IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 20-1104-CFC
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

TEVA PHARMACEUTICALS USA, INC.'S
ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals USA, Inc. ("Teva") hereby answers the Complaint brought by Plaintiff Vanda Pharmaceuticals Inc. ("Vanda" or "Plaintiff"). Additionally, Teva hereby asserts counterclaims for declaratory judgment of invalidity and non-infringement of United States Patent Nos. 10,610,510 ("the '510 patent") and 10,610,511 ("the '511 patent") (collectively "the Asserted Patents").

With respect to the allegations made in the Complaint, Teva states as follows:

I. The Parties

1. Upon information and belief, admitted that Plaintiff Vanda is a Delaware corporation with its principal place of business at the address alleged. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in this paragraph and therefore denies them.

2. Admitted.

II. Nature of the Action

3. Teva admits that this purports to be an action for patent infringement of the Asserted Patents under the patent laws of the United States, Title 35, United States Code. Teva also admits that the Asserted Patents relate, at least in part, to the use of tasimelteon in the treatment of circadian rhythm disorders or sleep disorders. Teva denies the remaining allegations in Paragraph 3 of the Complaint.

4. Upon information and belief, admitted.

5. Admitted.

6. Admitted.

7. Admitted.

8. Upon information and belief, admitted.

9. Teva admits that its Detailed Statement explains that claims of the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the

manufacture, sale, or use of the proposed product described in the ANDA. Teva denies the remaining allegations of paragraph 9 of the Complaint.

10. Teva admits that its Detailed Statement explains that claims of the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, sale, or use of the proposed product described in the ANDA. Teva denies the remaining allegations of paragraph 10 of the Complaint.

11. Upon information and belief, admitted.

12. Denied.

13. Denied.

III. Jurisdiction

14. The allegations in Paragraph 14 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva admits that this Court has jurisdiction over the subject matter of this action.

15. The allegations in Paragraph 15 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest that the Court has personal jurisdiction over it for purposes of this matter only.

16. Admitted.

17. Admitted.

18. Teva admits that it prepared and filed ANDA No. 211601 seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation into the United States of the ANDA product before the expiration of the Asserted Patents. Teva denies the remaining allegations of Paragraph 18 of the Complaint.

19. Teva admits that it filed ANDA No. 211601 seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation into the United States of the ANDA product. Teva denies the remaining allegations of Paragraph 19 of the Complaint.

20. Teva admits that it filed ANDA No. 211601 seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation into the United States of the ANDA product before the expiration of the Asserted Patents. Teva denies the remaining allegations of Paragraph 20 of the Complaint.

IV. Venue

21. The allegations in Paragraph 21 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest venue for purposes of this matter only.

V. The Patents-In-Suit

(U.S. Patent Nos. 10,610,510 and 10,610,511)

U.S. Patent No. 10,610,510

22. In response to Paragraph 22 of the Complaint, Teva incorporates by reference Paragraphs 1 through 21 of this answer as if fully set forth herein.

23. Teva admits that the ’510 patent relates, at least in part, to methods of treating circadian rhythm disorders that involve “administering to a patient a dose of tasimelteon” and “determining whether the patient is a smoker.” Teva respectfully refers the Court to the patent itself for a full and accurate statement of its contents.

24. Teva admits that the quoted language is in the ’510 patent. Teva respectfully refers the Court to the patent itself for a full and accurate statement of its contents.

25. Teva admits that Exhibit A purports to be a copy of the ’510 patent titled “Treatment of Circadian Rhythm Disorders.” Teva admits that, on its face, the ’510 patent issued on April 7, 2020, and is assigned to Vanda. Teva further responds that, on its face, the ’510 patent lists Marlene M. Dressman, John J. Feeney, Louis W. Licamele, and Mihael H. Polymeropoulos as inventors. Teva denies that the patent was duly and legally issued. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 25 of the Complaint and on that basis denies them.

26. Teva admits that the ’510 patent relates, at least in part, to methods of treating circadian rhythm disorders that involve “administering to a patient a dose of tasimelteon” and “determining whether the patient is a smoker.” Teva respectfully refers the Court to the patent itself for a full and accurate statement of its contents.

U.S. Patent No. 10,610,511

27. In response to Paragraph 27 of the Complaint, Teva incorporates by reference Paragraphs 1 through 26 of this answer as if fully set forth herein.

28. Teva admits that the ’511 patent relates, at least in part, to the administration of “an effective dose of tasimelteon without food” to treat patients suffering from a circadian rhythm disorder or sleep disorder. Teva respectfully refers the Court to the patent itself for a full and accurate statement of its contents.

29. Teva admits that the quoted language is in the ‘511 patent. Teva respectfully refers the Court to the patent itself for a full and accurate statement of its contents.

