

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL
INDUSTRIES LTD., and TEVA
NEUROSCIENCE, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC
and AMNEAL PHARMACEUTICALS
CO. GMBH,

Defendants.

Civil Action No. 17-416

Electronically Filed

COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. (collectively “Plaintiffs” or “Teva”) bring this action for patent infringement and declaratory judgment against defendants Amneal Pharmaceuticals LLC (“Amneal LLC”), Amneal Pharmaceuticals Company GmbH (“Amneal GmbH”) (collectively “Amneal”), and herein allege as follows:

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 9,155,775 (“the ’775 patent”) arising under the patent laws of the United States, Title 35, United States Code. This action arises out of Amneal’s ongoing attempt to market, manufacture and sell a generic version of COPAXONE[®] 40 mg/mL, 1 mL syringe, injection (“COPAXONE[®]”), Teva’s

innovative treatment for patients with relapsing-remitting forms of multiple sclerosis, prior to the expiration of the '775 patent.

THE PARTIES

Teva

2. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, PA 19454-1090.

3. Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

4. Teva Neuroscience, Inc. (“Teva Neuroscience”) is a Delaware corporation with its principal place of business at 11100 Nall Ave, Overland Park, KS 66211.

Amneal

5. Upon information and belief, Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware.

6. Upon information and belief, Amneal GmbH is a limited liability company organized and existing under the laws of Switzerland with a principal place of business at Turnstrasse 30, 6312 Steinhausen – Switzerland.

JURISDICTION AND VENUE

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

10. Teva sells COPAXONE® throughout the United States, including within the State of New York.

Personal Jurisdiction Over Amneal Pharmaceuticals GmbH

11. Upon information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals GmbH.

12. Upon information and belief, Amneal Pharmaceuticals GmbH (through its business partner Amneal Pharmaceuticals LLC) markets, distributes and/or sells generic drugs within the State of New York and throughout the United States.

13. Upon information and belief, Amneal Pharmaceuticals GmbH (through its business partner Amneal Pharmaceuticals LLC) has engaged in and maintained systematic and continuous business contacts within the State of New York, and has purposefully availed itself of the benefits and protections of the laws of New York rendering it at home in New York.

14. Upon information and belief, Amneal Pharmaceuticals GmbH (through its business partner Amneal Pharmaceuticals LLC) routinely files Abbreviated New Drug Applications (“ANDAs”) with the U.S. Food & Drug Administration (“FDA”) and markets dozens of generic pharmaceutical products in the State of New York, including, *inter alia*, azithroprine, benazepril hydrochloride, estradiol norethindrone acetate, and tramadol hydrochloride.

15. Upon information and belief, Amneal Pharmaceuticals GmbH (through its business partner Amneal Pharmaceuticals LLC) has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of New York, including, *inter alia*, azithroprine, benazepril hydrochloride, estradiol norethindrone acetate, and tramadol hydrochloride.

16. Upon information and belief, Amneal Pharmaceuticals GmbH has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will harm and injure Teva, which manufactures COPAXONE[®] 40 mg/mL product for sale and use throughout the United States, including the State of New York.

17. Teva sells COPAXONE[®] 40 mg/mL product in the State of New York.

18. Upon information and belief, Amneal Pharmaceuticals GmbH (through their business partner Amneal Pharmaceuticals LLC) has applied for FDA approval to market and sell a generic version of COPAXONE[®] 40 mg/mL product throughout the United States, including in New York.

19. Upon information and belief, Amneal Pharmaceuticals GmbH (through their business partner Amneal Pharmaceuticals LLC) will market, sell, and offer for sale its proposed generic version of COPAXONE[®] 40 mg/mL product in the State of New York following FDA approval of that product.

20. Upon information and belief, as a result of Amneal Pharmaceuticals GmbH's (through their business partner Amneal Pharmaceuticals LLC) marketing, selling, or offering for sale of its generic version of COPAXONE[®] 40 mg/mL product in the State of New York, Teva will lose sales of COPAXONE[®] 40 mg/mL product and be injured in the State of New York.

