

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ADVERIO PHARMA GMBH, BAYER)
AG, MSD PHARMA GMBH, and)
MERCK SHARP & DOHME LLC,)
Plaintiffs,)
)
v.)
) C.A. No. 25-479-GBW
)
CHANGZHOU PHARMACEUTICAL)
FACTORY, TEVA)
PHARMACEUTICALS, INC.,)
TORRENT PHARMACEUTICALS)
LTD., TORRENT PHARMA INC., MSN)
LABORATORIES PRIVATE LIMITED,)
MSN PHARMACEUTICALS, INC.,)
ANNORA PHARMA PRIVATE)
LIMITED, and HETERO USA INC.,)
)
Defendants.)
)

ANSWER AND COUNTERCLAIMS

Defendants MSN Laboratories Private Limited (“MSN Laboratories”) and MSN Pharmaceuticals Inc. (“MSN Pharmaceuticals”) (collectively, “MSN” or “Defendants”) hereby answer the Complaint of Plaintiffs Adverio Pharma GmbH (“Adverio”), Bayer AG (“Bayer”), MSN Pharma GmbH (“MSD Pharma”) and Merck Sharp & Dohme LLC (“Merck LLC”) (collectively “Plaintiffs”), as follows:

NATURE OF THE ACTION¹

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by various defendants of Abbreviated New

¹ For ease of reference, MSN includes the headings contained in Plaintiffs’ Complaint. Although MSN believes that no response is necessary for each of Plaintiff’s headings, to the extent a response is required and that the headings could be construed to contain factual allegations, MSN denies the allegations.

Drug Applications (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs’ VERQUVO® products prior to the expiration of one or more of U.S. Patent Nos. 8,420,656 (“the ’656 patent”), 8,921,377 (“the ’377 patent”), 9,604,948 (“the ’948 patent”), 9,993,476 (“the ’476 patent”), 10,736,896 (“the ’896 patent”), and 11,439,642 (“the ’642 patent”) (collectively, the “Asserted Patents”).

ANSWER: Paragraph 1 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that Plaintiffs purport to state a claim for patent infringement of U.S. Patent Nos. 8,420,656 (“the ’656 patent”), 8,921,377 (“the ’377 patent”), 9,604,948 (“the ’948 patent”), 9,993,476 (“the ’476 patent”), 10,736,896 (“the ’896 patent”), and 11,439,642 (“the ’642 patent”) (collectively, the “Asserted Patents”), and that those claims purportedly arise under the patent laws of the United States. MSN admits that MSN Laboratories filed Abbreviated New Drug Application No. 220354 with the United States Food and Drug Administration (“FDA”) for approval to market vericiguat Tablets 2.5 mg, 5 mg and 10 mg vericiguat tablets (“MSN’s ANDA Products”). Otherwise denied.

PARTIES

Plaintiffs

2. Plaintiff Adverio is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, D-51373 Leverkusen, Germany. Adverio is the assignee of each of the Asserted Patents.

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

3. Plaintiff Bayer is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51373 Leverkusen.

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

4. Plaintiff MSD Pharma GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Levelingstr. 4a 81673, München, Bayern Germany. MSD Pharma is an exclusive licensee under each of the Asserted Patents.

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

5. Plaintiff Merck LLC is a limited liability company organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at 126 E. Lincoln Avenue, Rahway, NJ 07065. Merck LLC is the holder of New Drug Application (“NDA”) No. 214377 for VERQUVO® (vericiguat), which has been approved by the FDA.

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Changzhou

6. Upon information and belief, Changzhou Pharmaceutical Factory (“Changzhou”) is a corporation organized and existing under the laws of China, having a principal place of business at No. 518 Laodong East Road Changzhou, Jiangsu, 213018 China.

ANSWER: Paragraph 6 contains allegations regarding Changzhou and therefore no response is required from MSN. To the extent a response is required, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

7. Upon information and belief, Changzhou is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, upon information and belief, Changzhou files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as part of these ANDAs, Changzhou files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“Paragraph IV Certifications”) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Paragraph 7 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

8. Upon information and belief, Changzhou prepared and submitted ANDA No. 220264 for Changzhou’s 2.5 mg, 5 mg, and 10 mg vericiguat tablets (“Changzhou’s ANDA Products”).

ANSWER: Paragraph 8 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

9. Upon information and belief, following any FDA approval of ANDA No. 220264, Changzhou will market, distribute, offer for sale, and sell Changzhou's ANDA Products throughout the United States, including within Delaware.

ANSWER: Paragraph 9 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

10. Upon information and belief, following any FDA approval of ANDA No. 220264, Changzhou knows and intends that Changzhou's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States, including in Delaware.

ANSWER: Paragraph 10 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Teva

11. On information and belief, Teva Pharmaceuticals, Inc. ("Teva Inc.") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, #3, Parsippany, New Jersey 07054. On information and belief, Teva Pharmaceuticals, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd.").

ANSWER: Paragraph 11 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

12. On information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 124 Dvora HaNevi'a St. Tel Aviv 6944020, Israel.

ANSWER: Paragraph 12 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

13. On information and belief, Teva Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Teva Inc., acting in concert with Teva Ltd., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Teva Inc., acting in concert with Teva Ltd., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Paragraph 13 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

14. On information and belief, Teva Inc. and Teva Ltd. acted in concert to prepare and submit ANDA No. 220286 for Teva Inc.'s 2 mg, 5 mg, and 2.5 mg vericiguat tablets ("Teva's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Teva Ltd.

ANSWER: Paragraph 14 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

15. On information and belief, Teva Inc. and Teva Ltd. 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, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect Teva's ANDA Products at issue.

ANSWER: Paragraph 15 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

16. On information and belief, following any FDA approval of ANDA No. 220286, Teva Inc. and Teva Ltd. will act in concert to market, distribute, offer for sale, and sell Teva's ANDA Products throughout the United States and within Delaware. These three entities are hereafter collectively referred to as "Teva."

ANSWER: Paragraph 16 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

17. On information and belief, following any FDA approval of ANDA No. 220286, Teva knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: Paragraph 17 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Torrent

18. On information and belief, Defendant Torrent Pharmaceuticals, Limited is a corporation organized and existing under the laws of India, with a place of business at Torrent House, Off Ashram Road, Ahmedabad – 380 009, Gujarat, India.

ANSWER: Paragraph 18 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

19. On information and belief, Defendant Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey.

ANSWER: Paragraph 19 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

20. On information and belief, Defendant Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals, Limited, and is controlled and dominated by Torrent Pharmaceuticals, Limited.

ANSWER: Paragraph 20 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

21. On information and belief, Torrent Pharmaceuticals, Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Torrent Pharmaceuticals, Limited, acting in concert with Torrent Pharma Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Torrent Pharmaceuticals, Limited, acting in concert with Torrent Pharma Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Paragraph 21 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

22. On information and belief, and consistent with their practice with respect to other generic products, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. acted in concert to prepare and submit ANDA No. 220221 for Torrent Pharmaceuticals, Limited's 2.5 mg vericiguat tablets ("Torrent's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Torrent Pharmaceuticals, Limited.

ANSWER: Paragraph 22 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

23. On information and belief, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. 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, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Torrent's ANDA Product at issue.

ANSWER: Paragraph 23 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

24. On information and belief, following any FDA approval of ANDA No. 220221, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. will act in concert to market, distribute, offer for sale, and sell Torrent's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Torrent."

ANSWER: Paragraph 24 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

25. On information and belief, following any FDA approval of ANDA No. 220221, Torrent knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: Paragraph 25 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

MSN

26. On information and belief, defendant MSN Laboratories Private Ltd. is a corporation organized and existing under the laws of India, 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.

ANSWER: MSN admits that MSN Laboratories Private Ltd. 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, Sanath Nagar, Hyderabad 500018, India.

27. On information and belief, defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 20 Duke Rd, Piscataway, NJ 08854-3714.

ANSWER: MSN admits that MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware. MSN admits that its principal place of business is 20 Duke Road, Piscataway, New Jersey 08854.

28. On information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Private Ltd.

ANSWER: MSN admits that MSN Pharmaceuticals Inc. is a wholly-owned subsidiary of MSN Laboratories Private Ltd.

29. On information and belief, MSN Laboratories Private Ltd is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, MSN Laboratories Private Ltd, acting in concert with MSN Pharmaceuticals Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, MSN Laboratories Private Ltd., acting in concert with MSN Pharmaceuticals Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: MSN admits that MSN Laboratories Private Ltd. develops and manufactures generic pharmaceutical products which are then sold in the United States. The remaining allegations of Paragraph 29 contain legal conclusions and allegations to which no answer is required. To the extent a response is required, MSN admits that MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. prepared and submitted ANDA No. 220354 to the FDA. Otherwise denied.

30. On information and belief, and consistent with their practice with respect to other generic products, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. acted in concert to prepare and submit ANDA No. 220354 for MSN Laboratories Private Ltd.'s 2.5 mg, 5 mg, and 10 mg vericiguat tablets ("MSN's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of MSN Laboratories Private Ltd.

ANSWER: MSN admits that MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. prepared and submitted ANDA No. 220354 for MSN Laboratories Private Ltd.'s 2.5 mg, 5 mg, and 10 mg vericiguat tablets ("MSN's ANDA Products") to the FDA. The remaining allegations of Paragraph 30 contain legal conclusions and allegations to which no answer is required. To the extent a response is required, denied.

31. On information and belief, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. 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, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of

generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing MSN's ANDA Products at issue.

ANSWER: MSN admits MSN Pharmaceuticals Inc. is the U.S. agent of record for MSN Laboratories Private Ltd. The remaining allegations of Paragraph 31 contain legal conclusions and allegations to which no answer is required. To the extent a response is required, denied.

32. On information and belief, following any FDA approval of ANDA No. 220354, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. will act in concert to market, distribute, offer for sale, and sell MSN's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "MSN."

ANSWER: The allegations in Paragraph 32 relate to future conduct which has not yet occurred. To the extent a response is required, denied.

33. On information and belief, following any FDA approval of ANDA No. 220354, MSN knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: The allegations in Paragraph 33 relate to future conduct which has not yet occurred. To the extent a response is required, denied.

Annora

34. On information and belief, Annora Pharma Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidal Mandal, Sangareddy District, Telangana State, 502313, India.

ANSWER: Paragraph 34 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

35. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

ANSWER: Paragraph 35 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

36. On information and belief, Somaraju Indukuri, Ph.D., is the agent for service of process in the United States for Annora Pharma Private Limited. On information and belief, Somaraju Indukuri acts at the direction of, under the control of, and/or for the benefit of Annora Pharma Private Limited and is controlled by Annora Pharma Private Limited. On information and belief, Somaraju Indukuri holds title as Vice President, Regulatory Affairs, U.S. Agent, at Hetero USA Inc.

ANSWER: Paragraph 36 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

37. On information and belief, Annora Pharma Private Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Annora Pharma Private Limited, acting in concert with Hetero USA Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Annora Pharma Private Limited, acting in concert with Hetero USA Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Paragraph 37 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

38. On information and belief, and consistent with their practice with respect to other generic products, Annora Pharma Private Limited and Hetero USA Inc. acted in concert to prepare and submit ANDA No. 220244 for Annora Pharma Private Limited's 2.5 mg, 5 mg, and 10 mg vericiguat tablets ("Annora's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Annora Pharma Private Limited.

ANSWER: Paragraph 38 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

39. On information and belief, Annora Pharma Private Limited and Hetero USA Inc. 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, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic

pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Annora's ANDA Products at issue.

ANSWER: Paragraph 39 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

40. On information and belief, following any FDA approval of ANDA No. 220244, Annora Pharma Private Limited and Hetero USA Inc. will act in concert to market, distribute, offer for sale, and sell Annora's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Annora."

ANSWER: Paragraph 40 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

41. On information and belief, following any FDA approval of ANDA No. 220244, Annora knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: Paragraph 41 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

JURISDICTION AND VENUE

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

43. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, MSN admits that, to the extent

Plaintiffs have standing to assert claims of infringement of the patents-in-suit, the Court has subject matter jurisdiction. Otherwise denied.

44. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over each of the defendants.

ANSWER: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, MSN does not contest personal jurisdiction. Further, the remaining allegations in Paragraph 44 contains allegations regarding the other defendants and therefore no response is required from MSN. To the extent a response is required, MSN lacks knowledge or information sufficient to form a belief as to the Court's personal jurisdiction over the remaining defendants and therefore denies them.

