IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SK BIOPHARMACEUTICALS CO., LTD. AND SK LIFE SCIENCE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA U.S.A., INC., AND ZENARA PHARMA PVT. LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs SK Biopharmaceuticals Co., Ltd. and SK Life Science, Inc. (collectively, "Plaintiffs" or "SKBP"), by their undersigned attorneys, bring this action against Defendants Aurobindo Pharma Limited ("Aurobindo Limited"), Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA") (together, "Aurobindo"), and Zenara Pharma Pvt. Limited ("Zenara") (all collectively, "Defendants") and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq., and in particular 35 U.S.C §§ 271 (a–c, e), arises from (a) Aurobindo's submission to the United States Food and Drug Administration (FDA) of Abbreviated New Drug Application (ANDA) No. 219473 ("Aurobindo's ANDA"); and (b) Zenara's submission to the FDA of ANDA No. 219403 ("Zenara's ANDA") (together, "Defendants' ANDAs"). Through Zenara's ANDA, Zenara seeks approval to market generic versions of XCOPRI® (cenobamate) 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg tablets ("ANDA Products") prior to the expiration of SKBP's United States Patent Nos. 7,598,279 ("the '279 Patent") and 11,654,133 ("the '133 Patent") (together, "the Patents-in-Suit"). Through

Aurobindo's ANDA, Aurobindo seeks approval to market generic versions of XCOPRI® (cenobamate) 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg tablets ("ANDA Products") prior to the expiration of SKBP's '133 Patent. Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq., and in particular 35 U.S.C. §§ 271(a–c, e).

THE PARTIES

SKBP

3. Plaintiff SK Biopharmaceuticals Co., Ltd. is a corporation organized and existing under the laws of South Korea, having a principal place of business at 221 Pangyoyeok-Ro, Bundang-Gu, Seongnam-Si, Gyeonggi-Do 13494, Republic of Korea.

4. Plaintiff SK Life Science, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 461 From Road, 5th Floor, Paramus, New Jersey 07652. SK Life Science, Inc. is a wholly owned subsidiary of SK Biopharmaceuticals Co., Ltd.

Aurobindo

5. On information and belief, Defendant Aurobindo Limited is a corporation organized and existing under the laws of India, having a registered office at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad - 500038, Telangana, India, and a corporate office at Hyderabad Knowledge City, Plot No. 1, Survey No. 83/1, Raidurg Panmaktha, Ranga Reddy District, Hyderabad - 500032, Telangana, India.

6. On information and belief, Defendant Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

7. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Limited.

8. On information and belief, Aurobindo USA acts at the direction and for the benefit of Aurobindo Limited and is controlled and/or dominated by Aurobindo Limited.

9. On further information and belief, Aurobindo Limited and Aurobindo USA collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Aurobindo Limited and Aurobindo USA are agents of each other and/or operate in concert as integrated parts of the same business group and enter into agreements with each other that are nearer than arm's length.

10. On information and belief, Aurobindo Limited, in collaboration with Aurobindo USA, prepared and submitted Aurobindo's ANDA, and they continue to collaborate in seeking FDA approval of that application. Furthermore, the notice of Paragraph IV certification from Aurobindo dated May 6, 2024 ("Aurobindo's Notice Letter") was sent on behalf of both Aurobindo Limited and Aurobindo USA.

11. On information and belief, Aurobindo USA acts as the U.S. agent for Aurobindo Limited for purposes of regulatory submissions to FDA in seeking approval for generic drugs, including as the U.S. agent of Aurobindo Limited for Aurobindo's ANDA.

12. On information and belief, Aurobindo Limited relies on material assistance from Aurobindo USA to market, distribute, offer to sell, or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Aurobindo USA and Aurobindo

Limited intend to act collaboratively to commercially manufacture, market, distribute, offer to sell, or sell Aurobindo's ANDA Products in the event FDA approves Aurobindo's ANDA.

Zenara

13. On information and belief, Defendant Zenara is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 83/B, 84, 87-96 Phase III, IDA, Cherlapally, Hyderabad - 500051, Telangana, India.

JURISDICTION AND VENUE

14. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271, alleging infringement of one or more claims of the Patents-in-Suit. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

Aurobindo

15. This Court has personal jurisdiction over Aurobindo USA because it is a corporation organized and existing under the laws of the State of Delaware.

16. This Court has personal jurisdiction over Aurobindo Limited and Aurobindo USA because, *inter alia*, on information and belief, each of Aurobindo Limited and Aurobindo USA has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Aurobindo's ANDA Products in the State of Delaware upon approval of Aurobindo's ANDA.

17. On information and belief, Aurobindo Limited, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, has engaged in the research and development of Aurobindo's ANDA Products, and the preparation

and filing of Aurobindo's ANDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, and/or importation of Aurobindo's ANDA Products throughout the United States, including within the State of Delaware, and stands to benefit from the approval of Aurobindo's ANDA.

