IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, AND BRISTOL-MYERS SQUIBB COMPANY, Plaintiffs, v. CHANGZHOU PHARMACEUTICAL FACTORY, Defendants.	C.A. No. 24-623-CFC **ANDA CASE**

DEFENDANT CHANGZHOU PHARMACEUTICAL FACTORY'S
ANSWER TO COMPLAINT AND ADDITIONAL DEFENSES

Defendant Changzhou Pharmaceutical Factory ("Changzhou" or "Defendant"), by its attorneys, hereby submits its Answer and Additional Defenses to the Complaint filed by Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively "Pfizer"), and Bristol-Myers Squibb Company ("BMS") (collectively with Pfizer, "Plaintiffs"). Changzhou denies all allegations in Plaintiffs' Complaint, except those expressly admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Changzhou's submission of Abbreviated New Drug Application ("ANDA") No. 219385 (the "Changzhou ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Pfizer Inc.'s NURTEC ODT® (rimegepant sulfate) tablet before

the expiration of U.S. Patent Nos. 8,314,117 ("the '117 patent"), 8,759,372 ("the '372 patent"), and 11,083,724 ("the '724 patent") (collectively, "the patents-in-suit").

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou admits that Plaintiffs' Complaint purports to set forth an action for infringement arising from Changzhou's submission of Abbreviated New Drug Application ("ANDA") No. 219385 for its proposed rimegepant sulfate tablet product referring to Pfizer Inc.'s NURTEC ODT® (rimegepant sulfate) and United States Patent Nos. 8,314,117 ("the '117 patent"), 8,759,372 ("the '372 patent"), and 11,083,724 ("the '724 patent") (collectively, the "patents-in-suit") under the patent laws of the United States, Title 35 of the United States Code and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. Changzhou denies the remaining allegations in this paragraph.

THE PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

RESPONSE:

Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

3. Plaintiff Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

RESPONSE:

Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

4. Plaintiff BMS is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

RESPONSE:

Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

5. Upon information and belief, Defendant 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.

RESPONSE:

Admitted.

6. Upon information and belief, Changzhou is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

RESPONSE:

Changzhou admits that it manufactures and/or markets pharmaceutical

products. Changzhou denies the remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

7. On November 20, 2012, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '117 patent, entitled "CGRP Receptor Antagonists." The '117 patent is assigned to BMS. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '117 patent. A copy of the '117 patent is attached to this Complaint as Exhibit A.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou admits that a purported copy of the '117 patent was attached as Exhibit A to the Complaint and that on its face it is entitled "CGRP Receptor Antagonists," bears a date of patent of November 20, 2012 and lists Bristol-Myers Squibb Company as the assignee. Changzhou denies that the '117 patent was duly and legally issued and further denies any suggestion that the '117 patent is valid or enforceable. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

8. On June 24, 2014, the USPTO duly and legally issued the '372 patent, entitled "N-(5S,6S,9R)-5-Amino-6-(2,3-Difluorophenyl)-6,7,8,9-Tetrahydro-5H-Cyclohepta[b]Pyridin-9-yl-4-(2-Oxo-2,3-Dihydro-1H-Imidazo[4,5-b]Pyridin-1-yl)Piperidine-1-Carboxylate Salt." The '372 patent is assigned to BMS. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '372 patent. A copy of the '372 patent is attached to this Complaint as Exhibit B.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To

the extent an answer is required, Changzhou admits that a purported copy of the '372 patent was attached as Exhibit B to the Complaint and that on its face it is entitled "N-(5S,6S,9R)-5-Amino-6-(2,3-Difluorophenyl)-6,7,8,9-Tetrahydro-5H-Cyclohepta[b]Pyridin-9-yl-4-(2-Oxo-2,3-Dihydro-1H-Imidazo[4,5-b]Pyridin-1-yl)Piperidine-1-Carboxylate Salt," bears a date of patent of June 24, 2014 and lists Bristol-Myers Squibb Company as the assignee. Changzhou denies that the '372 patent was duly and legally issued and further denies any suggestion that the '372 patent is valid or enforceable. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