Changzhou

45. This Court has personal jurisdiction over Changzhou because, among other things, on information and belief: (1) Changzhou has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Changzhou's ANDA Products in the United States, including in Delaware; and (2) Changzhou will market, distribute, offer for sale, and/or sell Changzhou's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 220264, and will derive substantial revenue from the use or consumption of Changzhou's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 220264 is approved, the generic Changzhou products charged with infringing the Asserted Patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: Paragraph 45 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

46. Changzhou has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

ANSWER: Paragraph 46 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

47. Alternatively, if Changzhou's connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Changzhou is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Changzhou Pharmaceuticals, Limited in Delaware is consistent with the United States Constitution and laws. *See Fed. R. Civ. P. 4(k)(2).*

ANSWER: Paragraph 47 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

48. On information and belief, venue is proper in this district as to Changzhou because it is a Chinese corporation "not resident in the United States" that accordingly "may be sued in any judicial district" for venue purposes. 28 U.S.C. § 1391(c)(3); *see also In re HTC Corp.*, 889 F.3d 1349, 1355-56 (Fed. Cir. 2018) (reaffirming the "long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special" (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

ANSWER: Paragraph 48 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Teva

49. This Court has personal jurisdiction over Teva Inc. because, among other things, Teva Inc. is a corporation formed under the laws of the State of Delaware.

ANSWER: Paragraph 49 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

50. This Court has personal jurisdiction over Teva Inc. and Teva Ltd. because, among other things, on information and belief: (1) Teva Inc., acting in concert with Teva Ltd. has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products in the United States, including in Delaware; and (2) Teva Inc., acting in concert with Teva Ltd., acting in concert and/or as agents

of one another, will market, distribute, offer for sale, and/or sell Teva's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 220286, and will derive substantial revenue from the use or consumption of Teva's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 220286 is approved, the generic Teva products charged with infringing the Asserted Patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: Paragraph 50 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

51. Teva Ltd. and Teva Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

ANSWER: Paragraph 51 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

52. Alternatively, if Teva Ltd.'s connections with Delaware, including its connections with Teva Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Teva Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Teva Ltd. in Delaware is consistent with the United States Constitution and laws. *See Fed. R. Civ. P. 4(k)(2).*

ANSWER: Paragraph 52 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

53. On information and belief, venue is proper in this district as to Teva Inc. because, on information and belief, it is incorporated in Delaware, and thus the District of Delaware is the judicial district "where the defendant resides." 28 U.S.C. § 1400(b); see also *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation").

ANSWER: Paragraph 53 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

54. On information and belief, venue is proper in this district as to Teva Ltd. under 28 U.S.C. § 1391 because it is an Indian corporation “not resident in the United States” that accordingly “may be sued in any judicial district” for venue purposes. 28 U.S.C. § 1391(c)(3); *see also In re HTC Corp.*, 889 F.3d 1349, 1355-56 (Fed. Cir. 2018) (reaffirming the “long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special” (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

ANSWER: Paragraph 54 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

Torrent

55. This Court has personal jurisdiction over Torrent Pharma Inc. because, among other things, Torrent Pharma Inc. is a corporation formed under the laws of the State of Delaware.

ANSWER: Paragraph 55 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

56. This Court has personal jurisdiction over Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. because, among other things, on information and belief: (1) Torrent Pharmaceuticals, Limited, acting in concert with Torrent Pharma Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Torrent’s ANDA Product in the United States, including in Delaware; and (2) Torrent Pharmaceuticals, Limited and Torrent Pharma Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Torrent’s ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 220221, and will derive substantial revenue from the use or consumption of Torrent’s ANDA Product in the State of Delaware. On information and belief, if ANDA No. 220221 is approved, the generic Torrent product charged with infringing the Asserted Patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: Paragraph 56 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

57. Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

ANSWER: Paragraph 57 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

58. Alternatively, if Torrent Pharmaceuticals, Limited's connections with Delaware, including its connections with Torrent Pharma Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Torrent Pharmaceuticals, Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Torrent Pharmaceuticals, Limited in Delaware is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

ANSWER: Paragraph 58 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

59. On information and belief, venue is proper in this district as to Torrent Pharma Inc. because, on information and belief, it is incorporated in Delaware, and thus the District of Delaware is the judicial district "where the defendant resides." 28 U.S.C. § 1400(b); see also TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation").

ANSWER: Paragraph 59 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

60. On information and belief, venue is proper in this district as to Torrent Pharmaceuticals, Limited under 28 U.S.C. § 1391 because it is an Indian corporation "not resident in the United States" that accordingly "may be sued in any judicial district" for venue purposes. 28 U.S.C. § 1391(c)(3); see also In re HTC Corp., 889 F.3d 1349, 1355-56 (Fed. Cir. 2018) (reaffirming the "long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special" (quoting Brunette Mach. Works, Ltd. v. Kockum Indus., Inc., 406 U.S. 706, 714 (1972))).

ANSWER: Paragraph 60 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

MSN

61. This Court has personal jurisdiction over MSN Pharmaceuticals Inc. because, among other things, MSN Pharmaceuticals Inc. is a corporation formed under the laws of the State of Delaware.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN Pharmaceuticals does not contest personal jurisdiction in this judicial district, for the purposes of this action only. MSN admits that MSN Pharmaceuticals is organized under the laws of the State of Delaware. Otherwise denied.

62. This court has personal jurisdiction over MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. because, among other things, on information and belief: (1) MSN Laboratories Private Limited, acting in concert with MSN Pharmaceuticals Inc., has filed an ANDA for the purpose of 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 Delaware; and (2) MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell MSN's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 220354, and will derive substantial revenue from the use or consumption of MSN's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 220354 is approved, the generic MSN products charged with infringing the Asserted Patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN Laboratories does not contest personal jurisdiction in this judicial district, for the purposes of this action only. To the extent a response is required, MSN admits that MSN Laboratories and MSN Pharmaceuticals prepared and submitted ANDA No. 220354 to the FDA. Otherwise denied.

63. MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN Laboratories and MSN Pharmaceuticals do not contest personal jurisdiction in this judicial district, for the purposes of this action only. Otherwise denied.

64. Alternatively, if MSN Laboratories Private Limited's connections with Delaware, including its connections with MSN Pharmaceuticals Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, MSN Laboratories Private Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over MSN Laboratories Private Limited in Delaware is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN Laboratories does not contest personal jurisdiction in this judicial district, for the purposes of this action only. Otherwise denied.

65. On information and belief, venue is proper in this district as to MSN Pharmaceuticals Inc. because, on information and belief, it is incorporated in Delaware, and thus the District of Delaware is the judicial district "where the defendant resides." 28 U.S.C. § 1400(b); see also *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1521 (2017) ("[a]s applied to domestic corporations, 'reside[nce]' in § 1400(b) refers only to the State of incorporation").

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN does not contest that venue is proper in this district as to MSN Pharmaceuticals, for purposes of this action only.

66. On information and belief, venue is proper in this district as to MSN Laboratories Private Ltd. under 28 U.S.C. § 1391 because it is an Indian corporation "not resident in the United States" that accordingly "may be sued in any judicial district" for venue purposes. 28 U.S.C. § 1391(c)(3); see also *In re HTC Corp.*, 889 F.3d 1349, 1355-56 (Fed. Cir. 2018) (reaffirming the "long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special" (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN does not contest that venue is proper in this district as to MSN Laboratories, for purposes of this action only.

Annora

67. This Court has personal jurisdiction over Hetero Inc. because, among other things, Hetero Inc. is a corporation formed under the laws of the State of Delaware.

ANSWER: Paragraph 67 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

68. This court has personal jurisdiction over Annora Pharma Private Limited and Hetero Inc. because, among other things, on information and belief: (1) Annora Pharma Private Limited, acting in concert with Hetero Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Annora's ANDA Products in the United States, including in Delaware; and (2) Annora Pharma Private Limited and Hetero, Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Annora's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 220244, and will derive substantial revenue from the use or consumption of Annora's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 220244 is approved, the generic Annora products charged with infringing the Asserted Patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: Paragraph 68 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

69. Annora Pharma Private Limited and Hetero Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

ANSWER: Paragraph 69 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

70. Alternatively, if Annora Pharma Private Limited’s connections with Delaware, including its connections with Hetero Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Annora Pharma Private Limited is not subject to jurisdiction in any state’s courts of general jurisdiction, and exercising jurisdiction over Annora Pharma Private Limited in Delaware is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

ANSWER: Paragraph 70 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

71. On information and belief, venue is proper in the District of Delaware for Annora Pharma Private Limited because it is an Indian corporation “not resident in the United States” that accordingly “may be sued in any judicial district” for venue purposes. 28 U.S.C. § 1391(c)(3); see also *In re HTC Corp.*, 889 F.3d 1349, 1355-56 (Fed. Cir. 2018) (reaffirming the “long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special” (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

ANSWER: Paragraph 71 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

72. On information and belief, venue is proper in the District of Delaware for Hetero Inc. because it is incorporated in Delaware, and thus the District of Delaware is the judicial district “where the defendant resides.” 28 U.S.C. § 1400(b); see also *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1521 (2017) (“[a]s applied to domestic corporations, ‘reside[nce]’ in § 1400(b) refers only to the State of incorporation”).

ANSWER: Paragraph 72 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

FACTUAL BACKGROUND

73. VERQUVO® (active ingredient vericiguat) is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%. VERQUVO® is available as tablets in 2.5 mg, 10 mg, and 15 mg dosage strengths.

ANSWER: MSN admits that VERQUVO® (active ingredient vericiguat) is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%. MSN admits that VERQUVO® is available as tablets in 2.5 mg, 10 mg, and 15 mg dosage strengths.

The '656 Patent

74. The '656 patent, entitled “Substituted 5-fluoro-1H-pyrazolopyridines and their use,” was duly and legally issued on April 16, 2013. The '656 patent is attached as Exhibit A.

ANSWER: MSN admits that the '656 patent is titled “Substituted 5-fluoro-1H-pyrazolopyridines and their use,” and states on its face an issue date of April 16, 2013. MSN admits that Exhibit A appears to be a true and correct copy of the '656 patent. Otherwise denied.

75. As set forth in greater detail in the '656 patent, the claims of the '656 patent, incorporated by reference herein, cover, inter alia, vericiguat.

ANSWER: The '656 patent speaks for itself and is the best source for its content. Otherwise denied.

76. Pursuant to 21 U.S.C. § 355, the '656 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with VERQUVO®.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that VERQUVO® is listed in the Orange Book, and that the '656 patent is listed in the Orange Book in connection with VERQUVO®. Otherwise denied.

The '377 Patent

77. The '377 patent, entitled “Substituted 5-fluoro-1H-pyrazolopyridines and their use”, was duly and legally issued on December 30, 2014. The '377 patent is attached as Exhibit B.

ANSWER: MSN admits that the '377 patent is titled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," and states on its face an issue date of December 30, 2014. MSN admits that Exhibit B appears to be a true and correct copy of the '377 patent. Otherwise denied.

78. As set forth in greater detail in the '377 patent, the claims of the '377 patent, incorporated by reference herein, cover, inter alia, methods of treatment of heart failure by administration of an effective amount of vericiguat or a pharmaceutical composition comprising vericiguat.

ANSWER: The '377 patent speaks for itself and is the best source for its content. Otherwise denied.

79. Pursuant to 21 U.S.C. § 355, the '377 patent is listed in the Orange Book in connection with VERQUVO®.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that VERQUVO® is listed in the Orange Book, and that the '377 patent is listed in the Orange Book in connection with VERQUVO®. Otherwise denied.

The '948 Patent

80. The '948 patent, entitled "Process for preparing substituted 5-fluoro-1H-pyrazolopyridines," was duly and legally issued on March 28, 2017. The '948 patent is attached as Exhibit C.

ANSWER: MSN admits that the '948 patent is titled "Process for preparing substituted 5-fluoro-1Hpyrazolopyridines," and states on its face an issue date of March 28, 2017. MSN admits that Exhibit C appears to be a true and correct copy of the '948 patent. Otherwise denied.

81. As set forth in greater detail in the '948 patent, the claims of the '948 patent, incorporated by reference herein, cover, inter alia, vericiguat in crystalline form of polymorph I.

