IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 23-133-RGA
	)	
TEVA PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

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

Defendant Teva Pharmaceuticals Inc. ("Teva")[1] hereby answers the Complaint For Patent Infringement brought by Plaintiff Abbvie Inc. Additionally, Teva hereby asserts a counterclaim for declaratory judgment of invalidity of U.S. Patent No. 10,881,659 ("the '659 patent") and 11,045,470 ("the '470 patent") (collectively, "the patents-in-suit").

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

[1] In accordance with D.I. 7, all claims against Teva Pharmaceutical Industries Ltd. ("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.

NATURE OF THE ACTION[2]

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. 217650 (Teva's ANDA) to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, or sale of elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules ("Teva's ANDA Product"), before the expiration of the '659 patent and the '470 patent.

2. Denied

ORIAHNN®

3. Teva admits that the FDA-approved Prescribing Information for ORIAHNN states that it "is a combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women." Teva lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 3 of the Complaint and therefore denies them.

4. Teva admits that the FDA-approved Prescribing Information for ORIAHNN 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 ORIAHNN states that it results in "dose-dependent

[2] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of the ovarian sex hormones estradiol and progesterone and reduces bleeding associated with uterine fibroids." Teva lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 4 of the Complaint and therefore denies them.

5. Teva responds that New Drug Application ("NDA") No. 213388 was approved by the FDA on May 29, 2020. Teva admits that the FDA-approved Prescribing Information for ORIAHNN states that the dosage form for ORIAHNN "consists of two capsules…[t]he morning (AM) capsule…[and] [t]he evening (PM) capsule." Teva further admits that the FDA-approved Prescribing Information for ORIAHNN states that ORIAHNN's morning capsule contains "300 mg elagolix, 1 mg estradiol, and 0.5 mg norethindrone acetate," and ORIAHNN's evening capsule contains "300 mg elagolix." Teva lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 5 of the Complaint and therefore denies them.

6. Teva admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") includes ORIAHNN. Teva further admits that the Orange Book lists the '659 patent and the '470 patents for ORIAHNN.

THE PARTIES

7. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint and therefore denies them.

8. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and therefore denies them.

9. Admitted.

10. Teva responds that in accordance with D.I. 7, all claims against Teva Industries have been dismissed, and therefore no response is required.

11. Teva responds that in accordance with D.I. 7, all claims against Teva Industries have been dismissed, and therefore no response is required.

12. Teva responds that in accordance with D.I. 7, 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 12 of the Complaint.

13. Teva responds that in accordance with D.I. 7, 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 13 of the Complaint.

14. Teva responds that in accordance with D.I. 7, 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 14 of the Complaint.

15. Teva responds that in accordance with D.I. 7, 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 15 relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

JURISDICTION AND VENUE

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

17. The allegations in Paragraph 17 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.

18. The allegations in Paragraph 18 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).

19. Teva responds that in accordance with D.I. 7, 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. The allegations in Paragraph 19 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 19 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 19 of the Complaint.

20. The allegations in Paragraph 20 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 20 of the Complaint.

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 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 21 of the Complaint.

22. Teva admits that the website https://www.tevausa.com/globalassets/us/usa-files---global/teva-in-the-usa_factsheet_17.08.20.pdf, accessed Feb 16, 2023 states "Teva is the leading generic drug company in the United States, with a strong portfolio of specialty medicines." Teva admits that it conducts business in Delaware. The allegations in Paragraph 22 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 22 of the Complaint.

23. Teva responds that in accordance with D.I. 7, all claims against Teva Industries have been dismissed, and therefore no response is required as to allegations pertaining to Teva Industries.

24. Teva responds that in accordance with D.I. 7, 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 denies any remaining allegations in Paragraph 24 of the Complaint.

25. Teva responds that in accordance with D.I. 7, 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 25 of the Complaint.

26. Teva responds that in accordance with D.I. 7, 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 26 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 26 of the Complaint.