9. On August 10, 2021, the USPTO duly and legally issued the '724 patent, entitled "Rimegepant for CGRP Related Disorders." The '724 patent is assigned to Pfizer Ireland Pharmaceuticals. A copy of the '724 patent is attached to this Complaint as Exhibit C.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou admits that a purported copy of the '724 patent was attached as Exhibit C to the Complaint and that on its face it is entitled "Rimegepant for CGRP Related Disorders," bears a date of patent of August 10, 2021 and lists Biohaven Pharmaceutical Ireland DAC as the assignee. Changzhou denies that the '724 patent was duly and legally issued and further denies any suggestion that the '724 patent is valid or enforceable. Changzhou lacks

knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

NURTEC ODT®

10. Pfizer Inc. holds approved New Drug Application No. 212728 for rimegepant sulfate orally disintegrating tablets (trade name NURTEC ODT®) for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults.

RESPONSE:

Changzhou admits that based on the information published by the FDA Pfizer Inc. is identified as the holder of New Drug Application ("NDA") No. 212728. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

11. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NURTEC ODT®.

RESPONSE:

Changzhou admits that based on the information published by the FDA the patents-in-suit are listed in the Orange Book with respect to NURTEC ODT®. Changzhou lacks knowledge or information sufficient to form a belief as to the

truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

THE CHANGZHOU ANDA

12. Upon information and belief, Changzhou Pharmaceutical Factory prepared and submitted the Changzhou ANDA to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of rimegepant sulfate tablet orally disintegrating ("Changzhou's ANDA Product") before the expiration of the patents-in-suit.

RESPONSE:

Changzhou admits that Changzhou submitted ANDA No. 219385 to the FDA seeking approval to manufacture and sell its proposed rimegepant sulfate tablet orally disintegrating ("Changzhou's ANDA Product") prior to the expiration of the patents-in-suit. Changzhou denies the remaining allegations in this paragraph.

13. Upon information and belief, Changzhou's ANDA Product is a generic copy of NURTEC ODT®.

RESPONSE:

Changzhou admits that Changzhou's ANDA No. 219385 refers to NURTEC ODT® under NDA No. 212728 as the reference listed product. Changzhou denies the remaining allegations in this paragraph.

14. Upon information and belief, the Changzhou ANDA refers to and relies upon Pfizer Inc.'s New Drug Application No. 212728 and purports to contain data on the bioequivalence of Changzhou's ANDA Product to NURTEC ODT®.

RESPONSE:

Changzhou admits that Changzhou's ANDA No. 219385 refers to NURTEC ODT® under NDA No. 212728 as the reference listed product and contains data related to bioequivalence. Changzhou denies the remaining allegations in this paragraph.

15. By a letter to Pfizer Inc., Pfizer Ireland Pharmaceuticals, and BMS dated April 15, 2024 ("Changzhou's Paragraph IV Notice Letter"), Changzhou stated that the Changzhou ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable claim of the patents-in-suit will be infringed by the manufacture, use, or sale of Changzhou's ANDA Product (the "Paragraph IV Certifications"). Changzhou's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certifications.

RESPONSE:

Changzhou admits that it sent Plaintiffs a letter dated April 15, 2024 regarding "Notice of Paragraph IV Certification Re: Changzhou Pharmaceutical Factory's Rimegepant Sulfate Tablet Orally Disintegrating Eq. 75 mg Base; U.S. Patent Nos. 8,314,117; 8,759,372 and 11,083,724," along with detailed statements of factual and legal basis for Changzhou's assertion of invalidity, unenforceability and/or non-infringement of the patents-in-suit. Changzhou denies the remaining allegations in this paragraph.

16. Upon information and belief, if the FDA approves the Changzhou ANDA, Changzhou will manufacture, distribute, import, offer for sale and/or sell Changzhou's ANDA Product throughout the United States, including within the State of Delaware.

RESPONSE:

Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, denies those allegations.