18. On information and belief, following FDA approval of Aurobindo's ANDA, Aurobindo Limited intends to market, offer to sell, sell, or distribute Aurobindo's ANDA Products throughout the United States and within the State of Delaware that will, as explained below, infringe one or more claims of the '133 Patent protecting the XCOPRI® products. On information and belief, following FDA approval of Aurobindo's ANDA, Aurobindo knows and intends that Aurobindo's ANDA Products will be marketed, used, distributed, offered for sale, or sold in the United States and within the State of Delaware.

19. Each of Aurobindo Limited and Aurobindo USA has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, D.I. 30 at 10–11, 13, *Abbvie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332-MN (D. Del. Feb. 27, 2024); D.I. 10 at 10–17, *Taiho Pharm.Co., Ltd. et al. v. Eugia Pharma Specialties Ltd. et al.*, C.A. No. 23-1193-JLH (D. Del. October 30, 2023); D.I. 215 at 4–8, *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-GBW (D. Del. June 15, 2022). Aurobindo has purposefully availed itself of the rights, benefits, and privileges of the State of Delaware by asserting counterclaims in this Court.

20. This Court also has personal jurisdiction over Aurobindo Limited at least because, *inter alia*, (a) Aurobindo Limited has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products in the

United States, including in the State of Delaware; (b) Aurobindo Limited, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, will market, distribute, offer to sell, or sell Aurobindo's ANDA Products in the United States, including in the State of Delaware and to residents of this judicial district, upon approval of Aurobindo's ANDA, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Products in the State of Delaware; and (c) Aurobindo Limited has purposefully availed itself of the privilege of doing business in the State of Delaware by placing goods into the stream of commerce for distribution throughout the United States and within the State of Delaware and/or by selling, directly or through its agents, pharmaceutical products in the State of Delaware. On information and belief, if Aurobindo's ANDA is approved, Aurobindo's ANDA Products charged with infringing the '133 Patent would, *inter alia*, be marketed, distributed, offered for sale, and/or sold in the State of Delaware, prescribed by physicians practicing in Delaware, dispensed by in Delaware, and used by patients in Delaware, all of which would have a substantial effect on Delaware.

21. In the alternative, this Court has personal jurisdiction over Aurobindo Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law, (b) Aurobindo Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state, and (c) Aurobindo Limited has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Limited satisfies due process.

22. At least because, on information and belief, Aurobindo Limited is a foreign corporation, venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

23. At least because, on information and belief, Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b).

Zenara

24. This Court has personal jurisdiction over Zenara because, *inter alia*, on information and belief, Zenara has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Zenara's ANDA Products in the State of Delaware upon approval of Zenara's ANDA.

25. Zenara has not contested personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings. *See, e.g.*, D.I. 33 at 23, 25–26, *Harmony Biosciences, LLC et al. v. AET Pharma US Inc. et al.*, C.A. No. 23-1340-JLH (D. Del. Feb. 15, 2024); D.I. 9 at 2–3, *Pfizer Inc. et al. v. Zenara Pharma Prvt. Ltd.*, C.A. No. 23-924-GBW (D. Del. Sept. 25, 2023); D.I. 52 at 6, 10–15, *Abbvie Inc. et al. v. Alkem Labs. Ltd., et al.*, C.A. No. 22-1423-RGA (D. Del. February 28, 2023). Zenara has also purposefully availed itself of the rights, benefits, and privileges of the State of Delaware by asserting counterclaims in this Court. *See, e.g.*, D.I. 33 at 77–84, *Harmony Biosciences, LLC et al. v. AET Pharma US Inc. et al.*, C.A. No. 23-1340 (D. Del. Feb. 15, 2024).

26. On information and belief, Zenara, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, has engaged in the research and development of Zenara's ANDA Products, and the preparation and filing of Zenara's ANDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, and/or importation of Zenara's ANDA Products throughout the United States, including within the State of Delaware, and stands to benefit from the approval of Zenara's ANDA.

27. On information and belief, following FDA approval of Zenara's ANDA, Zenara intends to market, offer to sell, sell, or distribute Zenara's ANDA Products throughout the United States and within the State of Delaware that will, as explained below, infringe one or more claims of the Patents-in-Suit protecting the XCOPRI® products. On information and belief, following FDA approval of Zenara's ANDA, Zenara knows and intends that Zenara's ANDA Products will be marketed, used, distributed, offered for sale, and/or sold in the United States and within the State of Delaware.

28. This Court also has personal jurisdiction over Zenara at least because, *inter alia*, (a) Zenara has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Products in the United States, including in the State of Delaware; (b) Zenara, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, will market, distribute, offer to sell, and/or sell Zenara's ANDA Products in the United States, including in the State of Delaware and to residents of this judicial district, upon approval of Zenara's ANDA, and will derive substantial revenue from the use or consumption of Zenara's ANDA Products in the State of Delaware; and

(c) Zenara has purposefully availed itself of the privilege of doing business in the State of Delaware by placing goods into the stream of commerce for distribution throughout the United States and within the State of Delaware and/or by selling, directly or through its agents, pharmaceutical products in the State of Delaware. On information and belief, if Zenara's ANDA is approved, Zenara's ANDA Products charged with infringing the Patents-in-Suit would, *inter alia*, be marketed, distributed, offered for sale, and/or sold in the State of Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and used by patients in Delaware, all of which would have a substantial effect on Delaware.