27. Denied.

28. Teva responds that in accordance with D.I. 7, 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 28 of the Complaint.

29. Teva responds that in accordance with D.I. 7, all claims against Teva Industries have been dismissed, and therefore no response is required.

30. Teva responds that in accordance with D.I. 7, all claims against Teva Industries have been dismissed, and therefore no response is required. 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 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 30 of the Complaint.

31. Teva responds that in accordance with D.I. 7, 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 31 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 31 of the Complaint.

32. Teva responds that in accordance with D.I. 7, 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 '659 and '470 patents. The allegations in Paragraph 32 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 32 of the Complaint.

33. The allegations in Paragraph 33 relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

34. The allegations in Paragraph 34 relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

35. Denied.

36. Teva responds that in accordance with D.I. 7, 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 36 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 36 of the Complaint.

37. Teva responds that in accordance with D.I. 7, all claims against Teva Industries have been dismissed, and therefore no response is required.

38. Teva responds that in accordance with D.I. 7, 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 38 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 38 of the Complaint.

39. The allegations in Paragraph 39 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.

40. Teva responds that in accordance with D.I. 7, 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

41. Teva admits that the FDA lists AbbVie Inc. as the current holder of NDA No. 213388 associated with ORIAHNN ((elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules). Teva lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 41 of the Complaint and therefore denies them.

42. Teva admits that NDA No. 213388 was approved by the FDA on May 29, 2020. Teva further admits that the FDA-approved Prescribing Information for ORIAHNN states that it is "indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women." Teva lacks knowledge or information sufficient to form a

belief as to the truth of any remaining allegations in Paragraph 42 of the Compliant and therefore denies them.

43. Teva admits that the FDA-approved Prescribing Information for ORIAHNN states that it is "indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women." Teva further admits that the FDA-approved Prescribing Information for ORIAHNN states that it contains elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules. Teva lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 43 of the Complaint and therefore denies them.

The Asserted Patents

44. Teva admits that the face of the '659 patent bears the title "Methods of Treating Heavy Menstrual Bleeding." Teva further admits that the face of the '659 patent states that it was issued on January 5, 2021. Teva denies any remaining allegations of Paragraph 44 of the Complaint.

45. Teva admits that the Orange Book lists the expiration date of the '659 patent as March 14, 2034. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of the Complaint pertaining to the ownership status of the '659 patent and therefore denies those allegations. Teva denies any remaining allegations of Paragraph 45 of the Complaint.

46. Admitted.

47. Teva admits that the face of the '470 patent bears the title "Methods of Treating Heavy Menstrual Bleeding." Teva further admits that the face of the '470 patent states that it was issued on June 29, 2021. Teva denies any remaining allegations of Paragraph 47 of the Complaint.

48. Teva admits that the Orange Book lists the expiration date of the '470 patent as March 14, 2034. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of the Complaint pertaining to the ownership status of the '470 patent and therefore denies those allegations. Teva denies any remaining allegations of Paragraph 48 of the Complaint.

49. Admitted.

Teva's ANDA No. 217650

50. Admitted.

51. Admitted.

52. Admitted.

53. On information and belief, admitted.

54. The allegations in Paragraph 54 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 '659 PATENT

55. Teva incorporates by reference each and every response to Paragraphs 1-54 as though fully set forth herein.

56. Admitted.

57. Admitted.

58. 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 ORIAHNN, has the same dosage forms

and strengths as ORIAHNN, and is bioequivalent to ORIAHNN. Teva denies any remaining allegations of Paragraph 58 of the Complaint.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. The allegations in Paragraph 65 of the Complaint relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

66. Denied.

67. Denied.

68. Teva admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale Teva's ANDA Product. Teva denies any remaining allegations of Paragraph 68 of the Complaint.

