IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

INSYS THERAPEUTICS, INC. and INSYS DEVELOPMENT COMPANY, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-1308-CFC
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

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

Defendants Teva Pharmaceuticals USA, Inc., ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (together as "Teva") hereby answer the Complaint brought by Plaintiffs Insys Therapeutics, Inc. ("Insys Tx") and Insys Development Company, Inc. ("Insys Development") (collectively "Insys" or "Plaintiffs"). Additionally, Teva USA hereby asserts a counterclaim for declaratory judgment of invalidity of U.S. Patent Nos. 8,486,972 ("the '972 patent"); 8,486,973 ("the '973 patent"); 8,835,459 ("the '459 patent"); 8,835,460 ("the '460 patent"); 9,241,935 ("the '935 patent"); 9,289,387 ("the '387 patent"); 9,642,797 ("the '797 patent"); and 9,642,844 ("the '844 patent") (collectively "the patents-in-suit").

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

The Parties

1. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations.

2. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations.

3. Teva admits that Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva admits that Teva USA is an indirect, wholly-owned subsidiary of Teva Ltd.

4. Teva admits that Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva, 49131, Israel.

Nature of the Action

5. Teva admits that this purports to be an action for patent infringement of the patents-in-suit under the patent laws of the United States, Title 35, United States Code.

Jurisdiction and Venue

6. Teva admits that this action purports to arise under the patent laws of the United States. The remaining allegations in paragraph 6 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 pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. The allegations in paragraph 7 of the Complaint constitute conclusions of law to which no answer is required. To the extent that a response is required, Teva does not contest venue for purposes of this matter only. Teva denies the remaining allegations in paragraph 7 of the Complaint.

8. Teva admits that Teva USA is a Delaware corporation and that Teva USA's registered agent in Delaware is Corporate Creations Network Inc. located at 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810.

9. The allegations in paragraph 9 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva USA and Teva Ltd. do not contest that the Court has personal jurisdiction over them for purposes of this matter only. Teva denies the remaining allegations of paragraph 9 of the Complaint.

10. Teva admits Teva Ltd. is in the business of manufacturing and selling general pharmaceutical products. Teva denies the remaining allegations of paragraph 10.

11. Teva admits that Teva USA is in the business of manufacturing and distributing generic pharmaceutical products throughout United States, including in this judicial district. Teva denies the remaining allegations of paragraph 11.

12. Teva admits that Teva USA holds Pharmacy Wholesale Licenses from the State of Delaware under License Nos. A4-0001447 and -0001468 and Distributor/Manufacturer Licenses for Controlled Substances from the State of Delaware under License Nos. DM-0007115 and -0006546. Teva denies the remaining allegations of paragraph 12.

13. Teva admits that Teva USA filed the Abbreviated New Drug Application ("ANDA") No. 211209 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 13.

14. Denied.

15. The allegations in paragraph 15 of the Complaint constitute conclusions of law to which no answer is required. To the extent that a response is required, Teva does not contest personal jurisdiction or venue for purposes of this matter only. Otherwise, denied.

16. Teva admits that the pleadings associated with the civil actions specified in paragraph 16 of the Complaint speak for themselves. Otherwise, denied.

Insys's NDA and the Patents-in-Suit

17. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations.

18. Teva admits that Exhibit A purports to be a copy of United States Patent No. 8,486,972. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

19. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

20. Teva admits that Exhibit B purports to be a copy of United States Patent No. 8,486,973. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

21. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

22. Teva admits that Exhibit C purports to be a copy of United States Patent No. 8,835,459. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

23. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

24. Teva admits that Exhibit D purports to be a copy of United States Patent No. 8,835,460. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

25. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

26. Teva admits that Exhibit E purports to be a copy of United States Patent No. 9,241,935. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

27. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

28. Teva admits that Exhibit F purports to be a copy of United States Patent No. 9,289,387. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

29. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

30. Teva admits that Exhibit G purports to be a copy of United States Patent No. 9,642,797. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

31. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

32. Teva admits that Exhibit H purports to be a copy of United States Patent No. 9,642,844. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Plaintiffs' allegations and on that basis denies them.