29. In the alternative, this Court has personal jurisdiction over Zenara pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law, (b) Zenara is a foreign defendant not subject to general personal jurisdiction in the courts of any state, and (c) Zenara has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zenara satisfies due process.

30. At least because, on information and belief, Zenara is a foreign corporation, venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b).

SKBP PATENTS AND APPROVED XCOPRI® DRUG PRODUCTS

31. SKBP makes and sells XCOPRI® (cenobamate) 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg tablets (collectively, "XCOPRI®") for oral use to treat adult patients for partial-onset seizures. In the U.S., XCOPRI® is marketed by SK Life Science, Inc. A true and correct copy of the prescribing information for XCOPRI® is attached as Exhibit A.

32. The active ingredient in XCOPRI® is cenobamate.

33. The mechanism by which cenobamate exerts its therapeutic effects in patients with partial-onset seizures is unknown.

34. SK Life Science, Inc. is the holder of New Drug Application (NDA) No. 212839 under which FDA approved the marketing of XCOPRI® on March 10, 2020.

35. XCOPRI® is the first approved pharmaceutical product to contain cenobamate. In recognition of this breakthrough, the FDA granted XCOPRI® five years of regulatory exclusivity for a new chemical entity, which expires on March 10, 2025, pursuant to 21 C.F.R. § 314.108.

36. XCOPRI® and its approved uses are covered by claims of the Patents-in-Suit.

37. The Patents-in-Suit are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with NDA No. 212839.

38. SK Biopharmaceuticals Co., Ltd., as the assignee, owns the entire right, title, and interest in each of the Patents-in-Suit. SK Biopharmaceuticals Co., Ltd. has the right to enforce each of these patents. SK Life Science, Inc. is the exclusive licensee of the Patents-in-Suit.

39. The '279 Patent is entitled "Neurotherapeutic Azole Compounds." The '279 Patent was duly and legally issued by the U.S. Patent and Trademark Office (USPTO) on October 6, 2009. The Orange Book presently shows that the '279 Patent's term ends on October 30, 2032. A true and correct copy of the '279 Patent is attached as Exhibit B.

40. The '133 Patent is entitled "Use of [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] Carbamate in Combination Therapy." The '133 Patent was duly and legally issued by the USPTO on May 23, 2023. The Orange Book presently shows that the '133 Patent's term ends on June 16, 2039. A true and correct copy of the '133 Patent is attached as Exhibit C.

41. The Prescribing Information for XCOPRI® provides that XCOPRI® is indicated for the treatment of partial-onset seizures in adult patients. Ex. A at 1, 2. The recommended

maintenance dosage of XCOPRI® is 200 mg/day, with a maximum dose not to exceed 400 mg/day. Ex. A at 1.

42. Under the "Dosage and Administration" section of the XCOPRI® Prescribing Information, in section 2.1, the labeling instructs that XCOPRI® can be administered as a Monotherapy and Adjunctive Therapy, including as adjunctive therapy with phenytoin and phenobarbital. Ex. A at 2.

43. A Phase III study of cenobamate (NCT 02535091) evaluated, as a secondary objective, the pharmacokinetic effects of cenobamate on concomitant phenytoin and phenobarbital administration. Sperling et al., *Cenobamate (YKP3089) as adjunctive treatment for uncontrolled focal seizures in a large, phase 3, multicenter, open-label safety study*, 61 Epilepsia1000-1108, 1101 (2020). Of the 1339 patients participating in the study who received cenobamate, 114 received concomitant phenytoin, and 51 received concomitant phenobarbital. *Id.* at 1103. Phenytoin and phenobarbital remain available treatments for treating partial-onset epilepsy, with phenytoin being the 4th most commonly prescribed medication. *See* Terman et al., *Antiseizure medication treatment pathways for US Medicare beneficiaries with newly treated epilepsy*, 63 Epilepsia 1571-1579, 1577 at Table 3 (2022) (ranking phenytoin as the 4th most common treatment pathway in a retrospective study of 21,458 Medicare beneficiaries with newly treated epilepsy between 2014-2017); *see also* ClinCalc DrugStats Database, Phenytoin Drug Usage Statistics available at https://clincalc.com/DrugStats/Drugs/Phenytoin (last visited June 13, 2024) (reporting 1,616,629 total prescriptions and 270,818 patients in 2020 for phenytoin).

44. Section 6.1 of the XCOPRI® Prescribing Information, under "Clinical Trials Experience" provides that XCOPRI® was administered as adjunctive therapy to 1944 patients. Ex. A at 8.

45. The XCOPRI® Prescribing information provides instructions regarding how to dose XCOPRI® with one or more of phenytoin and phenobarbital.