ANSWER: The '948 patent speaks for itself and is the best source for its content. Otherwise denied.

82. Pursuant to 21 U.S.C. § 355, the '948 patent is listed in the Orange Book in connection with VERQUVO®.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that VERQUVO® is listed in the Orange Book, and that the '948 patent is listed in the Orange Book in connection with VERQUVO®. Otherwise denied.

The '476 Patent

83. The '476 patent, entitled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," was duly and legally issued on June 12, 2018. The '476 patent is attached as Exhibit D.

ANSWER: MSN admits that the '476 patent is titled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," and states on its face an issue date of June 12, 2018. MSN admits that Exhibit D appears to be a true and correct copy of the '476 patent. Otherwise denied.

84. As set forth in greater detail in the '476 patent, the claims of the '476 patent, incorporated by reference herein, cover, inter alia, methods of treating or preventing one or more of coronary heart disease, systolic or diastolic heart failure, angina pectoris, ischaemias, peripheral and cardiac vascular disorders, kidney failure, renal insufficiency, and increased microalbuminuria, comprising administering a therapeutically effective amount of vericiguat.

ANSWER: The '476 patent speaks for itself and is the best source for its content. Otherwise denied.

85. Pursuant to 21 U.S.C. § 355, the '476 patent is listed in the Orange Book in connection with VERQUVO®.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that VERQUVO® is listed in the Orange Book, and that the '476 patent is listed in the Orange Book in connection with VERQUVO®. Otherwise denied.

The '896 Patent

86. The '896 patent, entitled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," was duly and legally issued on August 11, 2020. The '896 patent is attached as Exhibit E.

ANSWER: MSN admits that the '896 patent is titled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," and states on its face an issue date of August 11, 2020. MSN admits that Exhibit E appears to be a true and correct copy of the '896 patent. Otherwise denied.

87. As set forth in greater detail in the '896 patent, the claims of the '896 patent, incorporated by reference herein, cover, inter alia, vericiguat and pharmaceutical formulations of vericiguat.

ANSWER: The '896 patent speaks for itself and is the best source for its content. Otherwise denied.

88. Pursuant to 21 U.S.C. § 355, the '896 patent is listed in the Orange Book in connection with VERQUVO®.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that VERQUVO® is listed in the Orange Book, and that the '896 patent is listed in the Orange Book in connection with VERQUVO®. Otherwise denied.

The '642 Patent

89. The '642 patent, entitled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," was duly and legally issued on September 13, 2022. The '642 patent is attached as Exhibit F.

ANSWER: MSN admits that the '642 patent is titled "Substituted 5-fluoro-1H-pyrazolopyridines and their use," and states on its face an issue date of September 13, 2022. MSN admits that Exhibit F appears to be a true and correct copy of the '642 patent. Otherwise denied.

90. As set forth in greater detail in the '642 patent, the claims of the '642 patent, incorporated by reference herein, cover, inter alia, methods of treating or preventing one or more of coronary heart disease, systolic or diastolic heart failure, angina pectoris, ischaemias, peripheral and cardiac vascular disorders, kidney failure, renal insufficiency, and increased microalbuminuria by administering a therapeutically effective amount of vericiguat.

ANSWER: The '642 patent speaks for itself and is the best source for its content. Otherwise denied.

91. Pursuant to 21 U.S.C. § 355, the '642 patent is listed in the Orange Book in connection with VERQUVO®.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that VERQUVO® is listed in the Orange Book, and that the '642 patent is listed in the Orange Book in connection with VERQUVO®. Otherwise denied.

[Alleged] Infringement by Changzhou

92. By letter dated March 17, 2025 (the “Changzhou Notice Letter”), Changzhou notified Plaintiffs that Changzhou had submitted to the FDA ANDA No. 220264 for Changzhou’s ANDA Products. These products are generic versions of VERQUVO®.

ANSWER: Paragraph 92 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

93. In the Changzhou Notice Letter, Changzhou stated that Changzhou’s ANDA Products contain vericiguat, which is a compound of the following formula:

ANSWER: Paragraph 93 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

94. In the Changzhou Notice Letter, Changzhou stated that the dosage form for Changzhou’s ANDA Products is an oral tablet.

ANSWER: Paragraph 94 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

95. On information and belief, the proposed labeling for Changzhou’s ANDA Products directs the use of Changzhou’s ANDA Products to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

ANSWER: Paragraph 95 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

96. On information and belief, the vericiguat in Changzhou's ANDA Products is in crystalline form of Polymorph I. In Changzhou's Notice Letter, Changzhou did not set forth any theory of noninfringement with respect to any claim of the '948 patent.

ANSWER: Paragraph 96 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

97. On information and belief, the manufacture, use (including in accordance with and as directed by Changzhou's proposed labeling for Changzhou's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 7 of the '656 patent.

ANSWER: Paragraph 97 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

98. On information and belief, the manufacture, use (including in accordance with and as directed by Changzhou's proposed labeling for Changzhou's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 8 of the '377 patent.

ANSWER: Paragraph 98 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

99. On information and belief, the manufacture, use (including in accordance with and as directed by Changzhou's proposed labeling for Changzhou's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '948 patent.

ANSWER: Paragraph 99 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

100. On information and belief, the manufacture, use (including in accordance with and as directed by Changzhou's proposed labeling for Changzhou's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '476 patent.

ANSWER: Paragraph 100 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

101. On information and belief, the manufacture, use (including in accordance with and as directed by Changzhou's proposed labeling for Changzhou's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '896 patent.

ANSWER: Paragraph 101 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

102. On information and belief, the manufacture, use (including in accordance with and as directed by Changzhou's proposed labeling for Changzhou's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '642 patent.

ANSWER: Paragraph 102 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

103. In the Changzhou Notice Letter, Changzhou indicated that, in connection with its ANDA No. 220264, Changzhou had filed Paragraph IV Certifications with respect to each of the Asserted Patents.

ANSWER: Paragraph 103 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

104. The purpose of ANDA No. 220264 was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou’s ANDA Products with their proposed labeling prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 104 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

105. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 105 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

106. Changzhou has knowledge of the claims of the Asserted Patents. Notwithstanding this knowledge, Changzhou has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264. On information and belief, by such activities, Changzhou specifically intends infringement of the Asserted patents.

ANSWER: Paragraph 106 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

107. On information and belief, Changzhou plans and intends to, and will, actively induce infringement of the Asserted Patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Paragraph 107 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

108. On information and belief, Changzhou knows that Changzhou's ANDA Products are especially made or adapted for use in infringing the Asserted Patents, and that Changzhou's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Changzhou plans and intends to, and will, contribute to infringement of the Asserted Patents immediately and imminently upon approval of ANDA No. 220264.

ANSWER: Paragraph 108 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

109. The foregoing actions by Changzhou constitute and/or will constitute infringement of the Asserted Patents, active inducement of infringement of the Asserted Patents, and/or contribution to the infringement by others of the Asserted Patents.

ANSWER: Paragraph 109 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

110. An actual case or controversy exists between Plaintiffs and Changzhou with respect to infringement of each of the Asserted Patents.

ANSWER: Paragraph 110 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

111. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Changzhou Notice Letter.

ANSWER: Paragraph 111 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

[Alleged] Infringement by Teva

112. By letter dated March 6, 2025 (the “Teva Notice Letter”), Teva notified Plaintiffs that Teva Pharmaceuticals, Inc. had submitted to the FDA ANDA No. 220286 for Teva’s ANDA Products. These products are generic versions of VERQUVO®.

ANSWER: Paragraph 112 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

113. In the Teva Notice Letter, Teva stated that Teva’s ANDA Products contain vericiguat, which is a compound of the following formula:

ANSWER: Paragraph 113 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

114. In the Teva Notice Letter, Teva stated that the dosage form for Teva’s ANDA Products is tablets for oral use.

ANSWER: Paragraph 114 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

115. On information and belief, the proposed labeling for Teva’s ANDA Products directs the use of Teva’s ANDA Products to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

ANSWER: Paragraph 115 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

116. On information and belief, the vericiguat in Teva’s ANDA Products is in crystalline form of Polymorph I. In Teva’s Notice Letter, Teva did not set forth any theory of noninfringement with respect to any claim of the ’948 patent, and indeed did not state that it had filed a paragraph IV certification with respect to the ’948 patent.

ANSWER: Paragraph 116 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

117. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 7 of the '656 patent.

ANSWER: Paragraph 117 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

118. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 8 of the '377 patent.

ANSWER: Paragraph 118 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

119. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '948 patent.

ANSWER: Paragraph 119 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

120. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '476 patent.

ANSWER: Paragraph 120 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

121. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '896 patent.

ANSWER: Paragraph 121 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

122. On information and belief, the manufacture, use (including in accordance with and as directed by Teva's proposed labeling for Teva's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '642 patent.

ANSWER: Paragraph 122 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

123. In the Teva Notice Letter, Teva indicated that, in connection with its ANDA No. 220286, Teva had filed a Paragraph IV Certification with respect to the '656 patent.

ANSWER: Paragraph 123 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

124. The purpose of ANDA No. 220286 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Products with their proposed labeling prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 124 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

125. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 125 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

126. On information and belief, Teva has knowledge of the claims of the Asserted Patents. On information and belief, notwithstanding this knowledge, Teva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220. On information and belief, by such activities, Teva specifically intends infringement of the Asserted Patents.

ANSWER: Paragraph 126 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

127. On information and belief, Teva plans and intends to, and will, actively induce infringement of the Asserted Patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Paragraph 127 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

128. On information and belief, Teva knows that Teva's ANDA Products are especially made or adapted for use in infringing the Asserted Patents, and that Teva's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Teva plans and intends to, and will, contribute to infringement of the Asserted Patents immediately and imminently upon approval of ANDA No. 220286.

ANSWER: Paragraph 128 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

129. The foregoing actions by Teva constitute and/or will constitute infringement of the Asserted Patents, active inducement of infringement of the Asserted Patents, and/or contribution to the infringement by others of the Asserted Patents.

ANSWER: Paragraph 129 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

130. An actual case or controversy exists between Plaintiffs and Teva with respect to infringement of each of the Asserted Patents.

ANSWER: Paragraph 130 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

131. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Teva Notice Letter.

ANSWER: Paragraph 131 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

[Alleged] Infringement by Torrent

132. By letter dated March 5, 2025 (the “Torrent Notice Letter”), Torrent notified Plaintiffs that Torrent had submitted to the FDA ANDA No. 220221 for Torrent’s ANDA Product. This product is a generic version of VERQUVO®.

ANSWER: Paragraph 132 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

133. The Torrent Notice Letter was accompanied by an Offer of Confidential Access to “certain information from” Torrent’s ANDA No. 220221. However, the Offer of Confidential Access was subject to unreasonably restrictive confidentiality provisions. In addition, the Torrent Notice Letter did not offer to provide additional information, such as samples of Torrent’s ANDA Product, which on information and belief is not accessible to the public.

ANSWER: Paragraph 133 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

134. In the Torrent Notice Letter, Torrent stated that Torrent's ANDA Product contains vericiguat, which is a compound of the following formula:

ANSWER: Paragraph 134 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

135. In the Torrent Notice Letter, Torrent stated that the dosage form for Torrent's ANDA Product is a tablet.

ANSWER: Paragraph 135 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

136. On information and belief, the proposed labeling for Torrent's ANDA Product directs the use of Torrent's ANDA Product to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

ANSWER: Paragraph 136 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

137. On information and belief, the vericiguat in Torrent's ANDA Product is in crystalline form of Polymorph I.

ANSWER: Paragraph 137 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

138. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product will infringe, literally and/or under the doctrine of equivalents, at least claim 7 of the '656 patent.

ANSWER: Paragraph 138 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

139. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product will infringe, literally and/or under the doctrine of equivalents, at least claim 8 of the '377 patent.

ANSWER: Paragraph 139 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

140. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '948 patent.

ANSWER: Paragraph 140 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

141. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '476 patent.

ANSWER: Paragraph 141 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

142. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '896 patent.

ANSWER: Paragraph 142 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

143. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '642 patent.

ANSWER: Paragraph 143 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

144. In the Torrent Notice Letter, Torrent indicated that, in connection with its ANDA No. 220221, Torrent had filed a Paragraph IV Certification with respect to the Asserted Patents.

