DUANE MORRIS LLP
By: Richard L. Renck
222 Delaware Avenue, Suite 1600
Wilmington, DE 19801-1659
Telephone: +1 302 657 4900
Fax: +1 302 657 4901
Attorneys for Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Company GmbH

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: COPAXONE 775 PATENT LITIGATION	C.A. No. 16-1267-GMS **(CONSOLIDATED)**

AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS COMPANY GMBH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., and TEVA NEUROSCIENCE, INC., Defendant.	C.A. No. 17-cv-00074-GMS

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Amneal Pharmaceuticals LLC ("Amneal LLC") and Amneal Pharmaceuticals Company GmbH ("Amneal GmbH") (collectively, "Amneal"), by

and through their undersigned counsel, file this Complaint against defendant Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. (collectively "Defendants" or "Teva") seeking declaratory relief with respect to United States Patent Nos. 9,155,775 and 9,763,993. In support of this Complaint for Declaratory Judgment, Amneal alleges as follows:

The Parties

1. Amneal LLC is a limited liability company organized and existing under the laws of the State of Delaware and has a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863.

2. Amneal GmbH is a limited liability company organized and existing under the laws of Switzerland and has a principal place of business at Turmstrasse 30, 6312 Steinhausen, Switzerland.

3. Upon information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

4. Upon information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company having a place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

5. Upon information and belief, Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 11100 Nall Ave, Overland Park, KS 66211.

Nature of the Action

6. Amneal brings this declaratory judgment action of non-infringement and invalidity of one or more claims of United States Patent No. 9,155,775 ("the '775 patent") and United States Patent No. 9,763,993 ("the '993 patent") under 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j). True and correct copies of the '775 patent and the '993 patent are attached hereto as Exhibits A and B, respectively.

7. Upon information and belief, on October 13, 2015, the United States Patent and Trademark Office ("PTO") issued the '775 patent, entitled "Process for Manufacturing Glatiramer Acetate Product." The '775 patent lists, on its face, Rakefet Cohen, Sasson Habbah, and Muhammad Safadi as inventors of the patent.

8. Upon information and belief, on September 19, 2017, the PTO issued the '993 patent, entitled "Process for Manufacturing Glatiramer Acetate Product." The '993 patent lists, on its face Rakefet Cohen, Sasson Habbah, and Muhammad Safadi as inventors of the patent.

9. Teva Ltd. is listed as the assignee on the face of the '775 and '993 patents.

10. Upon information and belief, Teva Ltd. alleges that it has granted Teva USA an exclusive license under the '775 and '993 patents to use, offer to sell, sell and import the COPAXONE® 40 mg/mL product in the United States.

11. Upon information and belief, Teva USA is the holder of New Drug Application ("NDA") number 20-622, approved by the United States Food and Drug Administration ("FDA") for the use of glatiramer acetate 40 mg/mL three times per week, marketed under the trade name COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis.

12. Upon information and belief, Teva's COPAXONE® 40 mg/mL product is supplied as single-dose prefilled syringes that contain 40 mg/mL of glatiramer acetate for injection. Teva's COPAXONE® 40 mg/mL product is manufactured by Teva Ltd., and marketed and sold in the United States, including this district, by Teva Neuroscience.

13. Amneal filed Abbreviated New Drug Application ("ANDA") No. 207553 under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate 40 mg/mL ("Amneal's ANDA Product").

