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. _____
MSN PHARMACEUTICALS INC. AND MSN LABORATORIES PRIVATE 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 MSN Pharmaceuticals Inc. ("MSN Inc.") and MSN Laboratories Private Limited ("MSN Limited") (together, "MSN") 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 MSN's submission to the United States Food and Drug Administration (FDA) of Abbreviated New Drug Application (ANDA) No. 219436 ("MSN's ANDA"). Through MSN's ANDA, MSN seeks approval to market generic versions of XCOPRI® (cenobamate) 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg tablets ("MSN's ANDA Products") prior to the expiration of SKBP's United States Patent No. 11,654,133 ("the '133 Patent" or "the Patent-in-Suit"). 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.

MSN

5. On information and belief, Defendant MSN Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Rd., Piscataway, NJ, 08854.

6. On information and belief, Defendant MSN Limited is a private limited company organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India.

7. On information and belief, MSN Inc. and MSN Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On information and belief, MSN Inc. is a wholly owned subsidiary of MSN Limited. On information and belief, MSN Inc. and MSN Limited 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.

8. The notice of Paragraph IV certification dated October 7, 2024 concerning MSN's ANDA ("MSN's Notice Letter") was sent on behalf of both MSN Inc. and MSN Limited.

9. On information and belief, MSN Inc. in collaboration with MSN Limited prepared and submitted MSN's ANDA, and they continue to collaborate in seeking FDA approval of that application.

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

11. On information and belief, MSN Limited relies on material assistance from MSN Inc. 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, MSN Inc. and MSN Limited intend to act collaboratively to commercially manufacture, market, distribute, offer to sell, or sell MSN's ANDA Products in the event FDA approves MSN's ANDA.

JURISDICTION AND VENUE

12. 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 '133 Patent. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

13. This Court has personal jurisdiction over MSN Inc. because it is a corporation organized and existing under the laws of the State of Delaware.

14. This Court has personal jurisdiction over MSN Inc. and MSN Limited because, *inter alia*, on information and belief, each of MSN Inc. and MSN Limited 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 MSN's ANDA Products in the State of Delaware upon approval of MSN's ANDA.

15. On information and belief, MSN 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 MSN's ANDA Products, and the preparation and filing of MSN'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 MSN's ANDA Products throughout the United States, including within the State of Delaware, and stands to benefit from the approval of MSN's ANDA.

16. On information and belief, following FDA approval of MSN's ANDA, MSN Limited intends to market, offer to sell, sell, or distribute MSN'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 MSN's ANDA, MSN knows and intends that MSN's ANDA Products will be marketed, used, distributed, offered for sale, or sold in the United States and within the State of Delaware.

17. Each of MSN Inc. and MSN Limited 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. 9 at 3–4, *Vanda Pharm. Inc. v. MSN Phams. Inc. et al.*, C.A. No. 24-

815-JLH (D. Del. September 13, 2024); D.I. 23 at 8–11, *Pfizer Inc. et al. v. MSN Labs. Private Ltd. et al.*, C.A. No. 24-315-JPM (D. Del. September 4, 2024); D.I. 13 at 6–9, *Pfizer Inc. et al. v. MSN Labs. Private Ltd. et al.*, C.A. No. 24-624-CFC (D. Del. July 23, 2024). MSN has also purposefully availed itself of the rights, benefits, and privileges of the State of Delaware by asserting counterclaims in this Court.

18. This Court also has personal jurisdiction over MSN Limited at least because, *inter alia*, (a) MSN Limited has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products in the United States, including in the State of Delaware; (b) MSN 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 MSN's ANDA Products in the United States, including in the State of Delaware and to residents of this Judicial District, upon approval of MSN's ANDA, and will derive substantial revenue from the use or consumption of MSN's ANDA Products in the State of Delaware; and (c) MSN 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 MSN's ANDA is approved, MSN'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.

19. In the alternative, this Court has personal jurisdiction over MSN Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law,

(b) MSN Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state, and (c) MSN 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 MSN Limited satisfies due process.

20. At least because, on information and belief, MSN Limited is a foreign corporation and MSN Inc. 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. §§ 1391(c)(3) and 1400(b).

SKBP PATENTS AND APPROVED XCOPRI® DRUG PRODUCTS

21. 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.

22. The active ingredient in XCOPRI® is cenobamate.

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

24. 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.

25. 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.

26. XCOPRI® and its approved uses are covered by claims of the '133 Patent.

27. The ’133 Patent is listed in FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) in connection with NDA No. 212839.

28. SK Biopharmaceuticals Co., Ltd., as the assignee, owns the entire right, title, and interest in the ’133 Patent. SK Biopharmaceuticals Co., Ltd. has the right to enforce the ’133 Patent. SK Life Science, Inc. is the exclusive licensee of the ’133 Patent.

29. 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 B.

30. 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.

31. 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, which would include co-administration with phenytoin or phenobarbital. Ex. A at 2.

32. 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).

33. 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.

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

35. 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.

36. Section 12.3 of the XCOPRI® Prescribing Information provides that "[m]ultiple doses of concomitant XCOPRI 200 mg once daily increased phenytoin mean C_{max} and AUC by 70% and 84%, respectively, and phenobarbital mean C_{max} 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 18.

