537. On information and belief, RK Pharma became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215945, in which it identified the '515 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

538. On information and belief, RK Pharma knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of RK Pharma's ANDA Product, with its labeling, will actively induce the direct infringement of the '515 patent.

539. On information and belief, RK Pharma knew or should have known that RK Pharma's ANDA Product will be especially made or especially adapted for use in an infringement of the '515 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, RK Pharma knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of RK Pharma's ANDA Product will actively contribute to the direct infringement of the '515 patent.

540. Unless and until RK Pharma is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

541. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of RK Pharma's ANDA No. 215945 be a date that is not earlier than the expiration date of the '515 patent.

COUNT XXVI

(Declaratory Judgment of Infringement of the '515 Patent Under 35 U.S.C. § 271(a)/(b) or (c) by RK Pharma)

542. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

543. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

544. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

545. On information and belief, RK Pharma will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of RK Pharma's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215945.

546. RK Pharma's actions, including but not limited to, the development of RK Pharma's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that RK Pharma has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute RK Pharma's ANDA Product.

547. RK Pharma has actual knowledge of the '515 patent.

548. On information and belief, RK Pharma became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV

certification to the FDA regarding ANDA No. 215945, in which it identified the '515 patent as one of the patents covering XADAGO® (safinamide) tablets.

549. On information and belief, RK Pharma's ANDA practices all limitations of at least claim 34 of the '515 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of RK Pharma's ANDA Product will constitute an act of direct infringement of the '515 patent.

550. On information and belief, RK Pharma will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

551. On information and belief, healthcare providers administering RK Pharma's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

552. On information and belief, RK Pharma possesses specific intent to encourage direct infringement of at least claim 40 of the '515 patent, including because RK Pharma's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and RK Pharma's ANDA Product have no substantial non-infringing uses, RK Pharma intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 40 the '515 patent.

553. On information and belief, upon awareness of the '515 patent, RK Pharma either actually knew of the potential for infringement of at least claim 40 of the '515 patent, or was

willfully blind as to the potential for that infringement at least because RK Pharma provides instructions for infringement of at least claim 40 of the '515 patent in its proposed product labeling.

554. The commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 40 of the '515 patent.

555. RK Pharma's Paragraph IV letter makes no allegations of non-infringement for claims 34 and 40 of the '515 patent.

556. On information and belief, RK Pharma knows that its ANDA Product is a material part of the method of at least claim 40 of the '515 patent, including as evidenced in the contents of its proposed label. On information and belief, RK Pharma's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 40 of the '515 patent, as evidenced in the contents of its proposed labeling. On information and belief, RK Pharma's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

557. Thus, on information and belief, RK Pharma will contribute to the infringement of at least claim 40 of the '515 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing RK Pharma's ANDA Product, which is a material for use in practicing the method of at least claim 40 of the '515 patent.

558. The commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product will constitute an act of contributory infringement of the '515 patent.

559. The commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

560. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of RK Pharma's ANDA Product before patent expiration will constitute direct infringement of at least claim 34 of the '515 patent, and active inducement of infringement and contributory infringement of at least claim 40 of the '515 patent.

561. Unless and until RK Pharma is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XXVII

(Infringement of the '485 Patent Under 35 U.S.C. § 271(e)(2) by RK Pharma)

562. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

563. RK Pharma submitted ANDA No. 215945 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product throughout the United States. By submitting the application, RK Pharma has committed an act of infringement of the '485 patent under 35 U.S.C. § 271(e)(2)(A).

564. On information and belief, RK Pharma will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

565. Healthcare providers administering RK Pharma's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct

infringement of at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

566. On information and belief, RK Pharma became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215945, in which it identified the '485 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

567. On information and belief, RK Pharma knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of RK Pharma's ANDA Product, with its labeling, will actively induce the direct infringement of the '485 patent.

568. On information and belief, RK Pharma knew or should have known that RK Pharma's ANDA Product will be especially made or especially adapted for use in an infringement of the '485 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, RK Pharma knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of RK Pharma's ANDA Product will actively contribute to the direct infringement of the '485 patent.