33. Denied. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and on that basis denies them.

34. Admitted.

Teva's ANDA and Paragraph IV Notification

35. Teva admits that Teva USA filed an ANDA 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 patents-in-suit. Teva further admits that the ANDA included a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act. Teva denies the remaining allegations in paragraph 35 of the Complaint.

36. Teva admits that Teva USA sent written notice of its ANDA and its Paragraph IV certifications to Plaintiffs by letter dated July 9, 2018, and sent by Federal Express and United States Postal Service. Teva denies the remaining allegation in paragraph 36 of the Complaint.

37. The allegations in paragraph 37 of the Complaint constitute conclusions of law to which no answer is required. To the extent that a response is required, Teva denies them.

38. Teva admits that Teva USA previously filed ANDA No. 210135 and that Insys filed action number 17-cv-1303-GMS against Teva in this District asserting the same patents as the instant action. Teva denies the remaining allegations of paragraph 38 of the Complaint.

39. Teva admits that Teva USA previously filed ANDA No. 211209 and that Insys filed action number 18-cv-414-GMS against Teva in this District asserting the same patents as the instant action. Teva denies the remaining allegations of paragraph 39.

40. Denied.

Teva's Infringement of the Patents-In-Suit

41. In response to paragraph 41 of the Complaint, Teva incorporates by reference paragraphs 1 through 40 of this answer as if fully set forth herein.

42. Teva admits that, according to the applicable law and regulations, Teva USA submitted ANDA 211209 seeking FDA approval of the ANDA product. Teva denies the remaining allegations of paragraph 42 of the Complaint.

43. Teva admits that, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva USA included with its ANDA certifications that claims of the patents-in-suit listed in the Orange Book for SUBSYS® 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 43 of the Complaint.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

Prayer for Relief

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

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE
(Failure to State a Claim)

Plaintiffs fail to state a claim upon which relief can be granted.

SECOND DEFENSE
(Noninfringement)

Teva has not infringed, directly or indirectly, any valid claim of the patents-in-suit, and is not liable for any infringement thereof.

THIRD DEFENSE
(Invalidity)

Each claim of the patents-in-suit 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.

COUNTERCLAIM

Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA") asserts the following counterclaim against Plaintiffs and Counterclaim Defendants Insys Therapeutics, Inc. ("Insys Tx") and Insys Development Company, Inc. ("Insys Development") (collectively "Insys" or "Counterclaim Defendants").

Nature of Counterclaim

1. This counterclaim includes a claim for a declaratory judgment that U.S. Patent Nos. 8,486,972 ("the '972 patent"); 8,486,973 ("the '973 patent"); 8,835,459 ("the '459 patent"); 8,835,460 ("the '460 patent"); 9,241,935 ("the '935 patent"); 9,289,387 ("the '387 patent");

9,642,797 ("the '797 patent"); and 9,642,844 ("the '844 patent") (collectively "the patents-in-suit") are invalid.

The Parties

2. Teva USA is a Delaware corporation. Its principal place of business is at 1090 Horsham Road, North Wales, Pennsylvania 19454.

3. On information and belief, Counterclaim Defendant Insys Tx is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286.

4. On information and belief, Counterclaim Defendant Insys Development is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286.

5. On information and belief, Insys Development is a wholly owned subsidiary of Insys Tx.

6. Counterclaim Defendants are the entities that filed the Complaint in this action on or about March 16, 2018.

Jurisdiction and Venue

7. 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.

8. This Court has subject matter jurisdiction over this counterclaim pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

9. Counterclaim Defendants have availed themselves of this forum in this action and are therefore subject to personal jurisdiction in this district.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400, and as a result of Counterclaim Defendants' choice of forum.

Count I
Declaratory Judgment of Invalidity of U.S. Patent No. 8,486,972

11. Teva USA realleges and incorporates by reference paragraphs 1 through 10 of this counterclaim as if fully set forth herein.

12. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 8,486,972 by filing ANDA No. 211209 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. 211209 would infringe that patent.

13. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '972 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

14. The '972 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.

15. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '972 patent.

16. Teva USA is entitled to a declaration by the Court that one or more claims of the '972 patent is invalid.

17. Teva USA 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. 8,486,973

18. Teva USA realleges and incorporates by reference paragraphs 1 through 17 of this counterclaim as if fully set forth herein.

19. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 8,486,973 by filing ANDA No. 211209 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. 211209 would infringe that patent.

20. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '973 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

21. The '973 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.

22. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '973 patent.

23. Teva USA is entitled to a declaration by the Court that one or more claims of the '973 patent is invalid.

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

Count III
Declaratory Judgment of Invalidity of U.S. Patent No. 8,835,459

25. Teva USA realleges and incorporates by reference paragraphs 1 through 24 of this counterclaim as if fully set forth herein.

26. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 8,835,459 by filing ANDA No. 211209 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. 211209 would infringe that patent.

27. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '459 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

28. The '459 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.

29. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '459 patent.

30. Teva USA is entitled to a declaration by the Court that one or more claims of the '459 patent is invalid.

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

Count IV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,835,460

32. Teva USA realleges and incorporates by reference paragraphs 1 through 31 of this counterclaim as if fully set forth herein.

33. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 8,835,460 by filing ANDA No. 211209 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. 211209 would infringe that patent.

34. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '460 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

35. The '460 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.

36. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '460 patent.

37. Teva USA is entitled to a declaration by the Court that one or more claims of the '460 patent is invalid.

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

Count V
Declaratory Judgment of Invalidity of U.S. Patent No. 9,241,935

39. Teva USA realleges and incorporates by reference paragraphs 1 through 38 of this counterclaim as if fully set forth herein.

40. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 9,241,935 by filing ANDA No. 211209 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. 211209 would infringe that patent.

41. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '935 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

42. The '935 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.

43. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '935 patent.

44. Teva USA is entitled to a declaration by the Court that one or more claims of the '935 patent is invalid.

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

Count VI
Declaratory Judgment of Invalidity of U.S. Patent No. 9,289,387

46. Teva USA realleges and incorporates by reference paragraphs 1 through 45 of this counterclaim as if fully set forth herein.

47. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 9,289,387 by filing ANDA No. 211209 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. 211209 would infringe that patent.

48. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '387 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

49. The '387 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.

50. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '387 patent.

51. Teva USA is entitled to a declaration by the Court that one or more claims of the '387 patent is invalid.

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

Count VII
Declaratory Judgment of Invalidity of U.S. Patent No. 9,642,797

53. Teva USA realleges and incorporates by reference paragraphs 1 through 52 of this counterclaim as if fully set forth herein.

54. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 9,642,797 by filing ANDA No. 211209 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. 211209 would infringe that patent.

55. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '797 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

56. The '797 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.

57. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '797 patent.

58. Teva USA is entitled to a declaration by the Court that one or more claims of the '797 patent is invalid.

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

Count VIII
Declaratory Judgment of Invalidity of U.S. Patent No. 9,642,844

60. Teva USA realleges and incorporates by reference paragraphs 1 through 59 of this counterclaim as if fully set forth herein.

61. Counterclaim Defendants have alleged in this action that Teva USA has infringed U.S. Patent No. 9,642,844 by filing ANDA No. 211209 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. 211209 would infringe that patent.

62. The manufacture, use, or sale of the proposed generic drug described in ANDA No. 211209 would not infringe any valid and enforceable claim of the '844 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

63. The '844 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.

64. A present, genuine, and justiciable controversy exists between Teva USA, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's ANDA Product would infringe any valid and enforceable claim of the '844 patent.

65. Teva USA is entitled to a declaration by the Court that one or more claims of the '844 patent is invalid.

66. Teva USA 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 ordering as follows:

(a) adjudicating and declaring the patents-in-suit are invalid; and

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

/s/ Nathan R. Hoeschen

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