46. Section 7 of the XCOPRI® Prescribing Information provides information regarding the co-administration of XCOPRI® with, among other drugs, phenytoin and phenobarbital. For patients concomitantly taking XCOPRI® and phenytoin, XCOPRI® Prescribing Information instructs physicians and patients to "gradually decrease phenytoin dosage by up to 50% as XCOPRI® is being titrated." Ex. A at Table 5. For patients concomitantly taking XCOPRI® and phenobarbital, XCOPRI® Prescribing Information instructs physicians and patients to "consider a reduction in dosage of phenobarbital." Ex. A at Table 5. This information about how to concomitantly dose XCOPRI® and phenytoin or phenobarbital is repeated in the "Drug Interactions" section on the first page of the XCOPRI® Prescribing Information.

47. Section 12.3 of the XCOPRI® Prescribing Information provides that "[m]ultiple doses of concomitant XCOPRI 200 mg once daily increased phenytoin mean Cmax and AUC by 70% and 84%, respectively, and phenobarbital mean Cmax and AUC by 34% and 37%, respectively." In contrast, "[n]o clinically significant differences in the pharmacokinetics of the following drugs were observed when used concomitantly with cenobamate: valproic acid, levetiracetam or lacosamide." Ex. A at 17.

48. The XCOPRI® Prescribing Information instructs that by reducing the amount of phenytoin by up to 50% when co-administered with XCOPRI®, the AUC of phenytoin will be reduced by at least 5%, to the level of AUC obtained after the administration of phenytoin to the patient without XCOPRI®.

49. The XCOPRI® Prescribing Information instructs that by reducing the amount of phenobarbital when co-administered with XCOPRI®, the AUC of phenobarbital will be reduced

by at least 5%, to the level of AUC obtained after the administration of phenobarbital to the patient without XCOPRI®.

DEFENDANTS' ANDAS AND NOTICES OF PARAGRAPH IV CERTIFICATION

Aurobindo

50. On information and belief, Aurobindo has submitted or caused to be submitted ANDA No. 219473 to FDA under 21 U.S.C. § 355(j) in order to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the cenobamate tablets described therein, as a purported generic version of XCOPRI®, prior to the expiration of the '133 Patent.

51. On information and belief, Aurobindo's ANDA Products are tablets that comprise 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg of cenobamate as the active pharmaceutical ingredient.

52. On information and belief, Aurobindo's ANDA Products will be accompanied by Prescribing Information substantially the same as the FDA-approved XCOPRI® Prescribing Information, and Aurobindo seeks FDA approval to sell and use Aurobindo's ANDA Products within the scope of the claims of the '133 Patent.

53. Aurobindo's Notice Letter represents that Aurobindo had submitted to FDA Aurobindo's ANDA with a purported Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the products described in Aurobindo's ANDA before the expiration of the '133 Patent listed in the Orange Book for XCOPRI®. Hence, through its ANDA, Aurobindo seeks to commercially manufacture, use, offer for sale, sell, or import into the United States Aurobindo's ANDA Products before the expiration of the '133 Patent.

54. On information and belief, if FDA approves Aurobindo's ANDA, Aurobindo will manufacture, offer to sell, and/or sell Aurobindo's ANDA Products within the United States, including within the State of Delaware, and/or will import Aurobindo's ANDA Products into the United States, including Delaware.

55. On information and belief, if FDA approves Aurobindo's ANDA, Aurobindo will actively induce or contribute to the manufacture, use, offer to sell, sale, and/or importation of Aurobindo's ANDA Products in the United States, including Delaware.

Zenara

56. On information and belief, Zenara has submitted or caused to be submitted ANDA No. 219403 to FDA under 21 U.S.C. § 355(j) in order to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the cenobamate tablets described therein, as a purported generic version of XCOPRI®, prior to the expiration of the Patents-in-Suit.

57. On information and belief, Zenara's ANDA Products are tablets that comprise 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg of cenobamate as the active pharmaceutical ingredient.

58. On information and belief, Zenara's ANDA Products will be accompanied by Prescribing Information that will be the substantially the same as the FDA-approved XCOPRI® Prescribing Information, and Zenara seeks FDA approval to sell and use Zenara's ANDA Products within the scope of the claims of the Patents-in-Suit.

59. Plaintiffs received a notice of Paragraph IV certification from Zenara dated May 10, 2024 ("Zenara's Notice Letter"). Zenara's Notice Letter represents that Zenara had submitted to FDA Zenara's ANDA with a purported Paragraph IV certification pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the products described in Zenara's ANDA, before the expiration of the '279 and '133 Patents. Hence, through its ANDA, Zenara seeks to commercially manufacture, use, offer for sale, sell, and/or import into the United States Zenara's ANDA Products before the expiration of the Patents-in-Suit.

60. In the Zenara Notice Letter, Zenara purported to offer confidential access to portions of ANDA No. 219403 on terms and conditions set forth in the Notice Letter ("Zenara Offer"). The Zenara Offer contained unreasonable restrictions on who could view the ANDA, well beyond those that would apply under a protective order. For example, the Zenara Offer permitted access only to attorneys from a single law firm, and also prohibited those attorneys from conducting patent prosecution for SKBP on any topic, or participating in FDA counseling for any client on any topic. The restrictions Zenara placed on access to ANDA No. 219403 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to the persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets or other confidential business information***." (emphasis added).