569. Unless and until RK Pharma is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

570. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of RK Pharma's ANDA No. 215945 be a date that is not earlier than the expiration date of the '485 patent.

COUNT XXVIII

(Declaratory Judgment of Infringement of the '485 Patent Under 35 U.S.C. § 271(b) or (c) by RK Pharma)

571. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

572. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

573. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

574. RK Pharma has actual knowledge of the '485 patent.

575. On information and belief, RK Pharma became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215945, in which it identified the '485 patent as one of the patents covering XADAGO® (safinamide) tablets.

576. On information and belief, RK Pharma will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of RK Pharma's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215945.

577. RK Pharma's actions, including but not limited to, the development of RK Pharma's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that RK Pharma has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute RK Pharma's ANDA Product.

578. On information and belief, RK Pharma will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA

approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the ’485 patent.

579. On information and belief, healthcare providers administering RK Pharma’s ANDA Product within the United States and according to the instructions in the product’s labeling will directly infringe at least claim 37 of the ’485 patent, either literally or under the doctrine of equivalents.

580. On information and belief, RK Pharma possesses specific intent to encourage direct infringement of at least claim 37 of the ’485 patent, including because RK Pharma’s labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and RK Pharma’s ANDA Product have no substantial non-infringing uses, RK Pharma intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 37 the ’485 patent.

581. On information and belief, upon awareness of the ’485 patent, RK Pharma either actually knew of the potential for infringement of at least claim 37 of the ’485 patent, or was willfully blind as to the potential for that infringement at least because RK Pharma provides instructions for infringement of at least claim 37 of the ’485 patent in its proposed product labeling.

582. The commercial manufacture, importation, use, sale, or offer for sale of RK Pharma’s ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 37 of the ’485 patent.

583. On information and belief, RK Pharma knows that its ANDA Product is a material part of the method of at least claim 37 of the ’485 patent, including as evidenced in the contents of its proposed label. On information and belief, RK Pharma’s ANDA Product was especially

made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 37 of the '485 patent, as evidenced in the contents of its proposed labeling. On information and belief, RK Pharma's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

584. Thus, on information and belief, RK Pharma will contribute to the infringement of at least claim 37 of the '485 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing RK Pharma's ANDA Product, which is a material for use in practicing the method of at least claim 37 of the '485 patent.

585. RK Pharma's Paragraph IV letter makes no allegations of non-infringement for claim 37 of the '485 patent.

586. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of RK Pharma's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

587. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of RK Pharma's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 37 of the '485 patent.

588. Unless and until RK Pharma is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XXIX

(Infringement of the '380 Patent Under 35 U.S.C. § 271(e)(2) by RK Pharma)

589. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

590. RK Pharma submitted ANDA No. 215945 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product throughout the United States. By submitting the application, RK Pharma has committed an act of infringement of the '380 patent under 35 U.S.C. § 271(e)(2)(A).

591. On information and belief, RK Pharma will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

592. Healthcare providers administering RK Pharma's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

593. On information and belief, RK Pharma became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215945, in which it identified the '380 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

594. On information and belief, RK Pharma knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of RK Pharma's ANDA Product, with its labeling, will actively induce the direct infringement of the '380 patent.

595. On information and belief, RK Pharma knew or should have known that RK Pharma's ANDA Product will be especially made or especially adapted for use in an infringement of the '380 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, RK Pharma knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of RK Pharma's ANDA Product will actively contribute to the direct infringement of the '380 patent.

596. Unless and until RK Pharma is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

597. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of RK Pharma's ANDA No. 215945 be a date that is not earlier than the expiration date of the '380 patent.

COUNT XXX

(Declaratory Judgment of Infringement of the '380 Patent Under 35 U.S.C. § 271(b) or (c) by RK Pharma)

598. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

599. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

600. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

601. RK Pharma has actual knowledge of the '380 patent.

602. On information and belief, RK Pharma became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods

of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215945, in which it identified the '380 patent as one of the patents covering XADAGO® (safinamide) tablets.