Prior and Pending Litigations Concerning Glatiramer Acetate

14. Teva has filed over a dozen patent infringement actions in this and other districts, against various entities that have sought approval from the FDA to

market and sell generic versions of Teva's 20 mg/mL daily COPAXONE® product and/or Teva's 40 mg/mL three-times-a-week ("TIW") COPAXONE® product. Teva has filed complaints alleging patent infringement against at least: (i) Sandoz Inc., Sandoz International GmbH, Novartis AG, and Momenta Pharmaceuticals, Inc. (hereinafter "Sandoz"), (ii) Mylan Pharmaceuticals Inc., Mylan Inc., and Natco Pharma Ltd. (hereinafter "Mylan"), (iii) Synthon Pharmaceuticals, Inc., Synthon Holding B.V., Synthon B.V., and Synthon S.R.O. Blankso (hereinafter "Synthon"), (iv) Doctor Reddy's Laboratories Ltd., and Doctor Reddy's Laboratories, Inc. (hereinafter "DRL"), (v) Biocon Ltd., and Apotex Corp. (hereinafter "Apotex"), and (vi) Amneal Pharmaceuticals LLC and Amneal GmbH.

15. Teva filed one of those complaints in this Court on February 3, 2015, against Amneal LLC for submission of ANDA No. 207553 relating to generic glatiramer acetate 40 mg/mL, asserting infringement of U.S. Patent Nos. 8,232,250 ("the '250 patent") and 8,399,413 ("the '413 patent") (*Teva Pharms. USA, Inc., et al. v. Amneal Pharms. LLC*, C.A. No. 15-124-GMS (D.Del.)).

16. On March 9, 2015, this Court consolidated multiple pending actions regarding glatiramer acetate 40 mg/mL products into *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.).

17. On April 10, 2015, Teva also sued Amneal LLC in this Court for patent infringement of U.S. Patent No. 8,969,302 ("the '302 patent") related to

ANDA No. 207553 (*Teva Pharms. USA, Inc., et al. v. Dr. Reddy's Labs, Ltd., et al.*, C.A. No. 1:15-0306-GMS (D.Del.)).

18. On April 30, 2015, Teva filed a First Amended Complaint in *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.). The First Amended Complaint named both Amneal LLC and Amneal GmbH as defendants.

19. On November 10, 2015, Teva filed a Second Amended Complaint in *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.). The Second Amended Complaint alleged patent infringement of U.S. Patent No. 9,155,776 ("the '776 patent"), related to ANDA No. 207553.

20. A bench trial was held before this Court in *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.) beginning on September 26 through October 6, 2016.

21. On December 19, 2016, Teva filed another suit against DRL, Sandoz, Mylan, Synthon, Amneal and Apotex for submission of their respective ANDAs relating to generic glatiramer acetate 40 mg/mL, asserting infringement of U.S. Patent No. 9,402,874 ("the '874 patent") (C.A. No. 1:16-cv-01267-GMS (D. Del.)).

22. On January 13, 2017, Teva filed suit against Sandoz in the U.S. District Court for the District of New Jersey (Civil Action No. 3:17-cv-00275-

FLW-DEA) asserting infringement of the '775 patent based on Sandoz's intent to commercially launch its ANDA product (hereinafter "Teva's New Jersey Complaint"). Teva's New Jersey Complaint alleges that "[u]pon information and belief, the processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL."

23. Teva's New Jersey Complaint further alleges that "[u]pon information and belief, [Sandoz] must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent in order for the product to be determined by the FDA to be the same as Teva's COPAXONE® 40 mg/mL and to meet any other requirements for FDA approval of [Sandoz's] Glatiramer Acetate Product."

24. On January 17, 2017, Teva filed a suit against Mylan in the U.S. District Court for the Northern District of West Virginia (Civil Action No. 1:17-cv-007) asserting infringement of the '775 patent based on Mylan's intent to commercially launch its ANDA product (hereinafter "Teva's West Virginia Complaint"). Teva's West Virginia Complaint alleges that "[u]pon information and belief, the processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL."

25. Teva's West Virginia Complaint further alleges that "[u]pon information and belief, [Mylan] must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent in order for the product to be determined by the FDA to be the same as Teva's COPAXONE® 40 mg/mL and to meet any other requirements for FDA approval of [Mylan's] Glatiramer Acetate Product."