61. On May 30, 2024, outside counsel for Plaintiffs contacted counsel for Zenara – who was designated as Zenara's agent for service in the Zenara Notice Letter – via email in an effort to negotiate reasonable terms of confidential access to Zenara's ANDA. Plaintiffs' correspondence included proposed modifications to the unduly restrictive Zenara Offer. Having received no substantive response, on June 5, 2024, Plaintiffs' counsel contacted Zenara's counsel again. Zenara's counsel responded that Zenara would not accept Plaintiffs' proposed modifications, but

made no attempt to engage in any negotiation of terms, despite Plaintiffs inviting such negotiation by further correspondence dated June 6, 2024. To date, Zenara has not responded further.

62. On information and belief, if FDA approves Zenara's ANDA, Zenara will manufacture, offer to sell, and/or sell Zenara's ANDA Products within the United States, including within the State of Delaware, and/or will import Zenara's ANDA Products into the United States, including Delaware.

63. On information and belief, if FDA approves Zenara's ANDA, Zenara will actively induce or contribute to the manufacture, use, offer to sell, sale, and/or importation of Zenara's ANDA Products in the United States, including Delaware.

* * *

64. Plaintiffs bring this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of each of the Zenara Notice Letter and the Aurobindo Notice Letter. *See* 21 U.S.C. § 355(c)(3)(C).

COUNT 1
INFRINGEMENT OF THE '133 PATENT BY AUROBINDO

65. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–64 as if fully set forth herein.

66. On information and belief, Aurobindo has submitted or caused the submission of Aurobindo's ANDA to FDA and continues to seek FDA approval of Aurobindo's ANDA.

67. On information and belief, Aurobindo has infringed at least claim 1 of the '133 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and seeking FDA approval of Aurobindo's ANDA prior to the expiration of the '133 Patent, entitling Plaintiffs to the relief provided by 35 U.S.C. §271(e)(4), including, *inter alia*, an

order of this Court that the effective date of approval for ANDA No. 219473 be a date which is not earlier than the expiration date of the '133 Patent.

68. Claim 1 of the '133 Patent recites:

> A method for treating a patient who is suffering from epilepsy with co-administering a therapeutically effective amount of (i) [(lR)-1-(2-chlorophenyl)-2-(tetrazol-2-yl) ethyl] carbamate (cenobamate) or a pharmaceutically acceptable salt thereof and (ii) one or two antiepileptic drugs, said method comprising:
>
> modifying the therapeutically effective amount of the antiepileptic drug to adjust AUC of the antiepileptic drug obtained after the co-administration having at least 5% difference to the level of AUC obtained after the administration of antiepileptic drug to the patient without cenobamate or a pharmaceutically acceptable salt thereof,
>
> wherein the therapeutically effective amount of cenobamate or a pharmaceutically acceptable salt thereof is from about 100 mg/day to about 400 mg/day, and
>
> wherein the antiepileptic drug is selected from the group consisting of phenobarbital and phenytoin.

69. Aurobindo's commercial manufacture, use in accordance with Aurobindo's proposed prescribing information, offer for sale, and/or sale within the United States, and/or importation into the United States of Aurobindo's ANDA Products, would directly infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the '133 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will make, use, offer for sale, or sell Aurobindo's ANDA Products within the United States, or will import Aurobindo's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce infringement of one or more claims of the '133 Patent. *See id.*

70. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, will market and distribute Aurobindo's ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Aurobindo's ANDA Products. On information and belief, Aurobindo will also knowingly and intentionally accompany Aurobindo's ANDA Products with proposed prescribing information and product insert that will include instructions for using or administering Aurobindo's ANDA Products. On information and belief, the proposed prescribing information and product insert accompanying Aurobindo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for XCOPRI®, attached as Exhibit A, and which, if followed, will instruct modifying the therapeutically effective dose of phenytoin or phenobarbital when co-administered with about 100 mg/day to about 400 mg/day of XCOPRI® to adjust the AUC of phenytoin or phenobarbital and will infringe one or more claims of the '133 Patent. Accordingly, Aurobindo will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Aurobindo's ANDA Products to directly infringe one or more claims of the '133 Patent. In addition, on information and belief, Aurobindo will encourage acts of direct infringement with knowledge of the '133 Patent and knowledge that it is encouraging infringement.

71. Aurobindo had actual and constructive notice of the '133 Patent prior to filing Aurobindo's ANDA and was aware that the filing of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '133 Patent would constitute an act of infringement of one or more claims of the '133 Patent. On information and belief, Aurobindo had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, and/or importation of

Aurobindo's ANDA Products would not contribute to and/or induce infringement of one or more claims of the '133 Patent.

72. On information and belief, Aurobindo filed Aurobindo's ANDA without adequate justification for asserting the '133 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '133 Patent renders this case "exceptional" under 35 U.S.C. § 285.

73. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing, and from actively inducing and contributing to the infringement of one or more claims of the '133 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Aurobindo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 2
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '133 PATENT BY AUROBINDO

74. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–73 as if fully set forth herein.

75. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

76. The '133 Patent includes claims that recite methods of administering [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate (cenobamate) and one or more of phenytoin or phenobarbital.

77. On information and belief, if Aurobindo's ANDA is approved, Aurobindo's ANDA Products will be made, offered for sale, sold, and/or otherwise distributed in the United States,

including in the State of Delaware, and/or will be imported into the United States, including the State of Delaware, by or through Aurobindo and its affiliates. Aurobindo will therefore directly infringe one or more claims of the '133 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

78. On information and belief, Aurobindo knows that healthcare professionals and/or patients will use Aurobindo's ANDA Products in accordance with the proposed prescribing information sought by Aurobindo's ANDA. On information and belief, the proposed prescribing information and product insert accompanying Aurobindo's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for XCOPRI®, attached as Exhibit A, and which, if followed, will instruct modifying the therapeutically effective dose of phenytoin or phenobarbital when co-administered with XCOPRI® to adjust the AUC and will infringe one or more claims of the '133 Patent. Aurobindo will therefore contribute to and/or induce infringement of one or more claims of the '133 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

79. On information and belief, Aurobindo's infringing activities, including the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products, will begin immediately after the FDA approves Aurobindo's ANDA. Any such conduct before the '133 Patent expires will directly infringe, contribute to the infringement of, and/or induce infringement of one or more claims of the '133 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

80. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Aurobindo concerning liability for the infringement

of one or more claims of the ’133 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

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

82. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT 3
INFRINGEMENT OF THE ’279 PATENT BY ZENARA

83. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–82 as if fully set forth herein.

84. On information and belief, Zenara has submitted or caused the submission of Zenara’s ANDA to FDA and continues to seek FDA approval of Zenara’s ANDA.

85. On information and belief, Zenara has infringed at least claim 11 the ’279 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Zenara’s ANDA with a Paragraph IV certification and seeking FDA approval of Zenara’s ANDA prior to the expiration of the ’279 Patent.

86. Claim 11 of the ’279 Patent provides:

> The azole of claim 10, wherein said compound is carbamic acid (R)-(+)-1-(2-chloro-phenyl)-2-tetrazol-2-yl-ethyl ester substantially free of its (S)enantiomer and said (R)-enantiomer is present to the extent of at least about 95%.

87. (R)-(+)-1-(2-chloro-phenyl)-2-tetrazol-2-yl-ethyl ester is also known as cenobamate.

88. Zenara’s commercial manufacture, use, offer for sale, and/or sale within the United States, and/or importation into the United States of Zenara’s ANDA Products, would directly infringe, actively induce infringement, and/or contribute to the infringement of one or more claims

of the ’279 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of Zenara’s ANDA, Zenara will make, use, offer for sale, and/or sell Zenara’s ANDA Products within the United States, and/or will import Zenara’s ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’279 Patent. *See id.*

89. On information and belief, upon FDA approval of Zenara’s ANDA, Zenara, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, will market and distribute Zenara’s ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Zenara’s ANDA Products. On information and belief, Zenara will also knowingly and intentionally accompany Zenara’s ANDA Products with proposed prescribing information and product insert that will include instructions for using or administering Zenara’s ANDA Products. On information and belief, the proposed prescribing information and product insert accompanying Zenara’s ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for XCOPRI®, attached as Exhibit A, and which, if followed, will infringe one or more claims of the ’279 Patent. Accordingly, Zenara will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of Zenara’s ANDA Products to directly infringe one or more claims of the ’279 Patent. In addition, on information and belief, Zenara will encourage acts of direct infringement with knowledge of the ’279 Patent and knowledge that it is encouraging infringement.

90. Zenara had actual and constructive notice of the ’279 Patent prior to filing Zenara’s ANDA and was aware that the filing of Zenara’s ANDA with the request for FDA approval prior

to the expiration of the ’279 Patent would constitute an act of infringement of one or more claims of the ’279 Patent. On information and belief, Zenara had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara’s ANDA Products would not contribute to and/or induce infringement of one or more claims of the ’279 Patent.

91. On information and belief, Zenara filed Zenara’s ANDA without adequate justification for asserting the ’279 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Zenara’s ANDA Products. Zenara’s conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the ’279 Patent renders this case “exceptional” under 35 U.S.C. § 285.

92. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing, and from actively inducing and contributing to the infringement of one or more claims of the ’279 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Zenara, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 4
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’279 PATENT BY ZENARA

93. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–92 as if fully set forth herein.