17. This action is being filed within 45 days of Plaintiffs' receipt of Changzhou's Paragraph IV Notice Letter.

RESPONSE:

Admitted.

JURISDICTION AND VENUE

18. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou admits that Plaintiffs' Complaint is for alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Changzhou does not contest subject matter jurisdiction solely for the limited purposes of this action only. Changzhou denies the remaining allegations of this paragraph.

19. This Court has personal jurisdiction over Changzhou because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Changzhou is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon

information and belief, Changzhou directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Changzhou's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of Changzhou's ANDA Product.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou does not contest personal jurisdiction solely for the limited purposes of this action only. Changzhou denies the remaining allegations of this paragraph.

20. Upon information and belief, Changzhou is the holder of the Changzhou ANDA.

RESPONSE:

Admitted.

21. Upon information and belief, Changzhou prepared and submitted the Changzhou ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the Changzhou ANDA.

RESPONSE:

Changzhou admits that Changzhou submitted ANDA No. 219385 to the FDA seeking approval to manufacture and sell Changzhou's ANDA Product. Changzhou denies the remaining allegations of this paragraph.

22. This Court also has personal jurisdiction over Changzhou because it has availed itself of the legal protections of the State of Delaware by previously consenting to personal jurisdiction in this judicial district. *See Astrazeneca AB v. Changzhou Pharm. Factory*, C.A. No. 21-1284 (D. Del.).

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou does not contest personal jurisdiction solely for the limited purposes of this action only. Changzhou denies the remaining allegations of this paragraph.

23. For these and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Changzhou.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou does not contest personal jurisdiction solely for the limited purposes of this action only. Changzhou denies the remaining allegations of this paragraph.

24. Venue is proper in this Court for Changzhou under 28 U.S.C. § 1391 because, upon information and belief, Changzhou is not a resident of the United States and may thus be sued in any judicial district.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent an answer is required, Changzhou does not contest venue solely for the limited purposes of this action only. Changzhou denies the remaining allegations of this paragraph.

COUNT I
(Infringement of the '117 Patent)

25. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE:

Changzhou realleges and incorporates each of its answers to proceeding paragraphs as if fully set forth herein.

26. Defendant has infringed one or more claims of the '117 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Changzhou ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Changzhou's ANDA Product before the expiration of the '117 patent.

RESPONSE:

Denied.

27. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '117 patent would infringe one or more claims of the '117 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

RESPONSE:

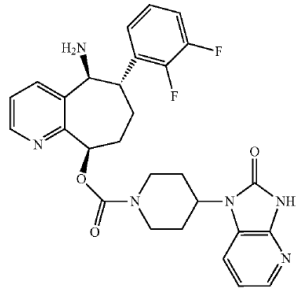
Denied.

28. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '117 patent would induce and/or contribute to the infringement of one or more claims of the '117 patent under 35 U.S.C. §§ 271(b) and/or (c).

RESPONSE:

Denied.

29. For example, claim 14 of the '117 patent recites:

> The compound of claim **1** (5S,6S,9R)-5-amino-6-(2,3-difluorophenyl)-6,7,8,9-tetrahydro-5H-cyclohepta[b]pyridin-9-yl 4-(2-oxo-2,3-dihydro-1H-imidazo[4,5-b]pyridin-1-yl)piperidine-1-carboxylate;
>
> 
>
> or a pharmaceutically acceptable salt thereof.

RESPONSE:

Changzhou admits that claim 14 of the '117 patent is purportedly reproduced in this paragraph and it speaks for itself. Changzhou denies the remaining allegations of this paragraph.

30. The chemical name and chemical structure recited in claim 14 correspond to the compound rimegepant. Upon information and belief, Changzhou's ANDA Product contains rimegepant sulfate. Rimegepant sulfate is a pharmaceutically acceptable salt of rimegepant.

