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Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ALLERGAN PHARMACEUTICALS)
INTERNATIONAL LIMITED and)
ALLERGAN USA, INC.,)
)
Plaintiffs,)
)
v.)
)
SUN PHARMACEUTICAL)
INDUSTRIES LTD., SUN,)
PHARMACEUTICAL INDUSTRIES,)
INC., and SUN PHARMA GLOBAL FZE)
)
Defendants.)

Case No. 2:20-cv-10176-SDW-LDW

DEFENDANT SUN PHARMACEUTICAL INDUSTRIES INC.'S ANSWER,
DEFENSES AND COUNTERCLAIMS

Defendant Sun Pharmaceutical Industries Inc. (“Sun” or “Defendant”), by and through its undersigned attorneys, hereby submits its Answers, Defenses, and Counterclaims. Except as specifically admitted herein, Defendant denies the allegations contained in the Complaint by Allergan Pharmaceuticals International Limited and Allergan USA, Inc. (collectively, “Allergan” or, “Plaintiffs”) and maintains that Plaintiffs are not entitled to any relief.

RESPONSE TO SPECIFIC ALLEGATIONS

Sun hereby answers the numbered paragraphs of the Complaint with the following correspondingly numbered responses:

NATURE OF THE ACTION

1. Paragraph 1 contains conclusions of law for which no response is required. To the extent a response is required, Sun admits that the Complaint purports to set forth claims of patent infringement concerning U.S. Patent No. 9,089,492 (“the ’492 Patent”). Sun further admits that Sun Pharmaceutical Industries Ltd. (“Sun, Ltd.”) submitted ANDA No. 214718 (“Sun’s ANDA”) through its U.S. Agent Sun Pharmaceutical Industries Inc. to the FDA to obtain approval to engage in the commercial manufacture, use or sale of Mesalamine delayed-release tablets USP, 800 mg, (“Sun’s ANDA Product”) prior to expiration of the ’492 patent. Sun is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1 of the Complaint, and therefore denies them.

PARTIES

2. Sun admits that Allergan Pharmaceuticals International Limited (“Allergan Pharma”) purports to be the owner of New Drug Application (“NDA”) No. 021830, directed to Asacol® HD (mesalamine) for the treatment of moderately active ulcerative colitis in adults. Sun is without

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of the Complaint, and therefore denies them.

3. Sun is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint, and therefore denies them.

4. Sun admits that Sun, Ltd. is a corporation organized and existing under the laws of India, having a place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Gurgaon (East), Mumbai, Maharashtra, India, 400063. Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products. To the extent a further answer is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any remaining allegations in paragraph 4.

5. Sun admits that Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540. Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products. To the extent a further answer is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any remaining allegations in paragraph 5.

6. Sun admits that Sun Global Pharma FZE (“Sun Global”) was a corporation organized and existing under the laws of the Sharjah, United Arab Emirates and had its principal place of business in United Arab Emirates. Sun Global no longer exists as a corporate entity.

7. Sun admits that Sun is, and Sun Global was once, a wholly-owned subsidiary of Sun, Ltd., directly or indirectly. Sun admits that certain corporate Sun entities are in the business of

manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products. To the extent a further answer is required, Sun does not contest personal jurisdiction in this Court for purposes of this action only. Sun denies any remaining allegations in Paragraph 7.

8. The allegations of Paragraph 8 contain legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun is either directly or indirectly a wholly owned subsidiary of Sun, Ltd. Sun Global no longer exists as a corporate entity. Sun denies the remaining allegations of Paragraph 8.

9. Sun admits that Sun, Ltd. submitted ANDA No. 214718 through its U.S. Agent Sun Pharmaceutical Industries Inc. to the FDA seeking approval of its ANDA Product.

10. Admitted.

11. Paragraph 11 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun denies the allegations of Paragraph 11 of the Complaint.

12. Paragraph 12 of the Complaint contains contentions about future events. Sun does not have sufficient information about these future events to admit or deny, and therefore Sun denies the allegations of Paragraph 12 of the Complaint.

13. Paragraph 13 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun denies the allegations of Paragraph 13 of the Complaint.

JURISDICTION AND VENUE

14. Sun admits that this civil action of purported patent infringement arises under the patent laws of the United States, and that this Court has subject matter jurisdiction over Plaintiffs' claim

under 28 U.S.C. §§ 1331 and 1338. Sun denies the remaining allegations of Paragraph 14.

15. Paragraph 15 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. Except as expressly admitted, Sun denies the allegations of Paragraph 15. For the purposes of this action only, Sun does not contest personal jurisdiction in this Court.

16. Paragraph 16 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. Except as expressly admitted, Sun denies the allegations of Paragraph 16. For the purposes of this action only, Sun does not contest personal jurisdiction in this Court.

17. Paragraph 17 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States and in New Jersey. Except as expressly admitted, Sun denies the allegations of Paragraph 17. For the purposes of this action only, Sun does not contest personal jurisdiction in this Court.