ANSWER: Paragraph 144 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

145. The purpose of ANDA No. 220221 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product with its proposed labeling prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 145 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

146. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 146 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

147. Torrent has knowledge of the claims of the Asserted Patents. Notwithstanding this knowledge, Torrent has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221. On information and belief, by such activities, Torrent specifically intends infringement of the Asserted Patents.

ANSWER: Paragraph 147 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

148. On information and belief, Torrent plans and intends to, and will, actively induce infringement of the Asserted Patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Paragraph 148 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

149. On information and belief, Torrent knows that Torrent's ANDA Product are especially made or adapted for use in infringing the Asserted Patents, and that Torrent's ANDA Product is not suitable for substantial noninfringing use. On information and belief, Torrent plans and intends to, and will, contribute to infringement of the Asserted Patents immediately and imminently upon approval of ANDA No. 220221.

ANSWER: Paragraph 149 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

150. The foregoing actions by Torrent constitute and/or will constitute infringement of the Asserted Patents, active inducement of infringement of the Asserted Patents, and/or contribution to the infringement by others of the Asserted Patents.

ANSWER: Paragraph 150 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

151. An actual case or controversy exists between Plaintiffs and Torrent with respect to infringement of each of the Asserted Patents.

ANSWER: Paragraph 151 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

152. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Torrent Notice Letter.

ANSWER: Paragraph 152 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

[Alleged] Infringement by MSN

153. By letter dated March 19, 2025 (the “MSN Notice Letter”), MSN notified Plaintiffs that MSN Laboratories Private Limited had submitted to the FDA ANDA No. 220354 for MSN’s ANDA Products. These products are generic versions of VERQUVO®.

ANSWER: MSN admits that it sent a letter to Plaintiffs regarding ANDA No. 220354 dated March 19, 2025 (“MSN Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I) and Section 505(j)(2)(B)(ii)(I) of the Federal Food, Drug and Cosmetic Act, and 21 C.F.R. § 314.95. The MSN Notice Letter speaks for itself and is the best source for its content. Otherwise denied.

154. The MSN Notice Letter was accompanied by an Offer of Confidential Access to “certain information from” MSN’s ANDA No. 220354, “including certain portions of DMF No. 040459.” However, the Offer of Confidential Access was subject to unreasonably restrictive confidentiality provisions. In addition, the MSN Notice Letter did not offer to provide additional information, such as samples of MSN’s ANDA Products, which on information and belief is not accessible to the public.

ANSWER: The MSN Notice Letter speaks for itself and is the best source for its content. To the extent a response is required, MSN admits the MSN Notice Letter was accompanied by an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). The Offer of Confidential Access speaks for itself and is the best source for its content. The remaining allegations in Paragraph 154 contain legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

155. In the MSN Notice Letter, MSN stated that MSN's ANDA Products contain vericiguat, which is a compound of the following formula:

ANSWER: The MSN Notice Letter speaks for itself and is the best source for its content. MSN admits that the MSN Notice Letters states that “[p]ursuant to 21 C.F.R. § 314.95(c)(4), the established name of the proposed drug product that is the subject of MSN's ANDA is Vericiguat tablets 2.5 mg, 5 mg, and 10 mg.”

156. In the MSN Notice Letter, MSN stated that the dosage form for MSN's ANDA Products is a tablet.

ANSWER: The MSN Notice Letter speaks for itself and is the best source for its content. MSN admits that the MSN Notice Letter states that “[p]ursuant to 21 C.F.R. § 314.95(c)(5), the active ingredient, strength, and dosage form of the proposed drug product is Vericiguat tablets 2.5 mg, 5 mg, and 10 mg.”

157. On information and belief, the proposed labeling for MSN's ANDA Products directs the use of MSN's ANDA Products to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

ANSWER: MSN's proposed product labeling submitted with ANDA No. 220354 speaks for itself and is the best source of its content. MSN admits that its ANDA No. 220354 seeks FDA approval for the same clinical indication as Plaintiffs' VERQUVO® product and that the “INDICATIONS AND USAGE” section of Plaintiffs' current product labeling for VERQUVO®

states: “Vericiguat tablets are a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.” Otherwise denied.

158. On information and belief, the vericiguat in MSN’s ANDA Products is in crystalline form of Polymorph I.

ANSWER: Denied.

159. On information and belief, the manufacture, use (including in accordance with and as directed by MSN’s proposed labeling for MSN’s ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of MSN’s ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 7 of the ’656 patent.

ANSWER: Paragraph 159 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

160. On information and belief, the manufacture, use (including in accordance with and as directed by MSN’s proposed labeling for MSN’s ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of MSN’s ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 8 of the ’377 patent.

ANSWER: Paragraph 160 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

161. On information and belief, the manufacture, use (including in accordance with and as directed by MSN’s proposed labeling for MSN’s ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of MSN’s ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the ’948 patent.

ANSWER: Paragraph 161 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

162. On information and belief, the manufacture, use (including in accordance with and as directed by MSN’s proposed labeling for MSN’s ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of MSN’s ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the ’476 patent.

ANSWER: Paragraph 162 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

163. On information and belief, the manufacture, use (including in accordance with and as directed by MSN's proposed labeling for MSN's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '896 patent.

ANSWER: Paragraph 163 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

164. On information and belief, the manufacture, use (including in accordance with and as directed by MSN's proposed labeling for MSN's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '642 patent.

ANSWER: Paragraph 164 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

165. In the MSN Notice Letter, MSN indicated that, in connection with its ANDA No. 220354, MSN had filed Paragraph IV Certifications with respect to each of the Asserted Patents.

ANSWER: The MSN Notice Letter speaks for itself and is the best source for its content. MSN admits that the Notice Letter provides “[n]otice of MSN Laboratories Private Limited's ANDA No. 220354 Concerning Vericiguat Tablets, 2.5 mg, 5 mg, and 10 mg with Paragraph IV Certification Concerning U.S. Patent Nos. 8,420,656; 8,921,377; 9,604,948; 9,993,476; 10,736,896; 11,439,642.” Otherwise denied.

166. The purpose of ANDA No. 220354 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products with their proposed labeling prior to the expiration of the Asserted Patents.

ANSWER: ANDA No. 220354 speaks for itself and is the best source of its content. MSN admits that it seeks FDA approval of ANDA No. 220354. Otherwise denied.

167. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the Asserted Patents.

ANSWER: The allegations in Paragraph 167 relate to future conduct which has not yet occurred. To the extent a response is required, denied.

168. MSN has knowledge of the claims of the Asserted Patents. Notwithstanding this knowledge, MSN has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354. On information and belief, by such activities, MSN specifically intends infringement of the Asserted Patents.

ANSWER: Paragraph 168 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN admits that it was aware of the Asserted Patents at least as of the date of the MSN Notice Letter. Otherwise denied.

169. On information and belief, MSN plans and intends to, and will, actively induce infringement of the Asserted Patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Paragraph 169 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

170. On information and belief, MSN knows that MSN's ANDA Products are especially made or adapted for use in infringing the Asserted Patents, and that MSN's ANDA Products are not suitable for substantial noninfringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the Asserted Patents immediately and imminently upon approval of ANDA No. 220354.

ANSWER: Paragraph 170 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

171. The foregoing actions by MSN constitute and/or will constitute infringement of the Asserted Patents, active inducement of infringement of the Asserted Patents, and/or contribution to the infringement by others of the Asserted Patents.

ANSWER: Paragraph 171 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

172. An actual case or controversy exists between Plaintiffs and MSN with respect to infringement of each of the Asserted Patents.

ANSWER: Paragraph 172 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

173. This action is being commenced before the expiration of forty-five days from the date Plaintiff received the MSN Notice Letter.

ANSWER: MSN admits that it sent its Notice Letter on March 20, 2025 and March 21, 2025 and Plaintiff filed its Complaint on April 18, 2025. Otherwise denied.

[Alleged] Infringement by Annora

174. By letter dated March 21, 2025 (the “Annora Notice Letter”), Annora notified Plaintiffs, among others, that Annora had submitted to the FDA ANDA No. 220244 for Annora’s ANDA Products. These products are generic versions of VERQUVO®.

ANSWER: Paragraph 174 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

175. In the Annora Notice Letter, Annora stated that Annora’s ANDA Products contain vericiguat, which is a compound of the following formula:

ANSWER: Paragraph 175 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

176. In the Annora Notice Letter, Annora stated that the dosage form for Annora’s ANDA Products is oral tablets.

ANSWER: Paragraph 176 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

177. On information and belief, the proposed labeling for Annora's ANDA Products directs the use of Annora's ANDA Products to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

ANSWER: Paragraph 177 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

178. On information and belief, the vericiguat in Annora's ANDA Products is in crystalline form of Polymorph I. In Annora's Notice Letter, Annora did not set forth any theory of noninfringement with respect to any claim of the '948 patent.

ANSWER: Paragraph 178 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

179. On information and belief, the manufacture, use (including in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 7 of the '656 patent.

ANSWER: Paragraph 179 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

180. On information and belief, the manufacture, use (including in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 8 of the '377 patent.

ANSWER: Paragraph 180 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

181. On information and belief, the manufacture, use (including in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '948 patent.

ANSWER: Paragraph 181 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

182. On information and belief, the manufacture, use (including in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '476 patent.

ANSWER: Paragraph 182 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

183. On information and belief, the manufacture, use (including in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 4 of the '896 patent.

ANSWER: Paragraph 183 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

184. On information and belief, the manufacture, use (including in accordance with and as directed by Annora's proposed labeling for Annora's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products will infringe, literally and/or under the doctrine of equivalents, at least claim 1 of the '642 patent.

ANSWER: Paragraph 184 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

185. In the Annora Notice Letter, Annora indicated that, in connection with its ANDA No. 220244, Annora had filed Paragraph IV Certifications with respect to each of the Asserted Patents.

ANSWER: Paragraph 185 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

186. The purpose of ANDA No. 220244 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products with their proposed labeling prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 186 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

187. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 187 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

188. Annora has knowledge of the claims of the Asserted Patents. Notwithstanding this knowledge, Annora has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244. On information and belief, by such activities, Annora specifically intends infringement of the Asserted Patents.

ANSWER: Paragraph 188 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

189. On information and belief, Annora plans and intends to, and will, actively induce infringement of the Asserted Patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: Paragraph 189 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

190. On information and belief, Annora knows that Annora's ANDA Products are especially made or adapted for use in infringing the Asserted Patents, and that Annora's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Annora plans and intends to, and will, contribute to infringement of the Asserted Patents immediately and imminently upon approval of ANDA No. 220244.

ANSWER: Paragraph 190 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

191. The foregoing actions by Annora constitute and/or will constitute infringement of the Asserted Patents, active inducement of infringement of the Asserted Patents, and/or contribution to the infringement by others of the Asserted Patents.

ANSWER: Paragraph 191 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

192. An actual case or controversy exists between Plaintiffs and Annora with respect to infringement of each of the Asserted Patents.

ANSWER: Paragraph 192 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

193. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Annora Notice Letter.

ANSWER: Paragraph 193 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 1

([Alleged] Infringement of the '656 Patent by Changzhou Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 194 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

195. Changzhou's submission of ANDA No. 220264 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products was an act of infringement of the '656 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 195 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

196. On information and belief, Changzhou has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '656 patent.

ANSWER: Paragraph 196 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

197. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the '656 patent.

ANSWER: Paragraph 197 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

198. The foregoing actions by Changzhou constitute and/or will constitute infringement of the '656 patent, active inducement of infringement of the '656 patent, and/or contribution to the infringement by others of the '656 patent.

ANSWER: Paragraph 198 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

199. Unless Changzhou is enjoined from infringing the '656 patent, actively inducing infringement of the '656 patent, and contributing to the infringement by others of the '656 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 199 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 2

(Declaration of [Alleged] Infringement of the '656 Patent by Changzhou)

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

ANSWER: Paragraph 200 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

201. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '656 patent.

ANSWER: Paragraph 201 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

202. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '656 patent.

ANSWER: Paragraph 202 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

203. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '656 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 203 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 3

([Alleged] Infringement of the '377 Patent by Changzhou Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 204 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

205. Changzhou's submission of ANDA No. 220264 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products was an act of infringement of the '377 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 205 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

206. On information and belief, Changzhou has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '377 patent.

ANSWER: Paragraph 206 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

207. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the '377 patent.