94. Plaintiffs’ claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

95. On information and belief, if Zenara’s ANDA is approved, Zenara’s ANDA Products will be made, offered for sale, sold, and/or otherwise distributed in the United States, including in the State of Delaware, and/or will be imported into the United States, including the

State of Delaware, by or through Zenara and its affiliates. Zenara will therefore directly infringe one or more claims of the '279 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

96. On information and belief, Zenara knows that healthcare professionals and/or patients will use Zenara's ANDA Products in accordance with the proposed prescribing information sought by Zenara's ANDA. On information and belief, the proposed prescribing information and product insert accompanying Zenara's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for XCOPRI®, attached as Exhibit A, and which, if followed, will infringe one or more claims of the '279 Patent. Zenara will therefore contribute to and/or induce infringement of one or more claims of the '279 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

97. On information and belief, Zenara's infringing activities, including the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Products, will begin immediately after the FDA approves Zenara's ANDA. Any such conduct before the '279 Patent expires will directly infringe, contribute to the infringement of, and/or induce infringement of one or more claims of the '279 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

98. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zenara concerning liability for the infringement of one or more claims of the '279 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

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

100. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT 5
INFRINGEMENT OF THE '133 PATENT BY ZENARA

101. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–100 as if fully set forth herein.

102. On information and belief, Zenara has submitted or caused the submission of Zenara's ANDA to FDA and continues to seek FDA approval of Zenara's ANDA.

103. On information and belief, Zenara has infringed at least claim 1 of the '133 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Zenara's ANDA with a Paragraph IV certification and seeking FDA approval of Zenara's ANDA prior to the expiration of the '133 Patent, entitling Plaintiffs to the relief provided by 35 U.S.C. §271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 219403 be a date which is not earlier than the expiration date of the '133 Patent.

104. Claim 1 of the '133 Patent recites:

> A method for treating a patient who is suffering from epilepsy with co-administering a therapeutically effective amount of (i) [(lR)-1-(2-chlorophenyl)-2-(tetrazol-2-yl) ethyl] carbamate (cenobamate) or a pharmaceutically acceptable salt thereof and (ii) one or two antiepileptic drugs, said method comprising:
>
> modifying the therapeutically effective amount of the antiepileptic drug to adjust AUC of the antiepileptic drug obtained after the co-administration having at least 5% difference to the level of AUC obtained after the administration of antiepileptic drug to the patient without cenobamate or a pharmaceutically acceptable salt thereof,
>
> wherein the therapeutically effective amount of cenobamate or a pharmaceutically acceptable salt thereof is from about 100 mg/day to about 400 mg/day, and
>
> wherein the antiepileptic drug is selected from the group consisting of phenobarbital and phenytoin.

105. Zenara's commercial manufacture, use in accordance with Zenara's proposed prescribing information, offer for sale, and/or sale within the United States, and/or importation into the United States of Zenara's ANDA Products, would directly infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the '133 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c). Accordingly, unless enjoined by this Court, upon FDA approval of Zenara's ANDA, Zenara will make, use, offer for sale, and/or sell Zenara's ANDA Products within the United States, or will import Zenara's ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, and/or induce infringement of one or more claims of the '133 Patent. *See id.*

106. On information and belief, upon FDA approval of Zenara's ANDA, Zenara, through its own actions and/or through the actions of one or more wholly owned subsidiaries, agents, and/or alter egos, will market and distribute Zenara's ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of Zenara's ANDA Products. On information and belief, Zenara will also knowingly and intentionally accompany Zenara's ANDA Products with a proposed prescribing information and product insert that will include instructions for using or administering Zenara's ANDA Products. On information and belief, the proposed prescribing information and product insert accompanying Zenara's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for XCOPRI®, attached as Exhibit A, and which, if followed, will instruct modifying the therapeutically effective dose of phenytoin or phenobarbital when co-administered with about 100 mg/day to about 400 mg/day of XCOPRI® to adjust the AUC of phenytoin or phenobarbital and will infringe one or more claims of the '133 Patent. Accordingly, Zenara will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of

Zenara's ANDA Products to directly infringe one or more claims of the '133 Patent. In addition, on information and belief, Zenara will encourage acts of direct infringement with knowledge of the '133 Patent and knowledge that it is encouraging infringement.

107. Zenara had actual and constructive notice of the '133 Patent prior to filing Zenara's ANDA and was aware that the filing of Zenara's ANDA with the request for FDA approval prior to the expiration of the '133 Patent would constitute an act of infringement of one or more claims of the '133 Patent. On information and belief, Zenara had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Products would not contribute to and/or induce infringement of one or more claims of the '133 Patent.

108. On information and belief, Zenara filed Zenara's ANDA without adequate justification for asserting the '133 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Zenara's ANDA Products. Zenara's conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '133 Patent renders this case "exceptional" under 35 U.S.C. § 285.

109. Plaintiffs will be irreparably harmed if Zenara is not enjoined from infringing, and from actively inducing and contributing to the infringement of one or more claims of the '133 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Zenara, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 6
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '133 PATENT BY ZENARA

110. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–109 as if fully set forth herein.

111. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

112. The '133 Patent includes claims that recite methods of administering [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate (cenobamate) and one or more of phenytoin or phenobarbital.