603. On information and belief, RK Pharma will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of RK Pharma's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215945.

604. RK Pharma's actions, including but not limited to, the development of RK Pharma's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that RK Pharma has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute RK Pharma's ANDA Product.

605. On information and belief, RK Pharma will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

606. On information and belief, healthcare providers administering RK Pharma's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

607. On information and belief, RK Pharma possesses specific intent to encourage direct infringement of at least claim 1 of the '380 patent, including because RK Pharma's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets

and RK Pharma's ANDA Product have no substantial non-infringing uses, RK Pharma intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 1 the '380 patent.

608. On information and belief, upon awareness of the '380 patent, RK Pharma either actually knew of the potential for infringement of at least claim 1 of the '380 patent, or was willfully blind as to the potential for that infringement at least because RK Pharma provides instructions for infringement of at least claim 1 of the '380 patent in its proposed product labeling.

609. The commercial manufacture, importation, use, sale, or offer for sale of RK Pharma's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 1 of the '380 patent.

610. On information and belief, RK Pharma knows that its ANDA Product is a material part of the method of at least claim 1 of the '380 patent, including as evidenced in the contents of its proposed label. On information and belief, RK Pharma's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 1 of the '380 patent, as evidenced in the contents of its proposed labeling. On information and belief, RK Pharma's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

611. Thus, on information and belief, RK Pharma's will contribute to the infringement of at least claim 1 of the '380 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing RK Pharma's ANDA Product, which is a material for use in practicing the method of at least claim 1 of the '380 patent.

612. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of RK Pharma's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

613. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of RK Pharma's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 1 of the '380 patent.

614. Unless and until RK Pharma is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNTS XXXI-XXXVI AGAINST ZENARA

COUNT XXXI

(Infringement of the '515 Patent Under 35 U.S.C. § 271(e)(2) by Zenara)

615. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

616. Zenara submitted ANDA No. 215913 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product throughout the United States. By submitting the application, Zenara has committed an act of infringement of the '515 patent under 35 U.S.C. § 271(e)(2)(A).

617. The commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product will constitute an act of direct infringement of the '515 patent, either literally or under the doctrine of equivalents.

618. On information and belief, Zenara will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval,

labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

619. Healthcare providers administering Zenara's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

620. On information and belief, Zenara became aware of the '515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215913, in which it identified the '515 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

621. On information and belief, Zenara knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Zenara's ANDA Product, with its labeling, will actively induce the direct infringement of the '515 patent.

622. On information and belief, Zenara knew or should have known that Zenara's ANDA Product will be especially made or especially adapted for use in an infringement of the '515 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Zenara knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Zenara's ANDA Product will actively contribute to the direct infringement of the '515 patent.

623. Unless and until Zenara is enjoined from infringing the ’515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

624. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Zenara’s ANDA No. 215913 be a date that is not earlier than the expiration date of the ’515 patent.

COUNT XXXII

(Declaratory Judgment of Infringement of the ’515 Patent Under 35 U.S.C. § 271(a)/(b) or (c) by Zenara)

625. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

626. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

627. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

628. On information and belief, Zenara will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 215913.

629. Zenara’s actions, including but not limited to, the development of Zenara’s ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Zenara has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Zenara’s ANDA Product.

630. Zenara has actual knowledge of the ’515 patent.

631. On information and belief, Zenara became aware of the ’515 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of

using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215913, in which it identified the '515 patent as one of the patents covering XADAGO® (safinamide) tablets.

632. On information and belief, Zenara's ANDA practices all limitations of at least claim 34 of the '515 patent, either literally or under the doctrine of equivalents, as detailed above, and thus the manufacture, importation, use, sale, and/or offer for sale of Zenara's ANDA Product will constitute an act of direct infringement of the '515 patent.

633. On information and belief, Zenara will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 40 of the '515 patent.

634. On information and belief, healthcare providers administering Zenara's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 40 of the '515 patent, either literally or under the doctrine of equivalents.