ANSWER: Paragraph 207 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

208. The foregoing actions by Changzhou constitute and/or will constitute infringement of the '377 patent, active inducement of infringement of the '377 patent, and/or contribution to the infringement by others of the '377 patent.

ANSWER: Paragraph 208 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

209. Unless Changzhou is enjoined from infringing the '377 patent, actively inducing infringement of the '377 patent, and contributing to the infringement by others of the '377 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 209 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 4

(Declaration of [Alleged] Infringement of the '377 Patent by Changzhou)

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

ANSWER: Paragraph 210 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

211. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '377 patent.

ANSWER: Paragraph 211 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

212. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '377 patent.

ANSWER: Paragraph 212 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

213. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '377 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 213 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 5

([Alleged] Infringement of the '948 Patent by Changzhou Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 214 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

215. Changzhou's submission of ANDA No. 220264 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products was an act of infringement of the '948 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 215 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

216. On information and belief, Changzhou has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '948 patent.

ANSWER: Paragraph 216 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

217. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the '948 patent.

ANSWER: Paragraph 217 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

218. On information and belief, the foregoing actions by Changzhou constitute and/or will constitute infringement of the '948 patent, active inducement of infringement of the '948 patent, and/or contribution to the infringement by others of the '948 patent.

ANSWER: Paragraph 218 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

219. Unless Changzhou is enjoined from infringing the '948 patent, actively inducing infringement of the '948 patent, and contributing to the infringement by others of the '948 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 219 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 6

(Declaration of [Alleged] Infringement of the '948 Patent by Changzhou)

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

ANSWER: Paragraph 220 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

221. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '948 patent.

ANSWER: Paragraph 221 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

222. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '948 patent.

ANSWER: Paragraph 222 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

223. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '948 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 223 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 7

([Alleged] Infringement of the '476 Patent by Changzhou under 35 U.S.C. §271(e)(2))

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

ANSWER: Paragraph 224 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

225. Changzhou's submission of ANDA No. 220264 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products was an act of infringement of the '476 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 225 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

226. On information and belief, Changzhou has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '476 patent.

ANSWER: Paragraph 226 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

227. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the '476 patent.

ANSWER: Paragraph 227 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

228. The foregoing actions by Changzhou constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and/or contribution to the infringement by others of the '476 patent.

ANSWER: Paragraph 228 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

229. Unless Changzhou is enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 229 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 8

(Declaration of [Alleged] Infringement of the '476 Patent by Changzhou)

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

ANSWER: Paragraph 230 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

231. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '476 patent.

ANSWER: Paragraph 231 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

232. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '476 patent.

ANSWER: Paragraph 232 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

233. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '476 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 233 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 9

([Alleged] Infringement of the '896 Patent by Changzhou under 35 U.S.C. §271 (e)(2))

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

ANSWER: Paragraph 234 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

235. Changzhou's submission of ANDA No. 220264 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products was an act of infringement of the '896 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 235 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

236. On information and belief, Changzhou has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '896 patent.

ANSWER: Paragraph 236 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

237. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the '896 patent.

ANSWER: Paragraph 237 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

238. The foregoing actions by Changzhou constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and/or contribution to the infringement by others of the '896 patent.

ANSWER: Paragraph 238 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

239. Unless Changzhou is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 239 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 10

(Declaration of [Alleged] Infringement of the '896 Patent by Changzhou)

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

ANSWER: Paragraph 240 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

241. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '896 patent.

ANSWER: Paragraph 241 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

242. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '896 patent.

ANSWER: Paragraph 242 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

243. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '896 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 243 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 11

([Alleged] Infringement of the '642 Patent by Changzhou Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 244 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

245. Changzhou's submission of ANDA No. 220264 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Changzhou's ANDA Products was an act of infringement of the '642 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 245 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

246. On information and belief, Changzhou has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Changzhou's ANDA Products with their proposed labeling prior to the expiration of the '642 patent.

ANSWER: Paragraph 246 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

247. Changzhou intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220264, i.e., prior to the expiration of the '642 patent.

ANSWER: Paragraph 247 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

248. The foregoing actions by Changzhou constitute and/or will constitute infringement of the '642 patent, active inducement of infringement of the '642 patent, and/or contribution to the infringement by others of the '642 patent.

ANSWER: Paragraph 248 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

249. Unless Changzhou is enjoined from infringing the '642 patent, actively inducing infringement of the '642 patent, and contributing to the infringement by others of the '642 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 249 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 12

(Declaration of [Alleged] Infringement of the '642 Patent by Changzhou)

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

ANSWER: Paragraph 250 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

251. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Changzhou on the other regarding Changzhou's liability for infringement, active inducement of, and contribution to infringement of the '642 patent.

ANSWER: Paragraph 251 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

252. An actual case or controversy exists between Plaintiffs and Changzhou with respect to Changzhou's liability for infringement of the '642 patent.

ANSWER: Paragraph 252 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

253. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Changzhou's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '642 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 253 contains allegations regarding Changzhou and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 13

([Alleged] Infringement of the '656 Patent by Teva Under 35 U.S.C. §271(e)(2))

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

ANSWER: Paragraph 254 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

255. Teva's submission of ANDA No. 220286 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Products was an act of infringement of the '656 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 255 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

256. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Products with their proposed labeling prior to the expiration of the '656 patent.

ANSWER: Paragraph 256 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

257. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the '656 patent.

ANSWER: Paragraph 257 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

258. The foregoing actions by Teva constitute and/or will constitute infringement of the '656 patent, active inducement of infringement of the '656 patent, and/or contribution to the infringement by others of the '656 patent.

ANSWER: Paragraph 258 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

259. Unless Teva is enjoined from infringing the '656 patent, actively inducing infringement of the '656 patent, and contributing to the infringement by others of the '656 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 259 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 14

(Declaration of [Alleged] Infringement of the '656 Patent by Teva)

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

ANSWER: Paragraph 260 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

261. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement, active inducement of, and contribution to infringement of the '656 patent.

ANSWER: Paragraph 261 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

262. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '656 patent.

ANSWER: Paragraph 262 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

263. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '656 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 263 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 15

(Declaration of [Alleged] Infringement of the '377 Patent by Teva)

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

ANSWER: Paragraph 264 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

265. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement, active inducement of, and contribution to infringement of the '377 patent.

ANSWER: Paragraph 265 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

266. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Products with their proposed labeling prior to the expiration of the '377 patent.

ANSWER: Paragraph 266 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

267. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the '377 patent.

ANSWER: Paragraph 267 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

268. The foregoing actions by Teva constitute and/or will constitute infringement of the '377 patent, active inducement of infringement of the '377 patent, and/or contribution to the infringement by others of the '377 patent.

ANSWER: Paragraph 268 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

269. Unless Teva is enjoined from infringing the '377 patent, actively inducing infringement of the '377 patent, and contributing to the infringement by others of the '377 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 269 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

270. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '377 patent.

ANSWER: Paragraph 270 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

271. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '377 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 271 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 16

(Declaration of [Alleged] Infringement of the '948 Patent by Teva)

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

ANSWER: Paragraph 272 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

273. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement, active inducement of, and contribution to infringement of the '948 patent.

ANSWER: Paragraph 273 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

274. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Products with their proposed labeling prior to the expiration of the '948 patent.

ANSWER: Paragraph 274 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

275. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the '948 patent.

ANSWER: Paragraph 275 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

276. On information and belief, the foregoing actions by Teva constitute and/or will constitute infringement of the '948 patent, active inducement of infringement of the '948 patent, and/or contribution to the infringement by others of the '948 patent.

ANSWER: Paragraph 276 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

277. Unless Teva is enjoined from infringing the '948 patent, actively inducing infringement of the '948 patent, and contributing to the infringement by others of the '948 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 277 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

278. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '948 patent.

ANSWER: Paragraph 278 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

279. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '948 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 279 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 17

(Declaration of [Alleged] Infringement of the '476 Patent by Teva)

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

ANSWER: Paragraph 280 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

281. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement, active inducement of, and contribution to infringement of the '476 patent.

ANSWER: Paragraph 281 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

282. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Products with their proposed labeling prior to the expiration of the '476 patent.

ANSWER: Paragraph 282 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

283. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the '476 patent.

ANSWER: Paragraph 283 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

284. The foregoing actions by Teva constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and/or contribution to the infringement by others of the '476 patent.

ANSWER: Paragraph 284 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

285. Unless Teva is enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 285 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

286. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '476 patent.

ANSWER: Paragraph 286 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

287. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '476 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 287 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 18

(Declaration of [Alleged] Infringement of the '896 Patent by Teva)

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

ANSWER: Paragraph 288 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

289. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement, active inducement of, and contribution to infringement of the '896 patent.

ANSWER: Paragraph 289 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

290. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Products with their proposed labeling prior to the expiration of the '896 patent.

ANSWER: Paragraph 290 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

291. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the '896 patent.

ANSWER: Paragraph 291 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

292. The foregoing actions by Teva constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and/or contribution to the infringement by others of the '896 patent.

ANSWER: Paragraph 292 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

293. Unless Teva is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 293 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

294. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '896 patent.

ANSWER: Paragraph 294 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

295. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '896 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 295 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 19

(Declaration of [Alleged] Infringement of the '642 Patent by Teva)

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

ANSWER: Paragraph 296 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

297. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Teva on the other regarding Teva's liability for infringement, active inducement of, and contribution to infringement of the '642 patent.

ANSWER: Paragraph 297 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

298. On information and belief, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Teva's ANDA Products with their proposed labeling prior to the expiration of the '642 patent.

ANSWER: Paragraph 298 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

299. Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220286, i.e., prior to the expiration of the '642 patent.

ANSWER: Paragraph 299 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

300. The foregoing actions by Teva constitute and/or will constitute infringement of the '642 patent, active inducement of infringement of the '642 patent, and/or contribution to the infringement by others of the '642 patent.

ANSWER: Paragraph 300 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

301. Unless Teva is enjoined from infringing the '642 patent, actively inducing infringement of the '642 patent, and contributing to the infringement by others of the '642 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 301 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

302. An actual case or controversy exists between Plaintiffs and Teva with respect to Teva's liability for infringement of the '642 patent.

ANSWER: Paragraph 302 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

303. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '642 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 303 contains allegations regarding Teva and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 20

([Alleged] Infringement of the '656 Patent by Torrent Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 304 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

305. Torrent's submission of ANDA No. 220221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product was an act of infringement of the '656 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 305 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

306. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Product with its proposed labeling prior to the expiration of the '656 patent.

ANSWER: Paragraph 306 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

307. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the '656 patent.

ANSWER: Paragraph 307 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

308. The foregoing actions by Torrent constitute and/or will constitute infringement of the '656 patent, active inducement of infringement of the '656 patent, and/or contribution to the infringement by others of the '656 patent.

ANSWER: Paragraph 308 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

309. Unless Torrent is enjoined from infringing the '656 patent, actively inducing infringement of the '656 patent, and contributing to the infringement by others of the '656 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 309 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 21

(Declaration of [Alleged] Infringement of the '656 Patent by Torrent)

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

ANSWER: Paragraph 310 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

311. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Torrent on the other regarding Torrent's liability for infringement, active inducement of, and contribution to infringement of the '656 patent.

ANSWER: Paragraph 311 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

312. An actual case or controversy exists between Plaintiffs and Torrent with respect to Torrent's liability for infringement of the '656 patent.

ANSWER: Paragraph 312 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

313. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Torrent's ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '656 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 313 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 22

([Alleged] Infringement of the '377 Patent by Torrent Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 314 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

315. Torrent's submission of ANDA No. 220221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product was an act of infringement of the '377 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 315 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

316. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Product with its proposed labeling prior to the expiration of the '377 patent.

ANSWER: Paragraph 316 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

317. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the '377 patent.

ANSWER: Paragraph 317 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

318. The foregoing actions by Torrent constitute and/or will constitute infringement of the '377 patent, active inducement of infringement of the '377 patent, and/or contribution to the infringement by others of the '377 patent.

ANSWER: Paragraph 318 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

319. Unless Torrent is enjoined from infringing the '377 patent, actively inducing infringement of the '377 patent, and contributing to the infringement by others of the '377 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 319 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 23

(Declaration of [Alleged] Infringement of the '377 Patent by Torrent)

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

ANSWER: Paragraph 320 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

321. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Torrent on the other regarding Torrent's liability for infringement, active inducement of, and contribution to infringement of the '377 patent.