21. This Court also has personal jurisdiction over Amneal Pharmaceuticals GmbH under Federal Rule of Civil Procedure 4(k)(2).

22. Upon information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals GmbH for the reasons stated herein, including, *inter alia*, Amneal Pharmaceuticals GmbH's activities in the forum, activities directed at the forum, and significant

contacts with the forum, all of which render Amneal Pharmaceuticals GmbH at home in this forum.

Personal Jurisdiction Over Amneal Pharmaceuticals LLC

23. Upon information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals LLC.

24. Upon information and belief, Amneal Pharmaceuticals LLC has significant commercial operations in this district, including a manufacturing facility at 75 Adams Avenue Hauppauge, New York 11788.

25. Upon information and belief, Amneal Pharmaceuticals LLC has significant commercial operations in this district, including a manufacturing and research and development facility at 50 Horseblock Road, Brookhaven, New York 11719.

26. Upon information and belief, Amneal Pharmaceuticals LLC markets, distributes and/or sells generic drugs within the State of New York and throughout the United States.

27. Upon information and belief, Amneal Pharmaceuticals LLC has engaged in and maintained systematic and continuous business contacts within the State of New York, and has purposefully availed itself of the benefits and protections of the laws of New York rendering it at home in New York.

28. Upon information and belief, Amneal Pharmaceuticals LLC routinely files ANDAs and markets dozens of generic pharmaceutical products in the State of New York, including, *inter alia*, azithroprine, benazepril hydrochloride, estradiol norethindrone acetate, and tramadol hydrochloride.

29. Upon information and belief, Amneal Pharmaceuticals LLC has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products

in the State of New York, including, *inter alia*, azithroprine, benazepril hydrochloride, estradiol norethindrone acetate, and tramadol hydrochloride.

30. Upon information and belief, Amneal Pharmaceuticals LLC has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will lead to harm and injury to Teva, which manufactures COPAXONE[®] 40 mg/mL product for sale and use throughout the United States, including the State of New York.

31. Teva sells COPAXONE[®] 40 mg/mL product in the State of New York.

32. Upon information and belief, Amneal Pharmaceuticals LLC has applied for FDA approval to market and sell a generic version of COPAXONE[®] 40 mg/mL product throughout the United States, including in New York.

33. Upon information and belief, Amneal Pharmaceuticals LLC will market, sell, and offer for sale its proposed generic version of COPAXONE[®] 40 mg/mL product in the State of New York following FDA approval of that product.

34. Upon information and belief, as a result of Amneal Pharmaceuticals LLC's marketing, selling, or offering for sale of its generic version of COPAXONE[®] 40 mg/mL product in the State of New York, Teva will lose sales of COPAXONE[®] 40 mg/mL product and be injured in the State of New York.

35. Upon information and belief, this Court has personal jurisdiction over Amneal Pharmaceuticals LLC for the reasons stated herein, including, *inter alia*, Amneal Pharmaceuticals LLC's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Amneal Pharmaceuticals LLC at home in the forum.

36. Upon information and belief, following any FDA approval of Amneal's ANDA, Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals GmbH will work in concert with

one another to make, use, import, offer to sell, and sell a generic version of COPAXONE[®] 40 mg/mL product throughout the United States, including in New York.

37. Upon information and belief, Amneal Pharmaceuticals GmbH. will manufacture Amneal's proposed generic version of COPAXONE[®] 40 mg/mL product on behalf of Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals LLC will act as the agent of Amneal Pharmaceuticals GmbH for importation and sale of that product in the United States, including New York.

BACKGROUND

The '775 Patent

38. The '775 patent, entitled "Process for Manufacturing Glatiramer Acetate Product," was duly and legally issued to Teva Ltd. by the United States Patent and Trademark Office on October 13, 2015, and expires on January 28, 2035. The '775 Patent has 27 claims.