RESPONSE:

Changzhou admits that claim 14 of the '117 patent speaks for itself. Changzhou admits that Changzhou's ANDA Product contains rimegepant sulfate. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

31. Upon information and belief, Defendant has acted with full knowledge of the '117 patent and without a reasonable basis for believing that it would not be liable for infringement of the '117 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Product with its proposed labeling immediately and imminently upon approval of the Changzhou ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '117 patent.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Changzhou admits that it was aware of the '117 patent as of the date of the filing of its ANDA. Changzhou denies the remaining allegations of this paragraph.

32. Upon information and belief, if the FDA approves the Changzhou ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '117 patent, and will do so immediately and imminently upon approval.

RESPONSE:

Denied.

33. Upon information and belief, Defendant knows that Changzhou's ANDA Product is especially made or adapted for use in infringing the '117 patent, and that Changzhou's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '117 patent immediately and imminently upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

34. Plaintiffs will be harmed substantially and irreparably if Defendant is not

enjoined from infringing the ’117 patent.

RESPONSE:

Denied.

35. Plaintiffs have no adequate remedy at law.

RESPONSE:

Denied.

36. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

RESPONSE:

Denied.

COUNT II
(Declaratory Judgment of Infringement of the ’117 Patent)

37. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE:

Changzhou realleges and incorporates each of its answers to proceeding paragraphs as if fully set forth herein.

38. There is a substantial and immediate controversy between Plaintiffs and Changzhou concerning the ’117 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C.
§§ 2201 and 2202 that Changzhou will infringe, actively induce infringement of, and/or contribute to the infringement of the ’117 patent upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

39. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '117 patent would infringe one or more claims of the '117 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

RESPONSE:

Denied.

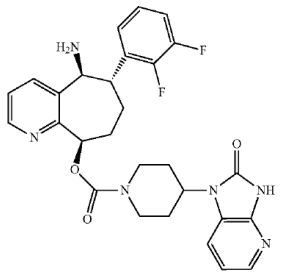
40. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '117 patent would induce and/or contribute to the infringement of one or more claims of the '117 patent under 35 U.S.C. §§ 271(b) and/or (c).

RESPONSE:

Denied.

41. For example, claim 14 of the '117 patent recites:

> The compound of claim **1** (5S,6S,9R)-5-amino-6-(2,3-difluorophenyl)-6,7,8,9-tetrahydro-5H-cyclohepta[b]pyridin-9-yl 4-(2-oxo-2,3-dihydro-1H-imidazo[4,5-b]pyridin-1-yl)piperidine-1-carboxylate;



> or a pharmaceutically acceptable salt thereof.

RESPONSE:

Changzhou admits that claim 14 of the '117 patent is purportedly reproduced in this paragraph and it speaks for itself. Changzhou denies the remaining

allegations of this paragraph.

42. The chemical name and chemical structure recited in claim 14 correspond to the compound rimegepant. Upon information and belief, Changzhou's ANDA Product will contain rimegepant sulfate. Rimegepant sulfate is a pharmaceutically acceptable salt of rimegepant.

RESPONSE:

Changzhou admits that claim 14 of the '117 patent speaks for itself. Changzhou admits that Changzhou's ANDA Product contains rimegepant sulfate. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

43. Upon information and belief, Defendant has acted with full knowledge of the '117 patent and without a reasonable basis for believing that it would not be liable for infringement of the '117 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Product with its proposed labeling immediately and imminently upon approval of the Changzhou ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '117 patent.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Changzhou admits that it was aware of the '117 patent as of the date of the filing of its ANDA. Changzhou denies the remaining allegations of this paragraph.

44. Upon information and belief, if the FDA approves the Changzhou ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of,

and/or contribute to the infringement of the '117 patent, and will do so immediately and imminently upon approval.

RESPONSE:

Denied.

45. Upon information and belief, Defendant knows that Changzhou's ANDA Product is especially made or adapted for use in infringing the '117 patent, and that Changzhou's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '117 patent immediately and imminently upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

46. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '117 patent.

RESPONSE:

Denied.

47. Plaintiffs have no adequate remedy at law.

RESPONSE:

Denied.

48. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

RESPONSE:

Denied.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Changzhou's ANDA Product with its proposed labeling will

infringe the '117 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

RESPONSE:

Denied.

COUNT III
(Infringement of the '372 Patent)

50. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE:

Changzhou realleges and incorporates each of its answers to proceeding paragraphs as if fully set forth herein.

51. Defendant has infringed one or more claims of the '372 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Changzhou ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Changzhou's ANDA Product before the expiration of the '372 patent.

RESPONSE:

Denied.

52. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '372 patent would infringe one or more claims of the '372 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

RESPONSE:

Denied.

53. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term

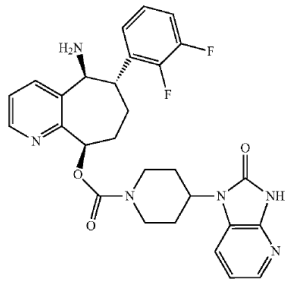
of the ’372 patent would induce and/or contribute to the infringement of one or more claims of the ’372 patent under 35 U.S.C. §§ 271(b) and/or (c).

RESPONSE:

Denied.

54. For example, claim 1 of the ’372 patent recites:

A hemisulfate salt of Compound (I):



RESPONSE:

Changzhou admits that claim 1 of the ’372 patent is purportedly reproduced in this paragraph and it speaks for itself. Changzhou denies the remaining allegations of this paragraph.

55. The chemical structure recited in claim 1 for Compound (I) corresponds to rimegepant. Upon information and belief, Changzhou’s ANDA Product will contain a hemisulfate salt of rimegepant.

RESPONSE:

Changzhou admits that claim 1 of the ’372 patent speaks for itself. Changzhou admits that Changzhou’s ANDA Product contains rimegepant sulfate. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

56. Upon information and belief, Defendant has acted with full knowledge of the '372 patent and without a reasonable basis for believing that it would not be liable for infringement of the '372 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Product with its proposed labeling immediately and imminently upon approval of the Changzhou ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '372 patent.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Changzhou admits that it was aware of the '372 patent as of the date of the filing of its ANDA. Changzhou denies the remaining allegations of this paragraph.

57. Upon information and belief, if the FDA approves the Changzhou ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '372 patent, and will do so immediately and imminently upon approval.

RESPONSE:

Denied.

58. Upon information and belief, Defendant knows that Changzhou's ANDA Product is especially made or adapted for use in infringing the '372 patent, and that Changzhou's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '372 patent immediately and imminently upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

59. Plaintiffs will be harmed substantially and irreparably if Defendant is not

enjoined from infringing the ’372 patent.

RESPONSE:

Denied.

60. Plaintiffs have no adequate remedy at law.

RESPONSE:

Denied.

61. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

RESPONSE:

Denied.

COUNT IV
(Declaratory Judgment of Infringement of the ’372 Patent)

62. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

RESPONSE:

Changzhou realleges and incorporates each of its answers to proceeding paragraphs as if fully set forth herein.

63. There is a substantial and immediate controversy between Plaintiffs and Changzhou concerning the ’372 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Changzhou will infringe, actively induce infringement of, and/or contribute to the infringement of the ’372 patent upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

64. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '372 patent would infringe one or more claims of the '372 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

RESPONSE:

Denied.

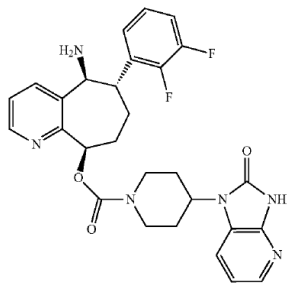
65. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '372 patent would induce and/or contribute to the infringement of one or more claims of the '372 patent under 35 U.S.C. §§ 271(b) and/or (c).

RESPONSE:

Denied.

66. For example, claim 1 of the '372 patent recites:

A hemisulfate salt of Compound (I):



RESPONSE:

Changzhou admits that claim 1 of the '372 patent is purportedly reproduced in this paragraph and it speaks for itself. Changzhou denies the remaining allegations of this paragraph.