ANSWER: Paragraph 321 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

322. An actual case or controversy exists between Plaintiffs and Torrent with respect to Torrent's liability for infringement of the '377 patent.

ANSWER: Paragraph 322 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

323. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Torrent's ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '377 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 323 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 24

([Alleged] Infringement of the '948 Patent by Torrent Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 324 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

325. Torrent's submission of ANDA No. 220221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product was an act of infringement of the '948 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 325 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

326. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Product with its proposed labeling prior to the expiration of the '948 patent.

ANSWER: Paragraph 326 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

327. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the '948 patent.

ANSWER: Paragraph 327 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

328. On information and belief, the foregoing actions by Torrent constitute and/or will constitute infringement of the '948 patent, active inducement of infringement of the '948 patent, and/or contribution to the infringement by others of the '948 patent.

ANSWER: Paragraph 328 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

329. Unless Torrent is enjoined from infringing the '948 patent, actively inducing infringement of the '948 patent, and contributing to the infringement by others of the '948 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 329 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 25

(Declaration of [Alleged] Infringement of the '948 Patent by Torrent)

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

ANSWER: Paragraph 330 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

331. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Torrent on the other regarding Torrent's liability for infringement, active inducement of, and contribution to infringement of the '948 patent.

ANSWER: Paragraph 331 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

332. An actual case or controversy exists between Plaintiffs and Torrent with respect to Torrent's liability for infringement of the '948 patent.

ANSWER: Paragraph 332 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

333. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Torrent's ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '948 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 333 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 26

([Alleged] Infringement of the '476 Patent by Torrent Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 334 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

335. Torrent's submission of ANDA No. 220221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product was an act of infringement of the '476 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 335 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

336. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Product with its proposed labeling prior to the expiration of the '476 patent.

ANSWER: Paragraph 336 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

337. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the '476 patent.

ANSWER: Paragraph 337 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

338. The foregoing actions by Torrent constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and/or contribution to the infringement by others of the '476 patent.

ANSWER: Paragraph 338 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

339. Unless Torrent is enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 339 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 27

(Declaration of [Alleged] Infringement of the '476 Patent by Torrent)

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

ANSWER: Paragraph 340 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

341. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Torrent on the other regarding Torrent's liability for infringement, active inducement of, and contribution to infringement of the '476 patent.

ANSWER: Paragraph 341 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

342. An actual case or controversy exists between Plaintiffs and Torrent with respect to Torrent's liability for infringement of the '476 patent.

ANSWER: Paragraph 342 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

343. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Torrent's ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '476 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 343 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 28

([Alleged] Infringement of the '896 Patent by Torrent Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 344 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

345. Torrent's submission of ANDA No. 220221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product was an act of infringement of the '896 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 345 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

346. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Product with its proposed labeling prior to the expiration of the '896 patent.

ANSWER: Paragraph 346 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

347. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the '896 patent.

ANSWER: Paragraph 347 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

348. The foregoing actions by Torrent constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and/or contribution to the infringement by others of the '896 patent.

ANSWER: Paragraph 348 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

349. Unless Torrent is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 349 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 29

(Declaration of [Alleged] Infringement of the '896 Patent by Torrent)

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

ANSWER: Paragraph 350 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

351. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Torrent on the other regarding Torrent's liability for infringement, active inducement of, and contribution to infringement of the '896 patent.

ANSWER: Paragraph 351 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

352. An actual case or controversy exists between Plaintiffs and Torrent with respect to Torrent's liability for infringement of the '896 patent.

ANSWER: Paragraph 352 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

353. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Torrent's ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '896 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 353 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 30

([Alleged] Infringement of the '642 Patent by Torrent Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 354 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

355. Torrent's submission of ANDA No. 220221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Product was an act of infringement of the '642 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 355 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

356. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Product with its proposed labeling prior to the expiration of the '642 patent.

ANSWER: Paragraph 356 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

357. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 220221, i.e., prior to the expiration of the '642 patent.

ANSWER: Paragraph 357 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

358. The foregoing actions by Torrent constitute and/or will constitute infringement of the '642 patent, active inducement of infringement of the '642 patent, and/or contribution to the infringement by others of the '642 patent.

ANSWER: Paragraph 358 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

359. Unless Torrent is enjoined from infringing the '642 patent, actively inducing infringement of the '642 patent, and contributing to the infringement by others of the '642 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 359 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 31

(Declaration of [Alleged] Infringement of the '642 Patent by Torrent)

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

ANSWER: Paragraph 360 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

361. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Torrent on the other regarding Torrent's liability for infringement, active inducement of, and contribution to infringement of the '642 patent.

ANSWER: Paragraph 361 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

362. An actual case or controversy exists between Plaintiffs and Torrent with respect to Torrent's liability for infringement of the '642 patent.

ANSWER: Paragraph 362 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

363. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Torrent's ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the '642 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 363 contains allegations regarding Torrent and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 32

([Alleged] Infringement of the '656 Patent by MSN Under 35 U.S.C. § 271(e)(2))

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

365. MSN's submission of ANDA No. 220354 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products was an act of infringement of the '656 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 365 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

366. On information and belief, MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import MSN's ANDA Products with their proposed labeling prior to the expiration of the '656 patent.

ANSWER: Paragraph 366 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

367. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the '656 patent.

ANSWER: Paragraph 367 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

368. The foregoing actions by MSN constitute and/or will constitute infringement of the '656 patent, active inducement of infringement of the '656 patent, and/or contribution to the infringement by others of the '656 patent.

ANSWER: Paragraph 368 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

369. Unless MSN is enjoined from infringing the '656 patent, actively inducing infringement of the '656 patent, and contributing to the infringement by others of the '656 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 369 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 33

(Declaration of [Alleged] Infringement of the '656 Patent by MSN)

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

371. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and MSN on the other regarding MSN's liability for infringement, active inducement of, and contribution to infringement of the '656 patent.

ANSWER: Paragraph 371 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

372. An actual case or controversy exists between Plaintiffs and MSN with respect to MSN's liability for infringement of the '656 patent.

ANSWER: Paragraph 372 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute

both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

373. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of MSN's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '656 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 373 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 34

([Alleged] Infringement of the '377 Patent by MSN Under 35 U.S.C. §271(e)(2))

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

375. MSN's submission of ANDA No. 220354 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products was an act of infringement of the '377 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 375 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

376. On information and belief, MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import MSN's ANDA Products with their proposed labeling prior to the expiration of the '377 patent.

ANSWER: Paragraph 376 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

377. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the '377 patent.

ANSWER: Paragraph 377 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

378. The foregoing actions by MSN constitute and/or will constitute infringement of the '377 patent, active inducement of infringement of the '377 patent, and/or contribution to the infringement by others of the '377 patent.

ANSWER: Paragraph 378 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

379. Unless MSN is enjoined from infringing the '377 patent, actively inducing infringement of the '377 patent, and contributing to the infringement by others of the '377 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 379 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 35

(Declaration of [Alleged] Infringement of the '377 Patent by MSN)

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

381. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and MSN on the other regarding MSN's liability for infringement, active inducement of, and contribution to infringement of the '377 patent.

ANSWER: Paragraph 381 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

382. An actual case or controversy exists between Plaintiffs and MSN with respect to MSN's liability for infringement of the '377 patent.

ANSWER: Paragraph 382 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute

both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

383. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of MSN's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '377 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 383 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 36

([Alleged] Infringement of the '948 Patent by MSN Under 35 U.S.C. § 271(e)(2))

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

385. MSN's submission of ANDA No. 220354 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products was an act of infringement of the '948 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 385 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

386. On information and belief, MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import MSN's ANDA Products with their proposed labeling prior to the expiration of the '948 patent.

ANSWER: Paragraph 386 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

387. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the '948 patent.

ANSWER: Paragraph 387 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

388. On information and belief, the foregoing actions by MSN constitute and/or will constitute infringement of the '948 patent, active inducement of infringement of the '948 patent, and/or contribution to the infringement by others of the '948 patent.

ANSWER: Paragraph 388 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

389. Unless MSN is enjoined from infringing the '948 patent, actively inducing infringement of the '948 patent, and contributing to the infringement by others of the '948 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 389 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 37

(Declaration of [Alleged] Infringement of the '948 Patent by MSN)

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

391. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and MSN on the other regarding MSN's liability for infringement, active inducement of, and contribution to infringement of the '948 patent.

ANSWER: Paragraph 391 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

392. An actual case or controversy exists between Plaintiffs and MSN with respect to MSN's liability for infringement of the '948 patent.

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

393. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of MSN's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '948 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: This paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 38

([Alleged] Infringement of the '476 Patent by MSN Under 35 U.S.C. § 271(e)(2))

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

395. MSN's submission of ANDA No. 220354 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products was an act of infringement of the '476 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 395 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

396. On information and belief, MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import MSN's ANDA Products with their proposed labeling prior to the expiration of the '476 patent.

ANSWER: Paragraph 396 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

397. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the '476 patent.

ANSWER: Paragraph 397 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

398. The foregoing actions by MSN constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and/or contribution to the infringement by others of the '476 patent.

ANSWER: Paragraph 398 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

399. Unless MSN is enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 399 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 39

(Declaration of Infringement [Alleged] of the '476 Patent by MSN)

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

401. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and MSN on the other regarding MSN's liability for infringement, active inducement of, and contribution to infringement of the '476 patent.

ANSWER: Paragraph 401 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

402. An actual case or controversy exists between Plaintiffs and MSN with respect to MSN's liability for infringement of the '476 patent.

ANSWER: Paragraph 402 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

403. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of MSN's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '476 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 403 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 40

([Alleged] Infringement of the '896 Patent by MSN Under 35 U.S.C. §271(e)(2))

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

405. MSN's submission of ANDA No. 220354 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products was an act of infringement of the '896 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 405 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

406. On information and belief, MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import MSN's ANDA Products with their proposed labeling prior to the expiration of the '896 patent.

ANSWER: Paragraph 406 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

407. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the '896 patent.

ANSWER: Paragraph 407 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

408. The foregoing actions by MSN constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and/or contribution to the infringement by others of the '896 patent.

ANSWER: Paragraph 408 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

409. Unless MSN is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 409 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 41

(Declaration of [Alleged] Infringement of the '896 Patent by MSN)

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

411. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and MSN on the other regarding MSN's liability for infringement, active inducement of, and contribution to infringement of the '896 patent.

ANSWER: Paragraph 411 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

412. An actual case or controversy exists between Plaintiffs and MSN with respect to MSN's liability for infringement of the '896 patent.

ANSWER: Paragraph 412 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

413. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of MSN's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '896 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 413 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 42

([Alleged] Infringement of the '642 Patent by MSN Under 35 U.S.C. §271(e)(2))

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

415. MSN's submission of ANDA No. 220354 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Products was an act of infringement of the '642 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 415 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

416. On information and belief, MSN has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import MSN's ANDA Products with their proposed labeling prior to the expiration of the '642 patent.

ANSWER: Paragraph contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

417. MSN intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220354, i.e., prior to the expiration of the '642 patent.

ANSWER: Paragraph 417 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

418. The foregoing actions by MSN constitute and/or will constitute infringement of the '642 patent, active inducement of infringement of the '642 patent, and/or contribution to the infringement by others of the '642 patent.

ANSWER: Paragraph 418 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

419. Unless MSN is enjoined from infringing the '642 patent, actively inducing infringement of the '642 patent, and contributing to the infringement by others of the '642 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 419 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 43

(Declaration of [Alleged] Infringement of the '642 Patent by MSN)

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

ANSWER: MSN repeats and incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

421. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and MSN on the other regarding MSN's liability for infringement, active inducement of, and contribution to infringement of the '642 patent.

ANSWER: Paragraph 421 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

422. An actual case or controversy exists between Plaintiffs and MSN with respect to MSN's liability for infringement of the '642 patent.

ANSWER: Paragraph 422 contains legal conclusions and allegations to which no response is required. To the extent a response is required, MSN states that the parties appear to dispute both: (i) whether MSN infringes the Asserted Patents; and (ii) whether the Asserted Patents are valid and/or enforceable. Otherwise denied.

423. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of MSN's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '642 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 423 contains legal conclusions and allegations to which no response is required. To the extent a response is required, denied.