30. Teva admits that Exhibit B purports to be a copy of the ’511 patent titled “Method of Treatment.” Teva admits that, on its face, the ’511 patent issued on April 7, 2020, and is assigned to Vanda. Teva further responds that, on its face, the ’511 patent lists Marlene M. Dressman, Mihael H. Polymeropoulos, and Paolo Baroldi as inventors. Teva denies that the patent was duly and legally issued. Teva

lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 30 of the Complaint and on that basis denies them.

31. Teva admits that the ’511 patent relates, at least in part, to methods of treating circadian rhythm disorders or sleep disorders using tasimelteon that involve “instructing the patient that tasimelteon should be taken without food.” Teva respectfully refers the Court to the patent itself for a full and accurate statement of its contents.

VI. Count I

(Infringement of the ’510 Patent)

32. In response to Paragraph 32 of the Complaint, Teva incorporates by reference Paragraphs 1 through 31 of this answer as if fully set forth herein.

33. Admitted.

34. Admitted.

35. Teva admits that it was aware of the ’510 patent from at least the filing of its Paragraph IV Certification for the ’510 patent. Teva denies the remaining allegations of paragraph 35 of the Complaint.

36. The allegations in Paragraph 36 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that the HETLIOZ® Label states, in part: “HETLIOZ is

indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).” Teva respectfully refers the Court to the HETLIOZ® Label for a complete and accurate statement of its contents. Teva denies the remaining allegations of Paragraph 36 of the Complaint.

37. The allegations in Paragraph 37 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that the HETLIOZ® Label states, in part: “The recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night.” Teva respectfully refers the Court to the HETLIOZ® Label for a complete and accurate statement of its contents. Teva denies the remaining allegations of Paragraph 37 of the Complaint.

38. The allegations in Paragraph 38 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that the HETLIOZ® Label states, in part: “Smoking causes induction of CYP1A2 levels. The exposure of tasimelteon in smokers was lower than in non-smokers and therefore the efficacy of HETLIOZ may be reduced in smokers [*see Clinical pharmacology (12.3)*].” To the extent that a response is required, Teva further admits that the HETLIOZ® Label states, in part: “Tasimelteon exposure decreased by approximately 40% in smokers, compared to nonsmokers [*see Use in Specific Populations (8.7)*].” Teva respectfully refers the

Court to the HETLIOZ® Label for a complete and accurate statement of its contents. Teva denies the remaining allegations of Paragraph 38 of the Complaint.

39. Admitted.

40. The allegations in Paragraph 40 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva denies the allegations of Paragraph 40 of the Complaint.

41. Admitted.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied

47. Teva denies that Plaintiff is entitled to any of the requested relief.

48. Teva denies that Plaintiff is entitled to any of the requested relief.

49. Teva denies that Plaintiff is entitled to any of the requested relief.

50. Denied.

51. Denied.

52. Denied.

VII. Count II

(Infringement of the ’511 Patent))

53. In response to Paragraph 53 of the Complaint, Teva incorporates by reference Paragraphs 1 through 52 of this answer as if fully set forth herein.

54. Admitted.

55. Admitted.

56. Teva admits that it was aware of the ’511 patent from at least the filing of its Paragraph IV Certification for the ’511 patent. Teva denies the remaining allegations of paragraph 56 of the Complaint.

57. The allegations in Paragraph 57 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that the HETLIOZ® Label states, in part: “HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).” Teva respectfully refers the Court to the HETLIOZ® Label for a complete and accurate statement of its contents. Teva denies the remaining allegations of Paragraph 57 of the Complaint.

58. The allegations in Paragraph 58 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that the HETLIOZ® Label states, in part: “The recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night.” Teva respectfully refers the Court to the HETLIOZ®

Label for a complete and accurate statement of its contents. Teva denies the remaining allegations of Paragraph 58 of the Complaint.

59. The allegations in Paragraph 59 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that the HETLIOZ® Label states, in part: "HETLIOZ should be taken without food *[see Clinical Pharmacology (12.3)]*." Teva respectfully refers the Court to the HETLIOZ® Label for a complete and accurate statement of its contents. Teva denies the remaining allegations of Paragraph 59 of the Complaint.

60. Teva admits that it filed ANDA No. 211601 to obtain approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24 and that the proposed label says, among other things, "[t]ake without food." Teva denies the remaining allegations of Paragraph 60.

61. The allegations in Paragraph 61 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva denies the allegations of Paragraph 61 of the Complaint.

62. Admitted.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Teva denies that Plaintiff is entitled to any of the requested relief.

69. Teva denies that Plaintiff is entitled to any of the requested relief.

70. Teva denies that Plaintiff is entitled to any of the requested relief.

71. Denied.

72. Denied.

73. Denied.

Prayer for Relief

This section of Plaintiff's Complaint constitutes a Prayer for Relief that do not require a response. Teva denies that Plaintiff is entitled to any of the requested relief or any other relief. Each averment and/or allegation contained in Plaintiff's Complaint that is not specifically admitted herein is hereby denied.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE
(Noninfringement)

Teva has not infringed, directly or indirectly, any valid claim of any of the Asserted Patents, and is not liable for any infringement thereof.

