IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 23-374-RGA
	)	
TEVA PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

DEFENDANT TEVA PHARMACEUTICALS, INC.'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals, Inc. ("Teva")[1], answers the Complaint for Patent Infringement brought by Plaintiff AbbVie Inc. ("AbbVie"). Additionally, Teva hereby asserts counterclaims for declaratory judgment of invalidity of U.S. Patent No. 11,542,239 ("the '239 patent").

With respect to the allegations made in the Complaint, upon knowledge with respect to Teva's own acts, and upon information and belief as to other matters, Teva responds and alleges and follows:

1. Teva admits that the above-captioned action purports to be a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, § 1, et. seq., and in particular under 35 U.S.C. § 271. Teva further admits that it submitted Abbreviated New Drug Application ("ANDA") No. 217642 (Teva's ANDA) to the

[1] In accordance with D.I. 8, all claims against Teva Pharmaceutical Industries Limited ("Teva Industries") have been dismissed without prejudice pursuant to Fed. R. Civ. P. 41(a)(2), and the case caption has been amended to remove Teva Industries. *Id*. at 4. Teva Industries takes no part in this Answer.

United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, or sale of elagolix sodium tablets, 150 mg and 200 mg ("Teva's ANDA Product"), before the expiration of the '239 patent.

2. Denied.

3. Admitted.

4. Teva admits that it is maintaining its certification for the '572, '351, and '551 patents. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4 of the Complaint and therefore denies them.

ORILISSA®

5. Teva admits that the FDA-approved Prescribing Information for ORILISSA states that it "is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis." Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 of the Complaint and therefore denies them.

6. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of the Complaint and therefore denies them.

7. Teva admits that the FDA-approved Prescribing Information for ORILISSA states that it "is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland." Teva further admits that the FDA-approved Prescribing Information for ORILISSA states that it is indicated for "the management of moderate to severe pain associated with endometriosis." Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 of the Complaint and therefore denies them.

8. Teva responds that New Drug Application ("NDA") No. 210450 was approved by

the FDA on July 23, 2018. Teva admits that the FDA-approved Prescribing Information for ORILISSA states that the dosage forms and strengths for ORILISSA are "[o]ral tablets: 150 mg and 200 mg." Teva further admits that the FDA-approved Prescribing Information for ORILISSA states that the "dosage and administration" for "normal liver function or mild hepatic impairment [is] 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months" and for "moderate hepatic impairment [is] 150 mg once daily for up to 6 months." Teva further admits that the FDA-approved Prescribing Information for ORILISSA states that it is indicated for "the management of moderate to severe pain associated with endometriosis." Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of the Complaint and therefore denies them.

9. Teva admits that the FDA lists AbbVie Inc. as the current holder of NDA No. 210450. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 9 of the Complaint and therefore denies them.

10. Teva admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") includes ORILISSA. Teva further admits that the Orange Book lists the '239 patent for ORILISSA EQ 150 MG Base, and the Orange Book lists the '239 patent for ORILISSA EQ 200 MG Base.

THE PARTIES

11. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint and therefore denies them.

12. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and therefore denies them.

13. Admitted.

14. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required.

15. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required.

16. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva admits that it conducts business in Delaware. Teva further admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale of Teva's ANDA Product. Teva denies any remaining allegations of Paragraph 16 of the Complaint.

17. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. To the extent a response is required, Teva admits that Teva's ANDA seeks approval for the manufacture and sale of Teva's ANDA Product. Teva denies any remaining allegations of Paragraph 17 of the Complaint.

18. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale of Teva's ANDA Product. Teva denies any remaining allegations of Paragraph 18 of the Complaint.

19. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva further responds that the allegations in Paragraph 19 relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

JURISDICTION AND VENUE

20. Teva incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

21. The allegations in Paragraph 21 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva admits that the above-captioned action purports to be a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C., § 1, et. seq., including 35 U.S.C. § 271.

22. The allegations in Paragraph 22 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

23. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. The allegations in Paragraph 23 pertaining to the likely destination of Teva's ANDA Product relate to future conduct to which no final decision has been made and Teva therefore denies those allegations. Teva further responds that the allegations in Paragraph 23 of the Complaint contain conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 23 of the Complaint.

24. The allegations in Paragraph 24 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 24 of the Complaint.

25. The allegations in Paragraph 25 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva admits that Corporation

Service Company, located at 251 Little Falls Drive, Wilmington, Delaware 19808, is its registered agent in the State of Delaware. Teva denies any remaining allegations in Paragraph 25 of the Complaint.