COUNT 44

([Alleged] Infringement of the '656 Patent by Annora Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 424 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

425. Annora's submission of ANDA No. 220244 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products was an act of infringement of the '656 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 425 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

426. On information and belief, Annora has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Annora's ANDA Products with their proposed labeling prior to the expiration of the '656 patent.

ANSWER: Paragraph 426 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

427. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the '656 patent.

ANSWER: Paragraph 427 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

428. The foregoing actions by Annora constitute and/or will constitute infringement of the '656 patent, active inducement of infringement of the '656 patent, and/or contribution to the infringement by others of the '656 patent.

ANSWER: Paragraph 428 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

429. Unless Annora is enjoined from infringing the '656 patent, actively inducing infringement of the '656 patent, and contributing to the infringement by others of the '656 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 429 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 45

(Declaration of [Alleged] Infringement of the '656 Patent by Annora)

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

ANSWER: Paragraph 430 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

431. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Annora on the other regarding Annora's liability for infringement, active inducement of, and contribution to infringement of the '656 patent.

ANSWER: Paragraph 431 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

432. An actual case or controversy exists between Plaintiffs and Annora with respect to Annora's liability for infringement of the '656 patent.

ANSWER: Paragraph 432 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

433. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '656 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 433 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 46

([Alleged] Infringement of the '377 Patent by Annora Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 434 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

435. Annora's submission of ANDA No. 220244 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products was an act of infringement of the '377 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 435 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

436. On information and belief, Annora has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Annora's ANDA Products with their proposed labeling prior to the expiration of the '377 patent.

ANSWER: Paragraph 436 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

437. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the '377 patent.

ANSWER: Paragraph 437 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

438. The foregoing actions by Annora constitute and/or will constitute infringement of the '377 patent, active inducement of infringement of the '377 patent, and/or contribution to the infringement by others of the '377 patent.

ANSWER: Paragraph 438 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

439. Unless Annora is enjoined from infringing the '377 patent, actively inducing infringement of the '377 patent, and contributing to the infringement by others of the '377 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 439 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 47

(Declaration of [Alleged] Infringement of the '377 Patent by Annora)

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

ANSWER: Paragraph 440 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

441. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Annora on the other regarding Annora's liability for infringement, active inducement of, and contribution to infringement of the '377 patent.

ANSWER: Paragraph 441 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

442. An actual case or controversy exists between Plaintiffs and Annora with respect to Annora's liability for infringement of the '377 patent.

ANSWER: Paragraph 442 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

443. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '377 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 443 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 48

([Alleged] Infringement of the '948 Patent by Annora Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 444 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

445. Annora's submission of ANDA No. 220244 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products was an act of infringement of the '948 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 445 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

446. On information and belief, Annora has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Annora's ANDA Products with their proposed labeling prior to the expiration of the '948 patent.

ANSWER: Paragraph 446 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

447. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the '948 patent.

ANSWER: Paragraph 447 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

448. On information and belief, the foregoing actions by Annora constitute and/or will constitute infringement of the '948 patent, active inducement of infringement of the '948 patent, and/or contribution to the infringement by others of the '948 patent.

ANSWER: Paragraph 448 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

449. Unless Annora is enjoined from infringing the '948 patent, actively inducing infringement of the '948 patent, and contributing to the infringement by others of the '948 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 449 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 49

(Declaration of [Alleged] Infringement of the '948 Patent by Annora)

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

ANSWER: Paragraph 450 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

451. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Annora on the other regarding Annora's liability for infringement, active inducement of, and contribution to infringement of the '948 patent.

ANSWER: Paragraph 451 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

452. An actual case or controversy exists between Plaintiffs and Annora with respect to Annora's liability for infringement of the '948 patent.

ANSWER: Paragraph 452 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

453. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '948 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 453 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 50

([Alleged] Infringement of the '476 Patent by Annora Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 454 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

455. Annora's submission of ANDA No. 220244 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products was an act of infringement of the '476 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 455 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

456. On information and belief, Annora has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Annora's ANDA Products with their proposed labeling prior to the expiration of the '476 patent.

ANSWER: Paragraph 456 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

457. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the '476 patent.

ANSWER: Paragraph 457 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

458. The foregoing actions by Annora constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and/or contribution to the infringement by others of the '476 patent.

ANSWER: Paragraph 458 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

459. Unless Annora is enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 459 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 51

(Declaration of [Alleged] Infringement of the '476 Patent by Annora)

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

ANSWER: Paragraph 460 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

461. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Annora on the other regarding Annora's liability for infringement, active inducement of, and contribution to infringement of the '476 patent.

ANSWER: Paragraph 461 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

462. An actual case or controversy exists between Plaintiffs and Annora with respect to Annora's liability for infringement of the '476 patent.

ANSWER: Paragraph 462 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

463. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '476 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 463 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 52

([Alleged] Infringement of the '896 Patent by Annora Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 464 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

465. Annora's submission of ANDA No. 220244 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products was an act of infringement of the '896 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 465 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

466. On information and belief, Annora has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Annora's ANDA Products with their proposed labeling prior to the expiration of the '896 patent.

ANSWER: Paragraph 466 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

467. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the '896 patent.

ANSWER: Paragraph 467 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

468. The foregoing actions by Annora constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and/or contribution to the infringement by others of the '896 patent.

ANSWER: Paragraph 468 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

469. Unless Annora is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 469 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 53

(Declaration of [Alleged] Infringement of the '896 Patent by Annora)

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

ANSWER: Paragraph 470 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

471. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Annora on the other regarding Annora's liability for infringement, active inducement of, and contribution to infringement of the '896 patent.

ANSWER: Paragraph 471 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

472. An actual case or controversy exists between Plaintiffs and Annora with respect to Annora's liability for infringement of the '896 patent.

ANSWER: Paragraph 472 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

473. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '896 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 473 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 54

([Alleged] Infringement of the '642 Patent by Annora Under 35 U.S.C. § 271(e)(2))

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

ANSWER: Paragraph 474 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

475. Annora's submission of ANDA No. 220244 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Annora's ANDA Products was an act of infringement of the '642 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 475 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

476. On information and belief, Annora has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Annora's ANDA Products with their proposed labeling prior to the expiration of the '642 patent.

ANSWER: Paragraph 476 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

477. Annora intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Annora's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 220244, i.e., prior to the expiration of the '642 patent.

ANSWER: Paragraph 477 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

478. The foregoing actions by Annora constitute and/or will constitute infringement of the '642 patent, active inducement of infringement of the '642 patent, and/or contribution to the infringement by others of the '642 patent.

ANSWER: Paragraph 478 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

479. Unless Annora is enjoined from infringing the '642 patent, actively inducing infringement of the '642 patent, and contributing to the infringement by others of the '642 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 479 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

COUNT 55

(Declaration of [Alleged] Infringement of the '642 Patent by Annora)

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

ANSWER: Paragraph 480 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

481. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Annora on the other regarding Annora's liability for infringement, active inducement of, and contribution to infringement of the '642 patent.

ANSWER: Paragraph 481 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

482. An actual case or controversy exists between Plaintiffs and Annora with respect to Annora's liability for infringement of the '642 patent.

ANSWER: Paragraph 482 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

483. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Annora's ANDA Products will infringe, induce the infringement of, and/or contribute to the infringement of the '642 patent under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 483 contains allegations regarding Annora and therefore no response is required from MSN. MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

PLAINTIFFS' PRAYER FOR RELIEF

In response to sections (m)–(p) and (u–w), MSN denies that Plaintiffs are entitled to any of the relief set forth in their request for relief or to any relief whatsoever. Sections (a)-(l) and (q)-(t) contain allegations about other Defendants and therefore no response is required from MSN.

AFFIRMATIVE DEFENSES

Without any admissions as to burden of proof, and expressly reserving its right to assert additional defenses, MSN states the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Invalidity of the '656 Patent)

The Asserted Claims of the '656 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 102, 103 and/or 112 *et seq.*, and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability.

THIRD AFFIRMATIVE DEFENSE

(Invalidity of the '377 Patent)

The Asserted Claims of the '377 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 102, 103 and/or 112 *et seq.*, and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability.

FOURTH AFFIRMATIVE DEFENSE

(Invalidity of the '948 Patent)

The Asserted Claims of the '948 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 102, 103 and/or 112 *et seq.*, and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability.

FIFTH AFFIRMATIVE DEFENSE

(Invalidity of the '476 Patent)

The Asserted Claims of the '476 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 102, 103 and/or 112 *et seq.*, and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability.

SIXTH AFFIRMATIVE DEFENSE

(Invalidity of the '896 Patent)

The Asserted Claims of the '896 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 102, 103 and/or 112 *et seq.*, and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability.

SEVENTH AFFIRMATIVE DEFENSE

(Invalidity of the '642 Patent)

The Asserted Claims of the '642 patent are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 102, 103 and/or 112 *et seq.*, and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability.

EIGHTH AFFIRMATIVE DEFENSE

(Non-Infringement of the '656 Patent)

MSN's manufacture, sale, use, offer for sale and/or importation of the MSN ANDA Product would not infringe any valid and enforceable claim of the '656 patent.

NINTH AFFIRMATIVE DEFENSE

(Non-Infringement of the '377 Patent)

MSN's manufacture, sale, use, offer for sale and/or importation of the MSN ANDA Product would not infringe any valid and enforceable claim of the '377 patent.

TENTH AFFIRMATIVE DEFENSE

(Non-Infringement of the '948 Patent)

MSN's manufacture, sale, use, offer for sale and/or importation of the MSN ANDA Product would not infringe any valid and enforceable claim of the '948 patent.

ELEVENTH AFFIRMATIVE DEFENSE

(Non-Infringement of the '476 Patent)

MSN's manufacture, sale, use, offer for sale and/or importation of the MSN ANDA Product would not infringe any valid and enforceable claim of the '476 patent.

TWELFTH AFFIRMATIVE DEFENSE

(Non-Infringement of the '896 Patent)

MSN's manufacture, sale, use, offer for sale and/or importation of the MSN ANDA Product would not infringe any valid and enforceable claim of the '896 patent.

THIRTEENTH AFFIRMATIVE DEFENSE

(Non-Infringement of the '642 Patent)

MSN's manufacture, sale, use, offer for sale and/or importation of the MSN ANDA Product would not infringe any valid and enforceable claim of the '642 patent.

FOURTEENTH AFFIRMATIVE DEFENSE

(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

FIFTEENTH AFFIRMATIVE DEFENSE

(No Injunctive Relief)

Plaintiffs may not seek injunctive relief against MSN because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

SIXTEENTH AFFIRMATIVE DEFENSE

(Reservation of Rights)

MSN reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

WHEREFORE, MSN prays that this Court enter judgment as follows:

- A. Dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;
- B. Adjudging, pursuant to one or more provisions of 35 U.S.C. §§ 102 and/or 103, that each Asserted Claim of the Asserted Patents is invalid;
- C. Denying Plaintiffs any award of damages, costs, or fees;
- D. Declaring this case exceptional and awarding MSN its reasonable attorneys' fees;
- E. Awarding MSN its costs; and
- F. Awarding MSN such other and further relief as this Court may deem just and proper.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Without admitting any of the allegations set forth in Plaintiffs' Complaint, other than those expressly admitted herein, and without prejudice to the rights of MSN Laboratories Private Limited ("MSN Laboratories") and MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") (collectively, "MSN" or "Counterclaim Plaintiffs") to plead additional Counterclaims as the facts of the matter warrant, Defendants and Counterclaim Plaintiffs hereby submit these Counterclaims against Adverio Pharma GmbH ("Adverio"), Bayer AG ("Bayer"), MSD Pharma GmbH ("MSD") and Merck Sharp & Dohme LLC ("Merck") (collectively "Counterclaim Defendants"):

PARTIES

1. Counterclaim Plaintiff MSN Laboratories 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.

2. Counterclaim Plaintiff MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, with its principal place of business at 20 Duke Rd., Piscataway, NJ 08854.

3. Counterclaim Defendant Adverio is a corporation organized and existing under the laws of the Federal Republic of Germany, with a principal place of business at Kaiser-Wilhelm-Allee 1, 51373 Leverkusen.

4. Counterclaim Defendant Bayer is a corporation organized and existing under the laws of the Federal Republic of Germany, with a principal place of business at Kaiser-Wilhelm-Allee 1, 51373 Leverkusen.