113. On information and belief, if Zenara's ANDA is approved, Zenara's ANDA Products will be made, offered for sale, sold, and/or otherwise distributed in the United States, including in the State of Delaware, and/or will be imported into the United States, including the State of Delaware, by or through Zenara and its affiliates. Zenara will therefore directly infringe one or more claims of the '133 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

114. On information and belief, Zenara knows that healthcare professionals and/or patients will use Zenara's ANDA Products in accordance with the proposed prescribing information sought by Zenara's ANDA. On information and belief, the proposed prescribing information and product insert accompanying Zenara's ANDA Products will include instructions that are substantially similar to the instructions found in the prescribing information for XCOPRI®, attached as Exhibit A, and which, if followed, will instruct modifying the therapeutically effective dose of phenytoin or phenobarbital when co-administered with XCOPRI® to adjust the AUC and will infringe one or more claims of the '133 Patent. Zenara will therefore contribute to and/or induce infringement of one or more claims of the '133 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

115. On information and belief, Zenara's infringing activities, including the commercial manufacture, use, offer for sale, sale, and/or importation of Zenara's ANDA Products, will begin

immediately after the FDA approves Zenara's ANDA. Any such conduct before the '133 Patent expires will directly infringe, contribute to the infringement of, and/or induce infringement of one or more claims of the '133 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

116. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zenara concerning liability for the infringement of one or more claims of the '133 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

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

118. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) The entry of an Order, in favor of Plaintiffs and against Aurobindo, that Aurobindo's submission of its ANDA to FDA seeking approval for the commercial manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of Aurobindo's ANDA Products before the expiration of the '133 Patent was an act of infringement of one or more claims of the '133 Patent pursuant to 35 U.S.C. § 271(e)(2)(A);

(b) The entry of an Order, in favor of Plaintiffs and against Zenara, that Zenara's submission of Zenara's ANDA to FDA seeking approval for the commercial manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of Zenara's ANDA Products before the expiration of the Patents-in-Suit was an act of infringement of one or more claims of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e)(2)(A);

(c) A Judgment, in favor of Plaintiffs and against Aurobindo, declaring that Aurobindo's commercial manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of Aurobindo's ANDA Products, and/or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '133 Patent by Aurobindo under one or more of 35 U.S.C. § 271(a), (b), and (c);

(d) A Judgment, in favor of Plaintiffs and against Zenara, declaring that Zenara's commercial manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of Zenara's ANDA Products, and/or inducing or contributing to such conduct, would constitute infringement of one or more claims of the Patents-in-Suit by Zenara under one or more of 35 U.S.C. § 271(a), (b), and (c);

(e) The entry of a judgment declaring that the Patents-in-Suit remain valid and enforceable;

(f) The entry of an Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 219473 shall be a date that is not earlier than the last of the expiration date of the '133 Patent, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(g) The entry of an Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 219403 shall be a date that is not earlier than the last of the expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(h) The entry of a preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Aurobindo, its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons or

entities acting or attempting to act in concert, participation, and/or in privity with Aurobindo, and its successors or assigns, from commercially manufacturing, using, offering for sale, and/or selling in the United States, and/or importing into the United States any product that infringes the '133 Patent, including Aurobindo's ANDA Products, and/or inducing or contributing to such conduct, until the expiration date of the '133 Patent, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(i) The entry of a preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Zenara, its officers, directors, agents, servants, employees, parents, subsidiaries, affiliates, other related business entities, and all other persons or entities acting or attempting to act in concert, participation, and/or in privity with Zenara, and its successors or assigns, from commercially manufacturing, using, offering for sale, and/or selling in the United States, and/or importing into the United States any product that infringes the Patents-in-Suit, including Zenara's ANDA Products, and/or inducing or contributing to such conduct, until the last of the expiration dates of the Patents-in-Suit, including any extensions or regulatory exclusivities, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(j) A declaration under 28 U.S.C. § 2201 that if Aurobindo, its officers, directors, agents, servants, employees, representatives, attorneys, parents, subsidiaries, affiliates, other related business entities, and all other persons or entities acting or attempting to act in concert, participation, or in privity with Aurobindo, or acting on Aurobindo's behalf, engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of Aurobindo's ANDA Products, then this conduct will constitute an act of direct or indirect infringement of one or more claims of the '133 Patent;

(k) A declaration under 28 U.S.C. § 2201 that if Zenara, its officers, directors, agents, servants, employees, representatives, attorneys, parents, subsidiaries, affiliates, other related business entities, and all other persons or entities acting or attempting to act in concert, participation, or in privity with Zenara, or acting on Zenara's behalf, engage in the commercial manufacture, use, offer for sale, and/or sale in the United States, and/or importation into the United States, of Zenara's ANDA Products, then this conduct will constitute an act of direct or indirect infringement of one or more claims of the Patents-in-Suit;

(l) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Products, and/or any product that infringes the Patents-in-Suit, and/or induce or contribute to such conduct, prior to the expiration of such patents, including any extensions or regulatory exclusivities;

(m) The entry of judgment declaring that Aurobindo's acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(n) The entry of judgment declaring that Zenara's acts render this case an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(o) An award to Plaintiffs of their costs and expenses in this action; and

(p) Such other and further relief this Court deems just and proper.

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