18. Paragraph 18 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun admits that Sun, Ltd. properly notified Plaintiffs of its ANDA filing by letter of June 23, 2020 pursuant to 21 U.S.C. § 355(j)(2)(b). Sun denies the

remaining allegations of Paragraph 18.

19. Paragraph 19 of the Complaint contains contentions about future events. Sun does not have sufficient information about these future events to admit or deny, and therefore Sun denies the allegations of Paragraph 19 of the Complaint. Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

20. Paragraph 20 of the Complaint contains contentions about future events. Sun does not have sufficient information about these future events to admit or deny, and therefore Sun denies the allegations of Paragraph 20 of the Complaint. Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

21. Paragraph 21 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

22. Admitted.

23. Admitted.

24. Paragraph 24 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

25. Paragraph 25 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

26. Paragraph 26 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest personal jurisdiction in this

Court for the purposes of this action only.

27. Paragraph 27 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest venue in this judicial district for the purposes of this action only.

28. Paragraph 28 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest venue in this judicial district for the purposes of this action only.

29. Paragraph 29 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun does not contest venue in this judicial district for the purposes of this action only.

ALLERGAN'S ASACOL® HD DRUG PRODUCT

30. Sun admits that NDA No. 021830 is directed to a delayed-release oral tablet containing 800 mg of mesalamine, and that Allergan markets Asacol® HD which is approved for the treatment of moderately active ulcerative colitis in adults. Sun is without knowledge sufficient to form a belief in the remaining allegations of Paragraph 30 and therefore denies them.

31. Sun admits that the '492 patent is listed in the Orange Book in connection with NDA No. 021830. Sun denies the remaining allegations of Paragraph 31.

32. Paragraph 32 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun has not challenged the listing of the '492 patent in the Orange Book.

SUN'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

33. Paragraph 33 of the Complaint contains legal conclusions to which no answer is

required. To the extent a response is required, Sun admits that Sun, Ltd. sent its Notice Letter, dated June 23, 2020, to Plaintiffs. Sun further admits that Sun Ltd.'s Notice Letter states that its ANDA contains a paragraph IV certification for the '492 patent asserting that the claims of the '492 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun Ltd.'s ANDA Product. Except as expressly admitted, Sun denies the allegations of Paragraph 33 of the Complaint.

34. Admitted.

35. Sun admits that Sun, Ltd. sent its Notice Letter, dated June 23, 2020, to Plaintiffs pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Sun further admits that Sun Ltd.'s Notice Letter advises Plaintiffs of the submission of its ANDA No. 214718, and of the submission of a paragraph IV certification for patents listed in the Orange Book in connection with NDA No. 021830. Sun denies the remaining allegations of Paragraph 35 of the Complaint.

36. Sun admits that Sun Ltd. submitted ANDA No. 214718 to the FDA seeking approval to engage in the commercial manufacture, use or sale of Sun's ANDA Product prior to expiration of the '492, '662, and '302 Patents. Sun denies the remaining allegations of Paragraph 36 of the Complaint.

37. Sun admits that Sun Ltd.'s Notice Letter states that the claims of the '492 patent are invalid and will not be infringed by Sun Ltd.'s ANDA Product. To the extent a further response is required, Sun denies the remaining allegations of Paragraph 37.

38. Paragraph 38 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun is without knowledge sufficient to form a belief in the remaining allegations of Paragraph 38 and therefore denies them.

COUNT I: ALLEGED INFRINGEMENT OF THE '492 PATENT

39. Sun incorporates by reference each of its answers to Paragraphs 1 through 38 of the Complaint as though fully set forth herein.

40. Sun admits that the '492 patent bears an issue date of July 28, 2015 and is entitled "Pharmaceutical Dosage Form with Multiple Coatings for Reduced Impact of Coating Fractures." Sun denies the remaining allegations of Paragraph 40.

41. Sun is without knowledge sufficient to form a belief in the allegations of Paragraph 41 and therefore denies them.

42. Sun admits Allergan USA sells Asacol® HD in the United States. Sun denies the remaining allegations of Paragraph 42.

43. Paragraph 43 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Sun is without knowledge sufficient to form a belief in the allegations of Paragraph 43 and therefore denies them.

44. Admitted.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Sun admits that Sun Ltd. was aware of the '492 patent prior to filing its ANDA.

Otherwise, denied.

54. Denied.

55. Denied.

ANSWER TO PLAINTIFFS' REQUEST FOR RELIEF

Sun denies that Plaintiffs are entitled to the relief sought against Sun in Paragraphs A.-H. of the Complaint or any relief at all for the allegations relating to Sun made in the Complaint.

SEPARATE DEFENSES

Sun pleads the following defenses in response to Plaintiffs' allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein.

FIRST DEFENSE

Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

On information and belief, the '492 patent and each of its claims are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, *et seq.*

THIRD DEFENSE

The '492 patent and each of its claims are invalid for failing to meet judicially-created requirements for patentability.

FOURTH DEFENSE

The manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any claim of the '492 patent, either literally or under the doctrine of equivalents.