635. On information and belief, Zenara possesses specific intent to encourage direct infringement of at least claim 40 of the '515 patent, including because Zenara's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Zenara's ANDA Product have no substantial non-infringing uses, Zenara intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 40 the '515 patent.

636. On information and belief, upon awareness of the '515 patent, Zenara either actually knew of the potential for infringement of at least claim 40 of the '515 patent, or was willfully blind as to the potential for that infringement at least because Zenara provides instructions for infringement of at least claim 40 of the '515 patent in its proposed product labeling.

637. The commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 40 of the '515 patent.

638. On information and belief, Zenara knows that its ANDA Product is a material part of the method of at least claim 40 of the '515 patent, including as evidenced in the contents of its proposed label. On information and belief, Zenara's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 40 of the '515 patent, as evidenced in the contents of its proposed labeling. On information and belief, Zenara's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

639. Thus, on information and belief, Zenara will contribute to the infringement of at least claim 40 of the '515 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Zenara's ANDA Product, which is a material for use in practicing the method of at least claim 40 of the '515 patent.

640. The commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product will constitute an act of contributory infringement of the '515 patent.

641. The commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

642. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Product before patent expiration will constitute direct infringement of at least claim 34 of the '515 patent, and active inducement of infringement and contributory infringement of at least claim 40 of the '515 patent.

643. Unless and until Zenara is enjoined from infringing the '515 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XXXIII

(Infringement of the '485 Patent Under 35 U.S.C. § 271(e)(2) by Zenara)

644. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

645. Zenara submitted ANDA No. 215913 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product throughout the United States. By submitting the application, Zenara has committed an act of infringement of the '485 patent under 35 U.S.C. § 271(e)(2)(A).

646. On information and belief, Zenara will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

647. Healthcare providers administering Zenara's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct

infringement of at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

648. On information and belief, Zenara became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215913, in which it identified the '485 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

649. On information and belief, Zenara knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of Zenara's ANDA Product, with its labeling, will actively induce the direct infringement of the '485 patent.

650. On information and belief, Zenara knew or should have known that Zenara's ANDA Product will be especially made or especially adapted for use in an infringement of the '485 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Zenara knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Zenara's ANDA Product will actively contribute to the direct infringement of the '485 patent.

651. Unless and until Zenara is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

652. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Zenara's ANDA No. 215913 be a date that is not earlier than the expiration date of the '485 patent.

COUNT XXXIV

(Declaratory Judgment of Infringement of the '485 Patent Under 35 U.S.C. § 271(b) or (c) by Zenara)

653. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

654. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

655. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

656. Zenara has actual knowledge of the '485 patent.

657. On information and belief, Zenara became aware of the '485 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215913, in which it identified the '485 patent as one of the patents covering XADAGO® (safinamide) tablets.

658. On information and belief, Zenara will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215913.

659. Zenara's actions, including but not limited to, the development of Zenara's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Zenara has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Zenara's ANDA Product.

660. On information and belief, Zenara will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 37 of the '485 patent.

661. On information and belief, healthcare providers administering Zenara's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 37 of the '485 patent, either literally or under the doctrine of equivalents.

662. On information and belief, Zenara possesses specific intent to encourage direct infringement of at least claim 37 of the '485 patent, including because Zenara's labeling for its ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Zenara's ANDA Product have no substantial non-infringing uses, Zenara intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 37 the '485 patent.

663. On information and belief, upon awareness of the '485 patent, Zenara either actually knew of the potential for infringement of at least claim 37 of the '485 patent, or was willfully blind as to the potential for that infringement at least because Zenara provides instructions for infringement of at least claim 37 of the '485 patent in its proposed product labeling.

664. The commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 37 of the '485 patent.

665. On information and belief, Zenara knows that its ANDA Product is a material part of the method of at least claim 37 of the '485 patent, including as evidenced in the contents of its proposed label. On information and belief, Zenara's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 37 of the '485 patent, as evidenced in the contents of its proposed labeling. On information and belief, Zenara's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

666. Thus, on information and belief, Zenara will contribute to the infringement of at least claim 37 of the '485 patent in this District and elsewhere in the United States by offering to sell, selling, importing, or otherwise distributing Zenara's ANDA Product, which is a material for use in practicing the method of at least claim 37 of the '485 patent.

667. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Zenara's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

668. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Zenara's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 37 of the '485 patent.

669. Unless and until Zenara is enjoined from infringing the '485 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT XXXV

(Infringement of the '380 Patent Under 35 U.S.C. § 271(e)(2) by Zenara)

670. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

671. Zenara submitted ANDA No. 215913 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product throughout the United States. By submitting the application, Zenara has committed an act of infringement of the '380 patent under 35 U.S.C. § 271(e)(2)(A).

672. On information and belief, Zenara will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

673. Healthcare providers administering Zenara's ANDA Product within the United States and according to the instructions in the product's labeling will constitute an act of direct infringement of at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

674. On information and belief, Zenara became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215913, in which it identified the '380 patent as a patent covering the approved product XADAGO® (safinamide) tablets.

675. On information and belief, Zenara knew or should have known that its commercial making, using, offering to sell, selling, importing or otherwise promoting and/or distributing of

Zenara's ANDA Product, with its labeling, will actively induce the direct infringement of the '380 patent.

676. On information and belief, Zenara knew or should have known that Zenara's ANDA Product will be especially made or especially adapted for use in an infringement of the '380 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, as evidenced by, for example, the contents of its proposed labeling. And, on information and belief, Zenara knew or should have known that its commercial offering to sell, selling, importing or otherwise distributing of Zenara's ANDA Product will actively contribute to the direct infringement of the '380 patent.

677. Unless and until Zenara is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

678. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Zenara's ANDA No. 215913 be a date that is not earlier than the expiration date of the '380 patent.

COUNT XXXVI

(Declaratory Judgment of Infringement of the '380 Patent Under 35 U.S.C. § 271(b) or (c) by Zenara)

679. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

680. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

681. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

682. Zenara has actual knowledge of the '380 patent.

683. On information and belief, Zenara became aware of the '380 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using XADAGO® (safinamide) tablets, or no later than when it submitted a paragraph IV certification to the FDA regarding ANDA No. 215913, in which it identified the '380 patent as one of the patents covering XADAGO® (safinamide) tablets.

684. On information and belief, Zenara will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Product immediately and imminently upon FDA approval of ANDA No. 215913.

685. Zenara's actions, including but not limited to, the development of Zenara's ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Zenara has made and will continue to make substantial preparation in the United States, including in the District of Delaware, to manufacture, sell, offer to sell, import or otherwise promote and/or distribute Zenara's ANDA Product.

686. On information and belief, Zenara will include within the packaging of its ANDA Product, or will otherwise make available to healthcare providers and patients upon FDA approval, labeling that instructs healthcare providers to perform the method of at least claim 1 of the '380 patent.

687. On information and belief, healthcare providers administering Zenara's ANDA Product within the United States and according to the instructions in the product's labeling will directly infringe at least claim 1 of the '380 patent, either literally or under the doctrine of equivalents.

688. On information and belief, Zenara possesses specific intent to encourage direct infringement of at least claim 1 of the '380 patent, including because Zenara's labeling for its

ANDA Product instructs users to perform the patented method, providing evidence of an affirmative intent to induce infringement. Furthermore, because XADAGO® (safinamide) tablets and Zenara's ANDA Product have no substantial non-infringing uses, Zenara intends for the use of its generic version of XADAGO® (safinamide) tablets to directly infringe at least claim 1 the '380 patent.

689. On information and belief, upon awareness of the '380 patent, Zenara either actually knew of the potential for infringement of at least claim 1 of the '380 patent, or was willfully blind as to the potential for that infringement at least because Zenara provides instructions for infringement of at least claim 1 of the '380 patent in its proposed product labeling.

690. The commercial manufacture, importation, use, sale, or offer for sale of Zenara's ANDA Product, with its labeling, will constitute an act of active inducement of infringement of at least claim 1 of the '380 patent.