26. On January 17, 2017, Teva filed suit against Synthon in the U.S. District Court for the Southern District of New York (Civil Action No. 1:17-cv-345) asserting infringement of the '775 patent based on Synthon's intent to commercially launch its ANDA product (hereinafter "Teva's New York Complaint"). Teva's New York Complaint alleges that "[u]pon information and belief, the processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL."

27. Teva's New York Complaint further alleges that "[u]pon information and belief, [Synthon] must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent in order for the product to be determined by the FDA to be the same as Teva's COPAXONE® 40 mg/mL and to meet any other requirements for FDA approval of [Synthon's] Glatiramer Acetate Product."

Existence of a Case of Actual Controversy

28. After close of business on Friday, January 20, 2017, Teva sent Amneal a letter seeking detailed information regarding the process for manufacturing Amneal's ANDA Product that is the subject of Amneal's ANDA No. 207553 for the "purpose of assessing infringement of the '775 patent." The letter provided only three (3) business days to respond. A copy of that letter is attached hereto as Exhibit C.

29. In view of at least (a) Teva's extensive history of filing patent infringement suits with respect to its COPAXONE® 20 mg/mL daily and COPAXONE® 40 mg/mL TIW products, (b) Teva's allegations in its New Jersey, West Virginia, and New York infringement complaints against Sandoz, Mylan and Synthon (respectively) that "the processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL," and (c) Teva's letter to Amneal threatening infringement of the '775 patent based on the Amneal's manufacturing process, Teva has posed an immediate and real threat of litigation against Amneal.

30. After Amneal sent Teva a courtesy copy of the Complaint in this action, Teva rushed to filed its own action against Amneal, alleging infringement of the '775 patent, in the United States District Court for the Eastern District of New York. That complaint overlaps with the issues in this Complaint and mirror

the allegations in several other separate '775 patent actions filed against several other defendants in various other districts. Teva has now stipulated and agreed that its '775 patent action against Amneal should be transferred to, and proceed in, this district.

31. The '993 patent issued from a continuation application of the application that issued as the '775 patent. Both patents name the same inventors (Rakefet Cohen, Sasson Habbah, and Muhammad Safadi) and the same assignee (Teva Ltd.). Further, both patents are entitled "Process for Manufacturing Glatiramer Acetate Product."

32. Amneal has made, and will continue to make, substantial preparations in connection with its request for FDA approval of its ANDA Product.

33. Upon FDA approval of Amneal's ANDA, Amneal will be able to market and sell its ANDA Product in the United States.

34. To avoid legal uncertainty and to protect Amneal's substantial investment (and anticipated future investment) in its ANDA Product, Amneal seeks declaratory relief with respect to the '775 and '993 patents.

35. Amneal has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '775 or '993 patents.

36. The totality of the circumstances support that a case or controversy exists with respect to the non-infringement and invalidity of the ’775 and ’993 patents.

Jurisdiction and Venue

37. This Court has subject matter jurisdiction over Amneal’s request for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, which are within the subject matter jurisdiction of this Court under 28 U.S.C. §§ 1331 and 1338(a).

38. Venue is proper as to both Teva USA and Teva Neuroscience in this Judicial District under 28 U.S.C. § 1400(b), since both are incorporated in the State of Delaware, and because they have agreed to venue in this Judicial District for this action (D.I. 42 at 5–6; D.I. 46 at 1).

39. Venue is proper as to Teva Ltd. in this Judicial District under 28 U.S.C. § 1391(c)(3) and because it has agreed to venue in this Judicial District for this action (D.I. 42 at 5–6; D.I. 46 at 1).

40. Teva’s threatening letter and prior litigations against Amneal and other defendants seeking approval to market generic glatiramer acetate products, including a glatiramer acetate 40 mg/mL product, give rise to an actual and justiciable controversy between Amneal and Teva as to the non-infringement and invalidity of the ’775 and ’993 patents. Absent a declaration of non-infringement

and invalidity, Teva's continued wrongful assertions of infringement related to Amneal's glatiramer acetate 40 mg/mL product that is the subject of ANDA No. 207553 will cause Amneal harm.