SECOND DEFENSE
(Invalidity)

Each claim of the Asserted Patents is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

RESERVATION OF DEFENSES

Teva reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") asserts the following counterclaims against Plaintiff and Counterclaim Defendant Vanda Pharmaceuticals Inc. ("Vanda").

Nature of Counterclaims

1. These counterclaims are for declaratory judgment that United States Patent Nos. 10,610,510 ("the '510 patent") and 10,610,511 ("the '511 patent") (collectively "the Asserted Patents") are invalid and not infringed.

The Parties

2. Teva Pharmaceuticals USA, Inc. is a Delaware corporation. Its principal place of business is at 400 Interpace Parkway, Parsippany, NJ 07054.

3. On information and belief and as alleged by Counterclaim Defendant, Vanda Pharmaceuticals Inc. is a Delaware corporation with its principal place of business at 2200 Pennsylvania Avenue NW, Suite 300E, Washington, DC 20037.

4. Counterclaim Defendant is the entity that filed the Complaint in this action on or about August 21, 2020.

Jurisdiction and Venue

5. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

7. Counterclaim Defendant has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this district.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400, and as a result of Counterclaim Defendant's choice of forum in filing this action.

Count I
Declaratory Judgment of Invalidity of U.S. Patent No. 10,610,510

9. Teva realleges and incorporates by reference Paragraphs 1 through 8 of these counterclaims as if fully set forth herein.

10. Counterclaim Defendant has alleged in this action that Teva infringed the ’510 patent by filing ANDA No. 211601 and that Teva’s manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed generic drug described in ANDA No. 211601 would infringe that patent.

11. The ’510 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

12. Accordingly, there is an actual, immediate, and justiciable controversy between the parties.

13. Teva is entitled to a declaration by the Court that one or more claims of the ’510 patent is invalid.

14. Teva is entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

Count II
Declaratory Judgment of Invalidity of U.S. Patent No. 10,610,511

15. Teva realleges and incorporates by reference Paragraphs 1 through 14 of these counterclaims as if fully set forth herein.

16. Counterclaim Defendant has alleged in this action that Teva infringed the '511 patent by filing ANDA No. 211601 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed generic drug described in ANDA No. 211601 would infringe that patent.

17. The '511 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or obviousness-type double patenting.

18. Accordingly, there is an actual, immediate, and justiciable controversy between the parties.

19. Teva is entitled to a declaration by the Court that one or more claims of the '511 patent is invalid.

20. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

Count III
Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,610,510

21. Teva realleges and incorporates by reference Paragraphs 1 through 20 of these counterclaims as if fully set forth herein.

22. No claim of the ’510 patent has been or will be infringed, either directly or indirectly, by Teva or by the users of Teva’s proposed generic drug described in ANDA No. 211601, either literally or under the doctrine of equivalents.

23. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendant concerning, *inter alia*, the issue of whether Teva’s manufacture, use, offer for sale, or sale of Teva’s proposed generic drug described in ANDA No. 211601 would infringe any valid and enforceable claim of the ’510 patent.

24. Teva is entitled to a declaratory judgment that the manufacture, use, offer for sale, or sale of Teva’s proposed generic drug described in ANDA No. 211601 has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the ’510 patent, either literally or under the doctrine of equivalents.

Count IV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,610,511

25. Teva realleges and incorporates by reference Paragraphs 1 through 24 of these counterclaims as if fully set forth herein.

26. No claim of the ’511 patent has been or will be infringed, either directly or indirectly, by Teva or by the users of Teva’s proposed generic drug described in ANDA No. 211601, either literally or under the doctrine of equivalents.

27. A present, genuine, and justiciable controversy exists between Teva and Counterclaim Defendant concerning, *inter alia*, the issue of whether Teva’s manufacture, use, offer for sale, or sale of Teva’s proposed generic drug described in ANDA No. 211601 would infringe any valid and enforceable claim of the ’511 patent.

28. Teva is entitled to a declaratory judgment that the manufacture, use, offer for sale, or sale of Teva’s proposed generic drug described in ANDA No. 211601 has not infringed, does not infringe, and will not infringe, either directly or indirectly, any claim of the ’511 patent, either literally or under the doctrine of equivalents.

Prayer for Relief

WHEREFORE, Teva prays that the Court enter judgment ordering as follows:

(a) declaring that the claims of the Asserted Patents are invalid;

(b) declaring that Teva does not infringe, either directly or indirectly, any claim of the Asserted Patents, either literally or under the doctrine of equivalents;

(c) if the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Teva reasonable attorney fees and costs reasonably incurred in prosecuting this action; and

(d) granting Teva such other and further relief as the Court deems just and appropriate.

/s/ Nathan R. Hoeschen

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Defendant

OF COUNSEL:
J.C. Rozendaal
Deirdre M. Wells
William H. Milliken
STERNE, KESSLER, GOLDSTEIN
& FOX P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600

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