26. Teva admits that the website https://www.tevausa.com/globalassets/us/usa-files---global/teva-in-the-usa_fact-sheet_17.08.20.pdf, accessed June 27, 2023 states, among other things, that "Teva is the leading generic drug company in the United States, with a strong portfolio of specialty medicines." The allegations in Paragraph 26 pertaining to the likely destination of Teva's ANDA Product relate to future conduct to which no final decision has been made and Teva therefore denies those allegations. Teva denies any remaining allegations of Paragraph 26 of the Complaint.

27. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries.

28. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. The allegations in Paragraph 28 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 28 of the Complaint.

29. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale of Teva's ANDA Product. Teva denies any remaining allegations of

Paragraph 29 of the Complaint.

30. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva further responds that the allegations in Paragraph 30 of the Complaint contain conclusions of law to which no response is required. To the extent that a response is required, Teva does not contest personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 30 of the Complaint.

31. Denied.

32. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale of Teva's ANDA Product. Teva denies any remaining allegations of Paragraph 32 of the Complaint.

33. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required.

34. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required. Teva further responds that the allegations in Paragraph 34 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 34 of the Complaint.

35. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva

Industries. Teva further responds that the allegations in Paragraph 35 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 35 of the Complaint.

36. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale of Teva's ANDA Product before the expiration of the '239 patent. The allegations in Paragraph 36 pertaining to the likely destination of Teva's ANDA Product relate to future conduct to which no final decision has been made and Teva therefore denies those allegations. Teva denies any remaining allegations in Paragraph 36 of the Complaint.

37. The allegations in Paragraph 37 relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

38. The allegations in Paragraph 38 relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

39. Denied.

40. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. Teva further responds that the allegations in Paragraph 40 of the Complaint further contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations of Paragraph 40 of the Complaint.

41. Teva responds that in accordance with D.I. 8, all claims against Teva Industries

have been dismissed, and therefore no response is required.

42. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries. The allegations in Paragraph 42 of the Complaint further contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest that this Court has personal jurisdiction over it for purposes of this action only. Teva denies any remaining allegations in Paragraph 42 of the Complaint.

43. The allegations in Paragraph 43 of the Complaint contain conclusions of law to which no response is required. To the extent a response is required, Teva does not contest venue for the purposes of this action only.

44. Teva responds that in accordance with D.I. 8, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries.

FACTUAL BACKGROUND

The NDA

45. Teva admits that the FDA lists AbbVie Inc. as the current holder of NDA No. 210450 associated with ORILISSA (elagolix sodium) tablets, for oral use, 150 mg and 200 mg. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 45 of the Complaint and therefore denies them.

46. Teva admits that NDA No. 210450 was approved by the FDA on July 23, 2018. Teva further admits that the FDA-approved Prescribing Information for ORILISSA states that it is "indicated for the management of moderate to severe pain associated with endometriosis." Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 46 of the Complaint and therefore denies them.

47. Teva admits that the FDA-approved Prescribing Information for ORILISSA states that it is "indicated for the management of moderate to severe pain associated with endometriosis." Teva further admits that the FDA-approved Prescribing Information for ORILISSA states that "ORILISSA (elagolix sodium) tablets for oral administration contain elagolix sodium, the sodium salt of the active moiety of elagolix." Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 47 of the Complaint and therefore denies them.

The Asserted Patent

48. Teva admits that the face of the '239 patent bears the title "Elagolix Sodium Compositions and Processes." Teva further admits that the face of the '239 patent states that it was issued on January 3, 2023. Teva denies the remaining allegations of Paragraph 48 of the Complaint.

49. Teva admits that the Orange Book lists the expiration date of the '239 patent as July 23, 2039. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 of the Complaint pertaining to the ownership status of the '239 patent and therefore denies those allegations. Teva denies the remaining allegations of Paragraph 49 of the Complaint.

50. Admitted.

Teva's ANDA No. 217642

51. Admitted.

52. On information and belief, admitted.

53. On information and belief, admitted.

54. On information and belief, admitted.

55. The allegations in Paragraph 55 of the Complaint relate to future conduct to

which no final decision has been made and Teva therefore denies those allegations.