691. On information and belief, Zenara knows that its ANDA Product is a material part of the method of at least claim 1 of the '380 patent, including as evidenced in the contents of its proposed label. On information and belief, Zenara's ANDA Product was especially made or especially adapted for use by a healthcare provider in a manner that will directly infringe at least claim 1 of the '380 patent, as evidenced in the contents of its proposed labeling. On information and belief, Zenara's ANDA Product is not a staple article of commerce suitable for substantial non-infringing use, as evidenced by the contents of its proposed labeling and the fact that it seeks FDA approval for a particular use. There are no suitable uses for safinamide mesylate tablets other than treating patients pursuant to the FDA's approval for such products.

692. Thus, on information and belief, Zenara's will contribute to the infringement of at least claim 1 of the '380 patent in this District and elsewhere in the United States by offering to

sell, selling, importing, or otherwise distributing Zenara's ANDA Product, which is a material for use in practicing the method of at least claim 1 of the '380 patent.

693. The commercial manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Zenara's ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs, for which damages are inadequate.

694. Plaintiffs are entitled to a declaratory judgment that the future manufacture, use, sale, offer for sale, importation or otherwise promotion and/or distribution of Zenara's ANDA Product before patent expiration will constitute active inducement of infringement and contributory infringement of at least claim 1 of the '380 patent.

695. Unless and until Zenara is enjoined from infringing the '380 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

a) A judgment be issued that each Defendant's submission and maintenance of its ANDA (i.e., Aurobindo's ANDA, MSN's ANDA, Optimus' ANDA, Prinston's ANDA, RK Pharma's ANDA, and Zenara's ANDA) infringed the '515, '485, and '380 patents under 35 U.S.C. § 271(e)(2)(A) by submitting it under section 505(j) of the Federal Food, Drug and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of each Defendant's ANDA Product (i.e., Aurobindo's ANDA Product, MSN's ANDA Product, Optimus' ANDA Product, Prinston's ANDA Product, RK Pharma's ANDA Product, and Zenara's ANDA Product) will constitute an act of infringement of the '515, '485, and '380 patents;

b) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of each of Defendant's ANDAs (i.e., Aurobindo's ANDA, MSN's ANDA, Optimus' ANDA, Prinston's ANDA, RK Pharma's ANDA, and Zenara's ANDA) shall be a date which is not earlier than the expiration dates of the '515, '485, and '380 patents, as extended by any applicable period of exclusivity;

c) That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining each Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the '515, '485 or '380 patents;

d) That a declaration be issued under 28 U.S.C. § 2201 and/or 2202 that the manufacture, use, offer for sale, sale and/or importation of each Defendant's ANDA Product (i.e., Aurobindo's ANDA Product, MSN's ANDA Product, Optimus' ANDA Product, Prinston's ANDA Product, RK Pharma's ANDA Product, and Zenara's ANDA Product) before expiration of the '515, '485, and '380 patents does and will infringe the '515, '485, and '380 patents;

e) That an order be issued preliminarily and permanently enjoining each Defendant and its affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, or acting on their behalf, from infringing the '515, '485, and '380 patents;

f) If Defendants engage in the commercial manufacture, use, offer to sell, sale, or importation of each Defendant's ANDA Product (i.e., Aurobindo's ANDA Product, MSN's ANDA Product, Optimus' ANDA Product, Prinston's ANDA Product, RK Pharma's ANDA

Product, and Zenara's ANDA Product) disclosed in its ANDA (i.e., Aurobindo's ANDA, MSN's ANDA, Optimus' ANDA, Prinston's ANDA, RK Pharma's ANDA, and Zenara's ANDA) prior to the expiration of the '515, '485, and '380 patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiffs damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found and/or assessed together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;

g) That this case be declared an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

h) That an accounting be performed of each Defendant's infringing activities not presented at trial and an award by the Court of additional damages for any such infringing sales; and

i) That this Court award such other and further relief as it may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable. Specifically, Plaintiffs demand a jury trial in the event that there is a launch at risk and damages are in issue.

Dated: June 10, 2021

FISH & RICHARDSON P.C.

By: */s/ Gregory R. Booker*

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