

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IBSA INSTITUT BIOCHIMIQUE, S.A.,)	
ALTERGON, S.A., MIST ACQUISITION,)	
LLC, and MIST PHARMACEUTICALS,)	
LLC,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 18-555-LPS
)	
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 Plaintiffs IBSA Institut Biochimique, S.A. (“IBSA”), Altergon, S.A. (“Altergon”), Mist Acquisition, LLC (“Mist”), and Mist Pharmaceuticals, LLC (“Mist Pharma”) (collectively, “Plaintiffs”). Additionally, Teva hereby asserts a counterclaim for declaratory judgment of invalidity of United States Patent Nos. 7,691,411 (“the ’411 patent”) and 7,723,390 (“the ’390 patent”) (collectively “the patents-in-suit”).

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

Nature of the Action

1. 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 based on Teva’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”). Teva further admits that it submitted ANDA No. 211369 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, or

importation into the United States, of the ANDA Product prior to the expiration United States Patent Nos. 7,691,411 and 7,723,390.

The Parties

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

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

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

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

6. Admitted.

The Patents-In-Suit

7. Teva admits that Exhibit A purports to be a copy of United States Patent No. 7,691,411, entitled "Pharmaceutical Formulae for Thyroid Hormones and Procedures for Obtaining Them." Teva further admits that Exhibit A, on its face, indicates that the United States Patent and Trademark Office issued the '411 patent on April 6, 2010. 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.

8. Teva admits that Exhibit B purports to be a copy of United States Patent No. 7,723,390. Teva further admits that Exhibit B, on its face, indicates that the United States Patent and Trademark Office issued the '390 patent on May 25, 2010. On its face the '390 patent is titled "Pharmaceutical Formulations for Thyroid Hormones." 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.

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

10. Admitted.

Teva's ANDA

11. Admitted.

12. Admitted.

13. Admitted.

14. Teva admits that, because Plaintiffs declined to agree to the terms of Teva's Offer of Confidential Access, Teva provided Plaintiffs with no further information regarding the ANDA Product beyond the information set forth in Teva's Paragraph IV Notification. Teva denies the remaining allegation in Paragraph 14 of the Complaint.

Jurisdiction and Venue

15. The allegations in Paragraph 15 of the Complaint constitute conclusions of law to which no response 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).

16. The allegations in Paragraph 16 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. Teva denies the remaining allegations of Paragraph 16 of the Complaint.

17. The allegations in Paragraph 17 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.

Count I
(Infringement of U.S. Patent No. 7,691,411)

18. In response to Paragraph 18 of the Complaint, Teva incorporates by reference Paragraphs 1 through 17 of this answer as if fully set forth herein.

19. Teva admits that, according to the applicable law and regulations, Teva submitted ANDA No. 211369 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States, of the ANDA Product prior to the expiration of the '411 patent. Teva denies the remaining allegations of Paragraph 19 of the Complaint.

20. Denied.

21. Denied.

22. Denied.

23. Denied.

Count II
(Infringement of U.S. Patent No. 7,723,390)

24. In response to Paragraph 24 of the Complaint, Teva incorporates by reference Paragraphs 1 through 17 of this answer as if fully set forth herein.

25. Teva admits that, according to the applicable law and regulations, Teva submitted ANDA No. 211369 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States, of the ANDA Product prior to the expiration of the '390 patent. Teva denies the remaining allegations of Paragraph 25 of the Complaint.

26. Denied.

27. Denied.

28. Denied.

29. 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”) asserts the following counterclaim against Plaintiffs and Counterclaim Defendants IBSA Institut Biochimique, S.A. (“IBSA”), Altergon, S.A. (“Altergon”), Mist Acquisition, LLC (“Mist”), and Mist Pharmaceuticals, LLC (“Mist Pharma”) (collectively “Counterclaim Defendants”).

Nature of Counterclaim

1. This counterclaim includes a claim for a declaratory judgment that United States Patent Nos. 7,691,411 (“the ’411 patent”) and 7,723,390 (“the ’390 patent”) (collectively “the patents-in-suit”) are invalid.

The Parties

2. Teva Pharmaceuticals USA, Inc. 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 IBSA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Via al Ponte, 13, CH-6900 Massagno, Switzerland.

4. On information and belief, Counterclaim Defendant Altergon is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Via Dogana Vecchia 2, CH-6901 Lugano, Switzerland.

5. On information and belief, Counterclaim Defendant Mist is a limited liability company formed and existing under the laws of Delaware, having a principal place of business at 11 Commerce Drive, Cranford, New Jersey 07016.

6. On information and belief, Counterclaim Defendant Mist Pharma is a limited liability company formed and existing under the laws of Delaware, having a principal place of business at 11 Commerce Drive, Cranford, New Jersey 07016.

7. Counterclaim Defendants are the entities that filed the Complaint in this action on or about April 13, 2018.

Jurisdiction and Venue

8. 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.

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

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

11. 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. 7,691,411**

12. Teva realleges and incorporates by reference Paragraphs 1 through 11 of this counterclaim as if fully set forth herein.

13. Counterclaim Defendants have alleged in this action that Teva has infringed U.S. Patent No. 7,691,411 by filing ANDA No. 211369 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. 211369 would infringe that patent.

14. The '411 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, 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 '411 patent.

16. Teva is entitled to a declaration by the Court that one or more claims of the '411 patent is invalid.

17. 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. 7,723,390

18. Teva 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 has infringed U.S. Patent No. 7,723,390 by filing ANDA No. 211369 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. 2211369 would infringe that patent.

20. The '390 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.

21. A present, genuine, and justiciable controversy exists between Teva, 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 '390 patent.

22. Teva is entitled to a declaration by the Court that one or more claims of the '390 patent is invalid.

23. 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 ordering as follows:

- (a) adjudicating and declaring the patents-in-suit are invalid; and
- (b) granting Teva such other and further relief as the Court deems just and appropriate.

OF COUNSEL:
J.C. Rozendaal
Michael Joffre
Deirdre Wells
STERNE, KESSLER, GOLDSTEIN & FOX
1100 New York Ave. NW, Suite 600
Washington, DC 20005
(202) 371-2600

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/s/ Karen E. Keller
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