COUNT I

ALLEGED INFRINGEMENT OF THE '239 PATENT

56. Teva incorporates by reference each and every response to Paragraphs 1-56 as though fully set forth herein.

57. Admitted.

58. Admitted.

59. Teva admits that by submitting Teva's ANDA, it has represented to the FDA that Teva's ANDA Product has the same active ingredient as ORILISSA, has the same dosage forms and strengths as ORILISSA, and is bioequivalent to ORILISSA. Teva denies the remaining allegations of Paragraph 59 of the Complaint.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. The allegations in Paragraph 66 of the Complaint relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

67. Denied.

68. Denied.

69. Teva admits it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale Teva's ANDA Product. Teva denies the remaining allegations of Paragraph 69 of the Complaint.

70. Denied.

REQUEST FOR RELIEF

This section of the Complaint constitutes Requests for Relief that do not require a response. Teva denies that AbbVie is entitled to any of the requested relief or any other relief.

GENERAL DENIAL

Each averment or allegation contained in Plaintiff's Complaint that is not specifically admitted in this Answer is denied.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE: NON-INFRINGEMENT OF U.S. PATENT NO. 11,542,239

Teva does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '239 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE: INVALIDITY OF U.S. PATENT NO. 11,542,239

Each claim of the '239 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, or a judicially created basis for invalidation.

RESERVATION OF DEFENSES

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

TEVA PHARMACEUTICALS, INC.'S COUNTERCLAIM

Defendant and Counterclaim Plaintiff Teva Pharmaceuticals, Inc. asserts the following counterclaim against Plaintiff and Counterclaim Defendant AbbVie Inc.

NATURE OF THE COUNTERCLAIMS

1. This counterclaim includes a claim for declaratory judgment that U.S. Patent No.

11,542,239 ("the '239 patent") (the "counterclaim patent-in-suit") is invalid.

THE PARTIES

2. Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. On information and belief, AbbVie Inc. is an entity organized and existing under the laws of Delaware with a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

JURISDICTION AND VENUE

4. These counterclaims arise 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.

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

6. Counterclaim Defendant has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this District for purposes of these counterclaims.

7. Venue is proper for these counterclaims under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

8. The '239 patent is titled "Elagolix Sodium Composition and Processes" and issued on January 3, 2023.

9. Upon information and belief and as alleged in Counterclaim Defendant's Complaint, Counterclaim Defendant owns rights, title, and interests in and to the counterclaim patent-in-suit.

10. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists Abbvie Inc., as the holder of the New Drug Application ("NDA") No. 210450 for

ORILISSA. On information and belief, the active ingredient in ORILISSA is elagolix sodium.

11. Teva submitted ANDA No. 217642 under 21 U.S.C. § 355(j) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, or importation of elagolix sodium tablets, 150 mg and 200 mg ("Teva's ANDA Product"), prior to the expiration of the '239 patent.

12. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva submitted a certification in ANDA No. 217642 stating that the claims of the '239 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva's ANDA Product.

13. In accordance with 21 U.S.C. § 355(j)(2)(B), Teva notified Counterclaim Defendant in writing that Teva's ANDA was filed with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '239 patent is invalid, unenforceable, and/or will not be infringed by Teva's ANDA Product ("Teva's Notice Letter"). In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(ii), Teva's Notice Letter included a detailed statement of the factual and legal basis for the certification that the '239 patent is invalid, unenforceable, and/or will not be infringed by Teva's ANDA Product.

14. On April 3, 2023, Counterclaim-Defendant sued Teva in the District of Delaware, alleging infringement of the '239 patent.

COUNT I: DECLARATORY JUDGMENT OF INVALIDITY OF THE '239 PATENT

15. Teva incorporates by reference, as though fully set forth herein, Paragraphs 1 through 14 of the counterclaim.

16. Counterclaim-Defendant has alleged in this action that Teva infringed the '239 patent by filing ANDA No. 217642 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed drug product described in ANDA No. 217642 would infringe the '239 patent.

17. The ’239 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or another judicially created basis for invalidation.

18. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Counterclaim-Defendant regarding the validity of the claims of the ’239 patent.

19. Teva is entitled to a declaration by the Court that one or more of the claims of the ’239 patent are invalid.

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

PRAYER FOR RELIEF

WHEREFORE, Teva prays that the Court enter judgment in its favor against Plaintiff/Counterclaim Defendant as follows:

(a) Declaring that the claims of the ’239 patent are invalid.

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

(c) Granting Teva such other and further relief as the Court deems just and appropriate.

/s/ Nathan R. Hoeschen
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
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Teva Pharmaceuticals, Inc.

OF COUNSEL:
J.C. Rozendaal
Deirdre M. Wells
Christina Dashe
STERNE KESSLER GOLDSTEIN & FOX, PLLC
1100 New York Ave. NW
Suite 600
Washington, D.C. 20005
(202) 371-2600

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