FIFTH DEFENSE

Plaintiffs are estopped from asserting any scope for any one of the claims of the '492 patent to cover and include Sun's ANDA Product because of amendments, representations, assertions, disclaimers, and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("USPTO") during prosecution of the application(s) leading to the issuance of the '492 patent.

SIXTH DEFENSE

To the extent not encompassed by Sun's Fifth Defense, Plaintiffs are estopped from construing the claims of the '492 patent to cover and include Sun's ANDA Product.

SEVENTH DEFENSE

Plaintiffs fail to state a proper claim for exceptional case under 35 U.S.C. § 285.

EIGHTH DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. §271(e)(2)(A) against any entity other than Sun Pharmaceutical Industries Ltd. because only this Sun entity owns and caused to be filed Sun's ANDA with a paragraph IV certification.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Sun reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Defendant/Counterclaimant Sun Pharmaceutical Industries Inc. (“Sun”), by and through their undersigned attorneys, counterclaim against Plaintiffs/Counter defendants Allergan Pharmaceuticals International Limited and Allergan USA, Inc. (“Counter defendants”) for declaratory judgment that no valid and enforceable claim of U.S. Patent No. 9,089,492 (“the ’492 patent”) is infringed or will be infringed under 35 U.S.C. § 271 by the submission of ANDA No. 214718 (“Sun’s ANDA”) or by the making, using, selling, offering for sale or importing of the drug product subject to Sun’s ANDA.

PARTIES

1. Counterclaimant Sun is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

2. On information and belief, and based on Counter defendants’ allegations, Counter defendant Allergan Pharma is a private company limited by shares under the laws of Ireland and having a registered office at Clonsaugh Business and Technology Park, Coolock, Dublin 17, Ireland.

3. On information and belief, Counter defendant Allergan USA is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

NATURE OF THE ACTION

4. Sun seeks a declaration that no valid and enforceable claim of the '492 patent is infringed by the mesalamine tablets described in Sun's ANDA and separately, that the '492 patent claims are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, *et seq.*

JURISDICTION AND VENUE

5. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

6. As a consequence of Counter defendants' Complaint against Sun, there is now an actual controversy between the parties concerning the infringement of the '492 patent.

7. This action arises under and the Court has jurisdiction over these counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2201(b) and 35 U.S.C. § 271 based on an actual controversy between Sun and Counter defendants arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court may declare the rights and legal relation of the parties pursuant to §§ 2201 and 2202 of Title 28 of the United States Code and § 271(e)(5) of Title 35 of the United States Code because the Counterclaims present an actual controversy within the Court's jurisdiction concerning the alleged infringement of the patent asserted by Counter defendants against Sun.

9. This Court has personal jurisdiction over the Counter defendants based, *inter alia*, on the filing by Counter defendants of this lawsuit in this jurisdiction.

10. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400(b),

and by Counter defendants' choice of forum.

COUNT I

(Declaratory Judgment of Invalidity of U.S. Patent No. 9,089,492)

11. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 10 of the Counterclaims as though fully set forth herein.

12. Counter defendants have asserted the '492 patent against Sun.

13. Counter defendants allege, and Sun denies, that the '492 patent is valid.

14. The '492 patent is invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 102, 103 and 112. Sun and Counter defendants have adverse legal interests, and there is a substantial controversy between Sun and Counter defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '492 patent.

15. Sun is entitled to a judicial declaration that the '492 patent is invalid.

COUNT II

(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,089,492)

16. Sun incorporates by reference and realleges its responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 15 of the Counterclaims as though fully set forth herein.

17. The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's proposed mesalamine delayed-release tablets

described in Sun's ANDA does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '492 patent.

18. Sun is entitled to a judicial declaration that the '492 patent is not infringed

PRAYER FOR RELIEF

WHEREFORE, Sun prays for the following relief:

- A. An order dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs;
- B. An order declaring that no valid and enforceable claim of the '492 patent is infringed by the submission of Sun's ANDA No. 214718 or by the making, use, sale, offer for sale, marketing or importation into the United States of mesalamine delayed-release tablets described in Sun's ANDA No. 214718;
- C. An order declaring that the claims of the '492 patent are invalid;
- D. An order declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Sun its attorneys' fees, costs, and expenses in this action; and
- E. Awarding Sun such other and further relief as the Court deems just and proper.

Dated: January 11, 2021

s/ Gregory D. Miller
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*Attorneys for Defendant Sun
Pharmaceutical Industries Inc.*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ Gregory D. Miller
Gregory D. Miller
Gregory.Miller@rivkin.com

Dated: January 11, 2021

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ Gregory D. Miller
Gregory D. Miller
Gregory.Miller@rivkin.com

Dated: January 11, 2021

CERTIFICATE OF SERVICE

I hereby certify that on this day I caused a true and correct copy of Defendant Sun Pharmaceutical Industries Inc.'s Answer, Defenses and Counterclaims to be served on all counsel of record via ECF.

By: s/ Gregory D. Miller
Gregory D. Miller
Gregory.Miller@rivkin.com

Dated: January 11, 2021