IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ADAPT PHARMA OPERATIONS LIMITED, ADAPT PHARMA INC., ADAPT PHARMA LIMITED, and OPIANT PHARMACEUTICALS, INC., *Plaintiffs*, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., *Defendants*.	Civil Action No. 2:18-cv-09880 (JLL)(JAD)

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

Defendants Teva Pharmaceuticals USA, Inc., ("Teva USA") and Teva Pharmaceutical Industries Ltd., ("Teva Ltd.") (together as "Teva") hereby answer the Complaint brought by plaintiffs Adapt Pharma Operations Limited ("Adapt Limited"), Adapt Pharma Inc. ("Adapt Inc."), Adapt Pharma Limited ("Adapt Pharma"), and Opiant Pharmaceuticals, Inc. ("Opiant," together with Adapt Limited, Adapt Inc., and Adapt Pharma "Plaintiffs"). Additionally, Teva USA hereby asserts a counterclaim for declaratory judgment of invalidity of U.S. Patent No. 9,775,838 ("the '838 patent").

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

The Nature of the Action

1. Teva admits that this purports to be an action for patent infringement of the '838 patent under the patent laws of the United States, Title 35, United States Code. Teva admits that

Teva USA filed ANDA No. 209522 with the FDA and seeks approval to market a generic version of Adapt Limited's naloxone hydrochloride nasal spray, 4 mg/spray. Teva denies that Teva Ltd. filed an ANDA. Teva lacks knowledge or information sufficient to form a belief about the truth of Plaintiffs' remaining allegations in paragraph 1 of the Complaint and therefore denies them.

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. 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, Pennsylvania 19454.

7. 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.

8. Teva admits that Teva USA is an indirect, wholly-owned subsidiary of Teva Ltd.

9. Teva admits that Teva USA has prepared and submitted ANDAs to the United States Food and Drug Administration. Teva further admits that it manufactures and distributes

generic drugs for sale and use throughout the United States, including in this Judicial District. Teva denies the remaining allegations in paragraph 9 of the Complaint.

10. Denied.

11. Denied.

The Patent-in-Suit

12. Teva admits that Exhibit A purports to be a copy of the ’838 patent. 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.

The Narcan® Nasal Spray 4 mg Drug Product

13. Teva admits that publicly available documents list Adapt Limited as the holder of NDA 208411, which is sold under the name Narcan® Nasal Spray 4 mg. Teva further admits that the FDA-approved label for Narcan® states that it is approved as “an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.” The remaining allegations in paragraph 13 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of those allegations and on that basis denies them.

14. Teva admits that the ’838 patent is listed with respect to Narcan® Nasal Spray 4 mg in the “Approved Drug Product with Therapeutic Equivalence” published by the United States Food and Drug Administration. Teva denies the remaining allegations in paragraph 14 of the Complaint.

Jurisdiction and Venue

15. Teva admits that this action purports to arise under the patent laws of the United States. The remaining allegations in paragraph 15 of the Complaint constitute conclusions of law to which no response is required. To the extent a response 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 a response is required, Teva admits that Teva USA is registered to do business in the State of New Jersey and that its New Jersey Entity ID No. is 0100250184. Teva USA admits that it holds licenses in the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler," with License Nos. 5003436 and 5000583, respectively. Teva further admits that Teva USA has employees located at 8 Gloria Lane, Fairfield, New Jersey 07004; 400 Interpace Pkwy #3, Parsippany, New Jersey 07054; and 208 Passaic Avenue, Fairfield, New Jersey 07004. Teva admits that 200 Elmora Avenue, Elizabeth, New Jersey 07202 was listed as the return address on Teva USA's written notice of its Paragraph IV certification for the '838 patent. Teva further admits that Teva USA has a registered agent in New Jersey. Teva denies the remaining allegations of paragraph 16.

17. The allegations in paragraph 17 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is required, Teva admits that Teva USA is in the business of manufacturing and distributing pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. Teva denies the remaining allegations of paragraph 17.

18. The allegations in paragraph 18 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is required, Teva admits that Teva USA has prepared and submitted ANDAs to the United States Food and Drug Administration. Teva denies the remaining allegations of paragraph 18.

19. Teva admits that Teva USA has customers in the State of New Jersey. Teva denies the remaining allegations of paragraph 19.

20. Teva admits that the pleadings associated with the civil actions specified in paragraph 20 of the Complaint speak for themselves; Teva respectfully refers the Court to the respective pleadings for a complete and accurate statement of their contents. Otherwise, denied.

21. Teva admits that the pleadings associated with the civil actions specified in paragraph 21 of the Complaint speak for themselves; Teva respectfully refers the Court to the respective pleadings for a complete and accurate statement of their contents. Otherwise, denied.

22. The allegations in paragraph 22 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva admits that Teva USA is an indirect, wholly-owned subsidiary of Teva Ltd. and that Teva USA is in the business of manufacturing and distributing pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. Teva denies the remaining allegations in paragraph 22.

23. Teva admits that the pleadings associated with the civil actions specified in paragraph 23 of the Complaint speak for themselves; Teva respectfully refers the Court to the respective pleadings for a complete and accurate statement of their contents. Otherwise, denied.

24. Teva admits that the pleadings associated with the civil actions specified in paragraph 24 of the Complaint speak for themselves; Teva respectfully refers the Court to the respective pleadings for a complete and accurate statement of their contents. Otherwise, denied.