37. 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®.

38. 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®.

MSN'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

39. On information and belief, MSN has submitted or caused to be submitted ANDA No. 219436 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.

40. On information and belief, MSN'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.

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

42. MSN's Notice Letter represents that MSN had submitted to FDA MSN'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 MSN's ANDA before the expiration of the '133 Patent listed in the Orange Book for XCOPRI®. Hence, through its ANDA, MSN seeks to commercially manufacture, use, offer for sale, sell, or import into the United States MSN's ANDA Products before the expiration of the '133 Patent.

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

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

45. In MSN's Notice Letter, MSN purported to offer confidential access to portions of ANDA No. 219436 on terms and conditions set forth in the Notice Letter ("MSN Offer"). The MSN Offer, however, contained unreasonable restrictions well beyond those that would apply under a protective order. The restrictions MSN placed on access to ANDA No. 219436 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." On October 21, 2024, outside counsel for Plaintiffs contacted counsel for MSN in an effort to negotiate reasonable terms of

confidential access to MSN's ANDA. Plaintiffs' correspondence included proposed modifications to the MSN Offer that are consistent with protective orders entered in recent litigation involving similar subject matter in this Judicial District, and consistent with the purpose of 21 U.S.C. § 355(j)(5)(C)(i)(III). On October 22, 2024, MSN's counsel responded that MSN was considering Plaintiffs' proposed revisions to the MSN Offer and would respond in the next few days. Having received no response for over two weeks, on November 7, 2024, Plaintiffs contacted counsel for MSN again. On November 8, 2024, MSN's counsel responded with edits to Plaintiffs' revision to the MSN Offer, including imposing additional unreasonable restrictions. On November 14, 2024, Plaintiffs asked MSN's counsel to reconsider Plaintiffs' proposed edits to the MSN Offer. To date, MSN has not responded further nor provided Plaintiffs access to its ANDA.

46. Plaintiffs bring this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of MSN's Notice Letter. *See* 21 U.S.C. § 355(c)(3)(C).

COUNT 1
INFRINGEMENT OF THE '133 PATENT BY MSN

47. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–46 as if fully set forth herein.

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

49. On information and belief, MSN has infringed at least claim 1 of the '133 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting MSN's ANDA with a Paragraph IV certification and seeking FDA approval of MSN'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. 219436 be a date which is not earlier than the expiration date of the '133 Patent.

50. 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.

51. MSN’s commercial manufacture, use in accordance with MSN’s proposed prescribing information, offer for sale, and/or sale within the United States, and/or importation into the United States of MSN’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 MSN’s ANDA, MSN will make, use, offer for sale, or sell MSN’s ANDA Products within the United States, or will import MSN’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.*

52. On information and belief, upon FDA approval of MSN’s ANDA, MSN, 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 MSN’s ANDA Products to resellers, pharmacies, hospitals and other clinics, healthcare professionals, and end users of MSN’s ANDA Products. On

information and belief, MSN will also knowingly and intentionally accompany MSN's ANDA Products with proposed prescribing information and product insert that will include instructions for using or administering MSN's ANDA Products. On information and belief, the proposed prescribing information and product insert accompanying MSN'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, MSN will induce physicians and other healthcare professionals, resellers, pharmacies, and end users of MSN's ANDA Products to directly infringe one or more claims of the '133 Patent. In addition, on information and belief, MSN will encourage acts of direct infringement with knowledge of the '133 Patent and knowledge that it is encouraging infringement.

53. MSN had actual and constructive notice of the '133 Patent prior to filing MSN's ANDA and was aware that the filing of MSN'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, MSN had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products would not contribute to and/or induce infringement of one or more claims of the '133 Patent.

54. On information and belief, MSN filed MSN'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 MSN's ANDA

Products. MSN'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.

55. Plaintiffs will be irreparably harmed if MSN 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 MSN, 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 MSN

56. Plaintiffs state, reallege, and incorporate by reference paragraphs 1–55 as if fully set forth herein.

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

58. 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.

59. On information and belief, if MSN's ANDA is approved, MSN'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 MSN and its affiliates. MSN 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).

60. On information and belief, MSN knows that healthcare professionals and/or patients will use MSN's ANDA Products in accordance with the proposed prescribing information

sought by MSN's ANDA. On information and belief, the proposed prescribing information and product insert accompanying MSN'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. MSN 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).

61. On information and belief, MSN's infringing activities, including the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Products, will begin immediately after the FDA approves MSN'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).

62. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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.

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

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

(c) 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. 219436 shall be a date that is not earlier than 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;

(d) The entry of a preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining MSN, 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 MSN, 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 MSN'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;

(e) A declaration under 28 U.S.C. § 2201 that if MSN, 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 MSN, or acting on MSN’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 MSN’s ANDA Products, then this conduct will constitute an act of direct or indirect infringement of one or more claims of the ’133 Patent;

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if MSN engages in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN’s ANDA Products, and/or any product that infringes the ’133 Patent, and/or induce or contribute to such conduct, prior to the expiration of such patents, including any extensions or regulatory exclusivities;

(g) The entry of judgment declaring that MSN’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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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