69. Denied.

COUNT II

ALLEGED INFRINGEMENT OF THE '470 PATENT

70. Teva incorporates by reference each and every response to Paragraphs 1-69 as though fully set forth herein.

71. Admitted.

72. Admitted.

73. 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 ORIAHNN, has the same dosage forms

and strengths as ORIAHNN, and is bioequivalent to ORIAHNN. Teva denies any remaining allegations of Paragraph 73 of the Complaint.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. The allegations in Paragraph 80 of the Complaint relate to future conduct to which no final decision has been made and Teva therefore denies these allegations.

81. Denied.

82. Denied.

83. Teva admits that it submitted Teva's ANDA to the FDA seeking approval for the manufacture and sale Teva's ANDA Product. Teva denies any remaining allegations of Paragraph 83 of the Complaint.

84. 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. 10,881,659

Teva does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '659 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE: INVALIDITY OF U.S. PATENT NO. 10,881,659

Each claim of the '659 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 any judicially created bases for invalidation.

THIRD DEFENSE: NON-INFRINGEMENT OF U.S. PATENT NO. 11,045,470

Teva does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '470 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE: INVALIDITY OF U.S. PATENT NO. 11,045,470

Each claim of the '470 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 any judicially created bases 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 COUNTERCLAIMS

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

NATURE OF THE COUNTERCLAIMS

1. These counterclaims include claims for declaratory judgment that U.S. Patent No. 10,881,659 ("the '659 patent") and 11,045,470 ("the '470 patent") (collectively, "the counterclaim patents-in-suit") are 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 '659 patent is titled "Methods of Treating Heavy Menstrual Bleeding" and issued on January 5, 2021.

9. The '470 patent is titled "Methods of Treating Heavy Menstrual Bleeding" and issued on June 29, 2021.

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

11. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists Abbvie Inc., as the holder of the New Drug Application ("NDA") No. 213388 for ORIAHNN. On information and belief, the active ingredients in ORIAHNN are elagolix sodium, estradiol, and norethindrone acetate.

12. Teva submitted ANDA No. 217650 under 21 U.S.C. § 355(j) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, or importation of elagolix sodium (eq. 300 mg base), estradiol (1 mg), and norethindrone acetate (0.5 mg) oral capsules copackaged with elagolix sodium (eq. 300 mg base) oral capsules ("Teva's ANDA Product"), prior to the expiration of the counterclaim patents-in-suit.

13. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva submitted a certification in ANDA No. 217650 stating that the claims of the counterclaim patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Teva's ANDA Product.

14. 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 counterclaim patents-in-suit are 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

counterclaim patents-in-suit are invalid, unenforceable, and/or will not be infringed by Teva's ANDA Product.

15. On February 3, 2023, Counterclaim-Defendant sued Teva in the District of Delaware, alleging infringement of the counterclaim patents-in-suit.

COUNT I: DECLARATORY JUDGMENT OF INVALIDITY OF THE '659 PATENT

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

17. Counterclaim-Defendant has alleged in this action that Teva infringed the '659 patent by filing ANDA No. 217650 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. 217650 would infringe the '659 patent.

18. The '659 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or other judicially created basis for invalidation.

19. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Counterclaim-Defendant regarding the validity of the claims of the '659 patent.

20. Teva is entitled to a declaration by the Court that one or more of the claims of the '659 patent are invalid.

21. 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 THE '470 PATENT

22. Teva incorporates by reference, as though fully set forth herein, Paragraphs 1 through 21 of the counterclaims

23. Counterclaim-Defendant has alleged in this action that Teva infringed the '470 patent by filing ANDA No. 217650 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. 217650 would infringe the '470 patent.

24. The '470 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or other judicially created basis for invalidation.

25. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Counterclaim-Defendant regarding the validity of the claims of the '470 patent.

26. Teva is entitled to a declaration by the Court that one or more of the claims of the '470 patent are invalid.

27. 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 judgement in its favor against Plaintiff/Counterclaim Defendant as follows:

(a) Declaring that the claims of the '659 patent are invalid;

(b) Declaring that the claims of the '470 patent are invalid;

(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

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