67. The chemical structure recited in claim 1 for Compound (I) corresponds to

rimegepant. Upon information and belief, Changzhou's ANDA Product will contain a hemisulfate salt of rimegepant.

RESPONSE:

Changzhou admits that claim 1 of the '372 patent speaks for itself. Changzhou admits that Changzhou's ANDA Product contains rimegepant sulfate. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

68. Upon information and belief, Defendant has acted with full knowledge of the '372 patent and without a reasonable basis for believing that it would not be liable for infringement of the '372 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Product with its proposed labeling immediately and imminently upon approval of the Changzhou ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '372 patent.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Changzhou admits that it was aware of the '372 patent as of the date of the filing of its ANDA. Changzhou denies the remaining allegations of this paragraph.

69. Upon information and belief, if the FDA approves the Changzhou ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '372 patent, and will do so immediately and imminently upon approval.

RESPONSE:

Denied.

70. Upon information and belief, Defendant knows that Changzhou's ANDA Product is especially made or adapted for use in infringing the '372 patent, and that Changzhou's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '372 patent immediately and imminently upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

71. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '372 patent.

RESPONSE:

Denied.

72. Plaintiffs have no adequate remedy at law.

RESPONSE:

Denied.

73. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

RESPONSE:

Denied.

74. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Changzhou's ANDA Product with its proposed labeling will infringe the '372 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

RESPONSE:

Denied.

COUNT V
(Infringement of the '724 Patent)

75. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

RESPONSE:

Changzhou realleges and incorporates each of its answers to proceeding paragraphs as if fully set forth herein.

76. Defendant has infringed one or more claims of the '724 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Changzhou ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Changzhou's ANDA Product before the expiration of the '724 patent.

RESPONSE:

Denied.

77. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

RESPONSE:

Denied.

78. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

RESPONSE:

Denied.

79. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

RESPONSE:

Changzhou admits that claim 1 of the '724 patent is purportedly reproduced in this paragraph and it speaks for itself. Changzhou denies the remaining allegations of this paragraph.

80. Upon information and belief, Changzhou's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Changzhou's ANDA Product will be in a form of an oral solid molded fast-dispersing dosage form.

RESPONSE:

Changzhou admits that Changzhou's ANDA Product contains a pharmaceutical composition containing rimegepant sulfate. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

81. Upon information and belief, Defendant has acted with full knowledge of the '724 patent and without a reasonable basis for believing that it would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendant

has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Product with its proposed labeling immediately and imminently upon approval of the Changzhou ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '724 patent.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Changzhou admits that it was aware of the '724 patent as of the date of the filing of its ANDA. Changzhou denies the remaining allegations of this paragraph.

82. Upon information and belief, if the FDA approves the Changzhou ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

RESPONSE:

Denied.

83. Upon information and belief, Defendant knows that Changzhou's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Changzhou's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

84. Pfizer will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '724 patent.

RESPONSE:

Denied.

85. Pfizer has no adequate remedy at law.

RESPONSE:

Denied.

86. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

RESPONSE:

Denied.

COUNT VI
(Declaratory Judgment of Infringement of the '724 Patent)

87. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

RESPONSE:

Changzhou realleges and incorporates each of its answers to proceeding paragraphs as if fully set forth herein.

88. There is a substantial and immediate controversy between Pfizer and Changzhou concerning the '724 patent. Pfizer is entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Changzhou will infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

89. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or

importation of Changzhou's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

RESPONSE:

Denied.

90. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Changzhou's ANDA Product within the United States, or importation of Changzhou's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

RESPONSE:

Denied.

91. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

RESPONSE:

Changzhou admits that claim 1 of the '724 patent is purportedly reproduced in this paragraph and it speaks for itself. Changzhou denies the remaining allegations of this paragraph.

92. Upon information and belief, Changzhou's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Changzhou's ANDA product will be in a form of an oral solid molded fast-dispersing dosage form.

RESPONSE:

Changzhou admits that Changzhou's ANDA Product contains a pharmaceutical composition containing rimegepant sulfate. Changzhou lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies those allegations.