41. Teva is subject to general and specific personal jurisdiction in this judicial district based on Teva's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Teva at home in this forum, including the marketing of COPAXONE® throughout the United States, including this district.

42. Teva has availed itself of the rights, benefits, and privileges of this forum by asserting claims for the purpose of litigating patent infringement disputes in this district related to COPAXONE®, including the filing by Teva of lawsuits in this jurisdiction, including, *e.g.*, *In re Copaxone*, C.A. No. 14-1171-GMS (D. Del.).

FIRST COUNT
(Declaratory Judgment of Non-infringement of the '775 patent)

43. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

44. Teva claims to be the owner of all legal rights, title, and interests in the '775 patent, including the right to enforce the '775 patent.

45. Amneal has not infringed and does not infringe—directly, contributorily, or by inducement—any claim of the '775 patent.

46. Amneal seeks and is entitled to a declaration of non-infringement of the '775 patent pursuant to Title 35 of the United States Code.

SECOND COUNT
(Declaratory Judgment of Invalidity of the '775 patent)

47. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

48. The claims of the '775 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 120, and/or based on other judicially-created bases for invalidation.

49. Amneal seeks and is entitled to a declaration of invalidity of the '775 patent pursuant to Title 35 of the United States Code.

THIRD COUNT
(Declaratory Judgment of Non-infringement of the '993 patent)

50. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

51. Teva claims to be the owner of all legal rights, title, and interests in the '993 patent, including the right to enforce the '993 patent.

52. Amneal has not infringed and does not infringe—directly, contributorily, or by inducement—any claim of the '993 patent.

53. Amneal seeks and is entitled to a declaration of non-infringement of the ’993 patent pursuant to Title 35 of the United States Code.

FOURTH COUNT
(Declaratory Judgment of Invalidity of the ’993 patent)

54. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

55. The claims of the ’993 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 120, and/or based on other judicially-created bases for invalidation.

56. Amneal seeks and is entitled to a declaration of invalidity of the ’993 patent pursuant to Title 35 of the United States Code.

Prayers for Relief

WHEREFORE, Amneal prays:

A. That this Court find and declare that the making, using, selling, offering for sale, marketing, or importation of Amneal’s ANDA product does not and will not directly or indirectly infringe, or induce or contribute to the infringement of, any valid claim of the ’775 and ’993 patents;

B. That this Court find and declare that the ’775 and ’993 patents and all of their claims are invalid;

C. That this Court enjoin Teva, and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Amneal or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Amneal, or charging them either orally or in writing with infringement of the '775 and '993 patents;

D. That this Court award Amneal all of its costs for this action;

E. That this Court finding this case to be exceptional under 35 U.S.C. § 285 or otherwise and awarding Amneal its costs and reasonable attorneys' fees; and

F. That this Court grant Amneal such other and further relief as the Court deems just and proper.

Dated: October 19, 2017

DUANE MORRIS LLP

/s/ Richard L. Renck

Richard L. Renck (3893)
222 Delaware Avenue, Suite 1600
Wilmington, DE 19801-1659
Telephone: +1 302 657 4900
Fax: +1 302 657 4901
RLRenck@duanemorris.com

Of Counsel:
Anthony J. Fitzpatrick
Vincent L. Capuano
Christopher S. Kroon
Carolyn A. Alenci
(all to be admitted *pro hac vice*)

DUANE MORRIS LLP
100 High Street, Suite 2400
Boston, MA 02110-1724
(857) 488-4200
AJFitzpatrick@duanemorris.com
VCapuano@duanemorris.com
CSKroon@duanemorris.com
CAAlenci@duanemorris.com

Patrick C. Gallagher
(to be admitted *pro hac vice*)
DUANE MORRIS LLP
190 South LaSalle Street, Suite 3700
Chicago, IL 60603-3433
(312) 499-6759
PCGallagher@duanemorris.com

Attorneys for Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Company GmbH

DM2\7971987.5