5. Counterclaim Defendant MSD is a corporation organized and existing under the laws of the Federal Republic of Germany, with a principal place of business at Kaiser-Wilhelm-Allee 1, 51373 Leverkusen.

6. Counterclaim Defendant Merck is a limited liability company organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at 126 E. Lincoln Avenue, Rahway, NJ 07065.

JURISDICTION AND VENUE

7. This is a declaratory judgment arising under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. Personal jurisdiction over Counterclaim Defendants is proper because, inter alia, Counterclaim Defendants subjected themselves to the Court's personal jurisdiction in Delaware by filing the Complaint in the above action in this judicial district, and because, on information and belief, either directly or through agents, they transact business in, and derive substantial revenue from, the State of Delaware.

9. Venue is proper in this judicial district under 28 U.S.C. § 1391, and as a result of Counterclaim Defendants' choice of forum.

BACKGROUND

10. United States Patent No. 8,420,656 ("the '656 patent"), attached to the Complaint as Exhibit 1, is titled "Substituted 5-Fluoro-1H-Pyrazolopyridines And Their Use" and states that it was issued on April 16, 2013.

11. United States Patent No. 8,921,377 (“the ’377 patent”), attached to the Complaint as Exhibit 2, is titled “Substituted 5-Fluoro-1H-Pyrazolopyridines And Their Use” and states that it was issued on December 30, 2014.

12. United States Patent No 9,604,948 (“the ’948 patent”), attached to the Complaint as Exhibit 3, is titled “Process for Preparing Substituted 5-Fluoro-1H-Pyrazolopyridines And Their Use” and states that it was issued on March 28, 2017.

13. United States Patent No 9,993,476 (“the ’476 patent”), attached to the Complaint as Exhibit 4, is titled “Substituted 5-Fluoro-1H-Pyrazolopyridines And Their Use” and states that it was issued on June 12, 2018.

14. United States Patent No. 10,736,896 (“the ’896 patent”), attached to the Complaint as Exhibit 5, is titled “Substituted 5-Fluoro-1H-Pyrazolopyridines And Their Use” and states that it was issued on August 11, 2020.

15. United States Patent No. 11,439,642 (“the ’642 patent”), attached to the Complaint as Exhibit 6, is titled “Substituted 5-Fluoro-1H-Pyrazolopyridines And Their Use” and states that it was issued on September 13, 2022.

16. The ’656, ’377, ’948, ’476, ’896, and ’642 patents (collectively, the “Asserted Patents”) are listed in Approved Drug Products with Therapeutic Evaluations (“the Orange Book”) for New Drug Application (“NDA”) No. 214377 for 2.5 mg, 5 mg and 10 mg vericiguat tablets, which are sold under the trade name VERQUVO®.

17. Counterclaim Defendant Adverio has averred that it is the assignee of each of the Asserted Patents and holds title to each of the Asserted Patents.

18. Counterclaim Defendant MSD has averred that it is the exclusive licensee of each of the Asserted Patents in the United States.

19. Counterclaim Defendant Merck has averred that it is the holder of NDA No. 214377 for 2.5 mg, 5 mg and 2.5 mg tablets of vericiguat, sold under the trade name VERQUVO®.

20. On April 18, 2025, Counterclaim Defendants filed this lawsuit alleging infringement of the Asserted Patents. Pursuant to their Complaint [D.I. 1], Counterclaim Defendants have alleged infringement of at least claim 7 of the '656 patent, claim 8 of the '377 patent, claim 1 of the '948 patent, claim 4 of the '476 patent, claim 4 of the '896 patent, and claim 1 of the '642 patent ("the Asserted Claims").

21. MSN submitted ANDA No. 220354 (the "MSN ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in the United States of vericiguat tablets 2.5 mg, 5 mg and 10 mg (the "MSN ANDA Products"). The MSN ANDA includes certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the MSN ANDA Products.

22. MSN sent notice of those certifications to Counterclaim Defendants on or about March 20, 2025 and March 21, 2025. Upon information and belief, and as Counterclaim Defendants allege in their Complaint, Counterclaim Defendants received those notifications.

23. As of May 26, 2010, the chemical structure of riociguat, i.e. BAY 63-2521, was known in the United States within the meaning of 35 U.S.C §102.

24. U.S. Patent No. 7,137,037 is prior art to the '656 patent.

25. U.S. Patent No. 7,137,037 is prior art to the '377 patent.

26. U.S. Patent No. 7,137,037 is prior art to the '948 patent.

27. U.S. Patent No. 7,137,037 is prior art to the '476 patent.

28. U.S. Patent No. 7,137,037 is prior art to the '896 patent.

29. U.S. Patent No. 7,137,037 is prior art to the '642 patent.

30. As of May 26, 2010, riociguat, i.e. BAY 63-2521, was being investigated in human clinical trials for the treatment of pulmonary hypertension

31. As of May 26, 2010, the chemical structure of nelociguat, i.e. BAY 60-4552, was known in the United States within the meaning of 35 U.S.C §102.

32. As of May 26, 2010, it was known that nelociguat, i.e. BAY 63-4552, was an active metabolite of riociguat, i.e. BAY 63-2521 in the United States within the meaning of 35 U.S.C §102..

33. As of May 26, 2010, nelociguat, i.e. BAY 63-4552, was being investigated in human clinical trials for biventricular heart failure.

34. A justiciable controversy exists as to the validity and enforceability of the Asserted Patents because Counterclaim Defendants have filed a Complaint seeking, *inter alia*, a judgment that MSN has infringed the Asserted Patents based on the submission of ANDA No. 220354 to the FDA, and that the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product as described in ANDA No. 220354 would constitute infringement of the Asserted Patents. MSN alleges that the Asserted Patents are unenforceable and that the Asserted Claims of the Asserted Patents are invalid. This controversy is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

FIRST COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '656 Patent)

35. MSN restates and incorporates herein by reference each of the foregoing paragraphs.

36. Each claim of the '656 patent is invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-

created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

37. MSN incorporates by reference MSN's Detailed Statement in the Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '656 patent are invalid.

38. The claims of the '656 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art identified in MSN'S Detailed Statement and/or prior art listed on the face of the '656 patent.

39. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that each of the claims in the '656 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

40. MSN is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

SECOND COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '377 Patent)

41. MSN restates and incorporates herein by reference each of the foregoing paragraphs.

42. Each claim of the '377 patent is invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

43. MSN incorporates by reference MSN's Detailed Statement in the Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '377 patent are invalid.

44. The claims of the '377 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art identified in MSN'S Detailed Statement and/or the prior art listed on the face of the '377 patent.

45. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that each of the claims in the '377 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

46. MSN is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

THIRD COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '948 Patent)

47. MSN restates and incorporates herein by reference each of the foregoing paragraphs.

48. Each claim of the '948 patent is invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

49. MSN incorporates by reference MSN's Detailed Statement in the Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '948 patent are invalid.

50. The claims of the '948 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art identified in MSN'S Detailed Statement and/or the prior art listed on the face of the '948 patent.

51. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that each of the claims in the '948 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

52. MSN is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '476 Patent)

53. MSN restates and incorporates herein by reference each of the foregoing paragraphs.

54. Each claim of the '476 patent is invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

55. MSN incorporates by reference MSN's Detailed Statement in the Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '476 patent are invalid.

56. The claims of the '476 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art identified in MSN'S Detailed Statement and/or the prior art listed on the face of the '476 patent.

57. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that each of the claims in the '476 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

58. MSN is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

FIFTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '896 Patent)

59. MSN restates and incorporates herein by reference each of the foregoing paragraphs.

60. Each claim of the '896 patent is invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

61. MSN incorporates by reference MSN's Detailed Statement in the Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '896 patent are invalid.

62. The claims of the '896 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art identified in MSN'S Detailed Statement and/or the prior art listed on the face of the '896 patent.

63. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that each of the claims in the '896 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

64. MSN is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

SIXTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '642 Patent)

65. MSN restates and incorporates herein by reference each of the foregoing paragraphs.

66. Each claim of the '642 patent is invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

67. MSN incorporates by reference MSN's Detailed Statement in the Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '642 patent are invalid.

68. The claims of the '642 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art identified in MSN'S Detailed Statement and/or the prior art listed on the face of the '642 patent.

69. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that each of the claims in the '642 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

70. MSN is entitled to an award of costs and expenses, including reasonable attorney fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

SEVENTH COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of the '656 Patent)

71. MSN relates and incorporates herein by reference each of paragraphs 1-70 of its counterclaims.

72. MSN has not infringed directly or indirectly any valid claim of the '656 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '656 patent.

73. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that MSN has not infringed,

directly or indirectly, any valid claim of the '656 patent by the submission of ANDA No. 220354 to the FDA, and that the manufacture, use, offer for sale, sale, and/or importation of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '656 patent.

74. MSN is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

EIGHTH COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of the '377 Patent)

75. MSN relates and incorporates herein by reference each of paragraphs 1-74 of its counterclaims.

76. MSN has not infringed directly or indirectly any valid claim of the '377 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '377 patent.

77. MSN has not infringed directly or indirectly any valid claim of the '377 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '377 patent.

78. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that MSN has not infringed, directly or indirectly, any valid claim of the '377 patent by the submission of ANDA No. 220354 to the FDA, and that the manufacture, use, offer for sale, sale, and/or importation of the MSN

Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '377 patent.

79. MSN is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

NINTH COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of the '948 Patent)

80. MSN relates and incorporates herein by reference each of paragraphs 1-79 of its counterclaims.

81. MSN has not infringed directly or indirectly any valid claim of the '948 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '948 patent.

82. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that MSN has not infringed, directly or indirectly, any valid claim of the '948 patent by the submission of ANDA No. 220354 to the FDA, and that the manufacture, use, offer for sale, sale, and/or importation of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '948 patent.

83. MSN is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

TENTH COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of the '476 Patent)

84. MSN relates and incorporates herein by reference each of paragraphs 1-83 of its counterclaims.

85. MSN has not infringed directly or indirectly any valid claim of the '476 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '476 patent.

86. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that MSN has not infringed, directly or indirectly, any valid claim of the '476 patent by the submission of ANDA No. 220354 to the FDA, and that the manufacture, use, offer for sale, sale, and/or importation of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '476 patent.

87. MSN is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

ELEVENTH COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of the '896 Patent)

88. MSN relates and incorporates herein by reference each of paragraphs 1-87 of its counterclaims.

89. MSN has not infringed directly or indirectly any valid claim of the '896 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the

United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '896 patent.

90. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that MSN has not infringed, directly or indirectly, any valid claim of the '896 patent by the submission of ANDA No. 220354 to the FDA, and that the manufacture, use, offer for sale, sale, and/or importation of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '896 patent.

91. MSN is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

TWELFTH COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of the '642 Patent)

92. MSN relates and incorporates herein by reference each of paragraphs 1-91 of its counterclaims.

93. MSN has not infringed directly or indirectly any valid claim of the '642 patent by submitting ANDA No. 220354 to the FDA, and the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the MSN Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '642 patent.

94. Because of the immediate and justiciable controversy between MSN and Counterclaim Defendants, a declaration is necessary and appropriate that MSN has not infringed, directly or indirectly, any valid claim of the '896 patent by the submission of ANDA No. 220354 to the FDA, and that the manufacture, use, offer for sale, sale, and/or importation of the MSN

Product does not infringe and will not infringe, directly or indirectly, any valid claim of the '642 patent.

95. MSN is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully requests that the Court enter judgment in its favor and against Counterclaim Defendants as follows:

- A. Dismissing with prejudice the entirety of Counterclaim Defendants' Complaint;
- B. Denying all remedies and relief sought by Counterclaim Defendants in the Complaint;
- C. Declaring that the claims of the Asserted Patents are invalid;
- D. Declaring that MSN has not infringed, directly or indirectly, any valid claim of the Asserted Patents by the submission of ANDA No. 220354 to the FDA;
- E. Declaring that the manufacture, use, offer for sale, sale in the United States, and/or importation into the United States, of the product described in ANDA No. 220354 does not infringe and will not infringe any valid claim of the Asserted Patents;
- F. Finding that this case is exceptional under 35 U.S.C. § 285;
- G. Awarding MSN its attorneys' fees, expenses, and costs of suit; and
- H. Awarding to MSN such other and further relief as the Court deems appropriate.

Dated: July 29, 2025

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