25. Denied.

26. Denied.

27. Denied.

28. The allegations in paragraph 28 of the Complaint constitute conclusions of law to which no response is required. To the extent that a response is required, Teva denies them. Teva does not contest personal jurisdiction in this Judicial District for the purpose of this action only.

29. Denied.

30. Teva admits that Teva USA has customers in the State of New Jersey. Otherwise, denied.

31. The allegations in paragraph 31 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 in this Judicial District for the purpose of this action only.

Acts Giving Rise to This Suit

32. Teva denies that Teva Ltd. filed an ANDA. 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 4 mg naloxone hydrochloride nasal spray. Otherwise, denied.

33. Denied.

34. Teva denies that Teva Ltd. filed an ANDA or provided written certification to the FDA. Teva admits that, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva USA certified that

the claims of the '838 patent listed in the Orange Book for Narcan® 4 mg are invalid, unenforceable, and/or will not be infringed by the manufacture, sale, or use of the proposed product described in Teva's ANDA. Otherwise, denied.

35. Teva denies that Teva Ltd. sent any written notice. Teva admits that Teva USA sent written notice of its ANDA and its Paragraph IV certifications to Plaintiffs, which was received by Plaintiffs on or about May 21, 2018. Otherwise, denied.

Count I: Infringement of the '838 Patent

36. In response to paragraph 36 of the Complaint, Teva incorporates by reference paragraphs 1 through 35 of this Answer as if fully set forth herein.

37. Teva admits that, according to the applicable laws and regulations, Teva USA submitted ANDA No. 209522 seeking FDA approval of its proposed product. Teva denies the remaining allegations in paragraph 37 of the Complaint.

38. Teva admits that there is justiciable controversy between Plaintiffs and Teva USA. Teva denies the remaining allegations in paragraph 38 of the Complaint.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. 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 of the '838 patent)

Teva has not infringed, directly or indirectly, any valid claim of the '838 patent, and is not liable for any infringement thereof.

THIRD DEFENSE
(Invalidity of the '838 patent)

Each claim of the '838 patent 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.

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 Adapt Pharma Operations Limited ("Adapt Limited"), Adapt Pharma Inc. ("Adapt Inc."), Adapt Pharma Limited ("Adapt Pharma"), and Opiant Pharmaceuticals, Inc. ("Opiant," together with Adapt Limited, Adapt Inc., and Adapt Pharma, "Counterclaim Defendants").

Nature of Counterclaim

1. This counterclaim includes a claim for a declaratory judgment that U.S. Patent No. 9,775,838 ("the '838 patent") is 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 and as alleged by Plaintiffs/Counterclaim Defendants, Counterclaim Defendant Adapt Limited is a limited company organized and existing under the laws of the Republic of Ireland, with a principal place of business at 45 Fitzwilliam Square, Dublin 2, Ireland.

4. On information and belief and as alleged by Plaintiffs/Counterclaim Defendants, Counterclaim Defendant Adapt Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 100 Matsonford Road, Building 4, Suite 201, Radnor, Pennsylvania 19087.

5. On information and belief and as alleged by Plaintiffs/Counterclaim Defendants, Counterclaim Defendant Adapt Pharma is a limited company organized and existing under the laws of the Republic of Ireland, with a principal place of business at 45 Fitzwilliam Square, Dublin 2, Ireland.

6. On information and belief and as alleged by Plaintiffs/Counterclaim Defendants, Counterclaim Defendant Opiant is a corporation organized and existing under the laws of Delaware, with a principal place of business at 201 Santa Monica Boulevard, Suite 500, Santa Monica, California 90401.

7. Counterclaim Defendants are the entities that filed the Complaint in this action on or about May 30, 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 Judicial District.

11. Venue in this Judicial District is proper under 28 U.S.C. §§ 1391 and 1400, and because Counterclaim Defendants have consented to venue by filing this action.

Count I
Declaratory Judgment of Invalidity of U.S. Patent No. 9,775,838

12. Teva USA realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1 through 11.

13. Counterclaim Defendants allege ownership of and exclusive license to the ’838 patent and have brought claims against Counterclaim Plaintiff alleging infringement of the ’838 patent.

14. The ’838 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

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

16. Teva USA is entitled to a declaration by the Court that one or more claims of the ’838 patent is invalid.

17. 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 '838 patent is invalid;

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

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

June 22, 2018

Respectfully submitted,

/s/ Michael E. Patunas

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COUNSEL FOR DEFENDANTS TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.

CERTIFICATE OF SERVICE

I, Michael E. Patunas, hereby certify that on this day of June 22, 2018, I caused a copy of Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd.'s Answer to the Complaint and Counterclaims to be served on counsel for Plaintiffs via the Court's ECF system.

/s/ Michael E. Patunas
Michael E. Patunas

RULE 11.2 CERTIFICATION

I hereby certify that the matters captioned *Adapt Pharma Operations Limited, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 16-07721 (consolidated) (JLL)(JAD) and *Adapt Pharma Operations Limited, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 18-05752 (JLL)(JAD) are related to the matter in controversy because the matter in controversy involves the same plaintiffs, the same defendants, the same patent families, and involves Abbreviated New Drug Applications seeking FDA approval to market naloxone hydrochloride drug products.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding nor are there any other non-parties known to Defendants that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: June 22, 2018

PATUNAS LAW LLC

/s/ Michael E. Patunas

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