93. Upon information and belief, Defendant has acted with full knowledge of the '724 patent and without a reasonable basis for believing that it would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Changzhou's ANDA Product with its proposed labeling immediately and imminently upon approval of the Changzhou ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '724 patent.

RESPONSE:

This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Changzhou admits that it was aware of the '724 patent as of the date of the filing of its ANDA. Changzhou denies the remaining allegations of this paragraph.

94. Upon information and belief, if the FDA approves the Changzhou ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

RESPONSE:

Denied.

95. Upon information and belief, Defendant knows that Changzhou's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that

Changzhou's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Changzhou ANDA.

RESPONSE:

Denied.

96. Pfizer will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '724 patent.

RESPONSE:

Denied.

97. Pfizer has no adequate remedy at law.

RESPONSE:

Denied.

98. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

RESPONSE:

Denied.

99. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Changzhou's ANDA Product with its proposed labeling will infringe the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

RESPONSE:

Denied.

GENERAL DENIAL

Changzhou denies each allegation of the Complaint not expressly admitted.

CHANGZHOU'S RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

Changzhou denies that Plaintiffs are entitled to any relief sought in Plaintiffs' Prayer for Relief.

CHANGZHOU'S ADDITIONAL DEFENSES

Without prejudice to the admissions and denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Changzhou asserts the following defenses to the Complaint without any admissions as to the burden of proof on any such defense.

FIRST ADDITIONAL DEFENSE
(Non-Infringement of the '117 Patent)

Changzhou has not infringed, is not infringing, and will not infringe any valid claim of the '117 Patent.

SECOND ADDITIONAL DEFENSE
(Invalidity of the '117 Patent)

Each and every claim of the '117 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity.

THIRD ADDITIONAL DEFENSE
(Non-Infringement of the '372 Patent)

Changzhou has not infringed, is not infringing, and will not infringe any valid claim of the '372 Patent.

FOURTH ADDITIONAL DEFENSE
(Invalidity of the '372 Patent)

Each and every claim of the '372 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity.

FIFTH ADDITIONAL DEFENSE
(Non-Infringement of the '724 Patent)

Changzhou has not infringed, is not infringing, and will not infringe any valid claim of the '724 Patent.

SIXTH ADDITIONAL DEFENSE
(Invalidity of the '724 Patent)

Each and every claim of the '724 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity.

EIGHTH ADDITIONAL DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted.

NINTH ADDITIONAL DEFENSE
(Additional Defenses)

Any additional defenses or counterclaims that discovery may reveal.

CHANGZHOU'S PRAYER FOR RELIEF

Changzhou respectfully requests that this Court enter judgment in its favor and against Plaintiffs as follows:

A. Dismissing the Complaint with prejudice, denying each and every request for relief in Plaintiffs' Prayer for Relief, and that Plaintiffs take nothing thereby;

B. Finding that each and every claim of the '117 patent is invalid and/or was not, is not, and will not be infringed by Changzhou;

C. Finding that each and every claim of the '372 patent is invalid and/or was not, is not, and will not be infringed by Changzhou;

D. Finding that each and every claim of the '724 patent is invalid and/or was not, is not, and will not be infringed by Changzhou;

E. Declaring that Plaintiffs are not entitled to any injunctive remedy for the '117, '372 and/or '724 patents;

F. Awarding Changzhou its costs and expenses in this action;

G. Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding to Changzhou its reasonable attorneys' fees; and

H. Awarding to Changzhou such further relief this Court may deem just, proper, or equitable.

Dated: August 5, 2024

Of Counsel:
Howard Wang
WINDELS MARX LANE & MITTENDORF, LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
hwang@windelsmarx.com

SMITH KATZENSTEIN JENKINS LLP

/s/ Daniel A. Taylor
Neal C. Belgam (No. 2721)
Daniel A. Taylor (No. 6934)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400

Counsel for Defendant Changzhou Pharmaceutical Factory