39. Rakefet Cohen, Sasson Habbah, and Muhammad Safadi are named inventors of the '775 patent.

40. Teva Ltd. is the sole owner, by assignment, of all rights, title and interest in the '775 patent.

41. Teva Ltd. has granted Teva USA an exclusive license under the '775 patent to use, offer to sell, sell and import the COPAXONE 40 mg/mL product in the United States.

42. A true and correct copy of the '775 patent is attached as Exhibit A.

Teva's COPAXONE[®] 40 mg/mL Product

43. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market COPAXONE[®] 40 mg/ml product.

44. 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 as COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

45. Teva’s innovative COPAXONE® 40 mg/mL product is supplied as single-dose prefilled syringes that contain 40 mg/ml glatiramer acetate for injection, manufactured by Teva Ltd., and marketed and sold in the United States by Teva Neuroscience.

46. The active drug ingredient in COPAXONE® 40 mg/mL is glatiramer acetate. Glatiramer acetate is a complex mixture of polypeptide chains made from four amino acid building blocks. The individual polypeptide chains in glatiramer acetate vary in length and the sequence in which the amino acids are connected together.

47. The invention claimed in the ’775 patent reflects, in part, the discovery that filtering pharmaceutical preparations of glatiramer acetate at temperatures of above 0° C to 17.5° C improves the filtration process used to manufacture pharmaceutical preparations and facilitates the commercial production of COPAXONE® 40 mg/mL.

48. Teva practices at least one of the claims of the ’775 patent in manufacturing COPAXONE® 40 mg/mL. In manufacturing COPAXONE® 40 mg/mL, Teva, *inter alia*, filters an aqueous pharmaceutical solution of glatiramer acetate and mannitol at a temperature of above 0° C to 17.5° C to produce a filtrate with improved filterability compared to the filterability of the solution at room temperature.

The Amneal ANDA

49. Amneal filed an ANDA 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 injection, 40 mg/mL, purported to be generic to Teva's COPAXONE[®] 40 mg/mL product ("Amneal's Glatiramer Acetate Product" or "Defendants' Glatiramer Acetate Product").

50. FDA assigned the ANDA for Amneal's Glatiramer Acetate Product the number 207553.

51. Upon information and belief, both Amneal Pharmaceuticals LLC. and Amneal Pharmaceuticals GmbH. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 207553.

52. In order to be approved by the FDA, the drug product described in an ANDA must be equivalent to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use.

53. In order to be approved by the FDA, the active ingredient in an ANDA product must be "the same as" the innovator's active ingredient. Thus, generic applicants must scientifically demonstrate that the active ingredient in their product is "the same as" the active ingredient in the innovator's product.

54. Given its complexity, COPAXONE[®] 40 mg/mL cannot be fully characterized. Moreover, the method of action of COPAXONE[®] 40 mg/mL has not been fully elucidated. Thus, while COPAXONE[®] 40 mg/mL has been demonstrated to be a safe and effective treatment for relapsing- remitting multiple sclerosis, the specific attributes of the product responsible for this safe and efficacious treatment have not been fully identified.

55. It is believed that the method of manufacturing COPAXONE® plays a role in the composition of, and therefore the action and effectiveness of Teva's COPAXONE® 40 mg/mL product.

56. Upon information and belief, Amneal has begun to manufacture and/or import commercial batches of Defendants' Glatiramer Acetate Product.

57. Upon information and belief, Defendants 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 Defendants' Glatiramer Acetate Product.

58. Upon 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.

59. Upon information and belief, Defendants intend to launch Defendants' Glatiramer Acetate Product upon receiving FDA approval which may occur as early as the first quarter of 2017, prior to the expiration of the '775 patent. Defendants have stated that they are working toward January 28, 2017 as their target for ANDA approval. *See In re Copaxone 40 mg Litigation*, C.A. No. 14-1171-GMS (D. Del.), Trial Tr. at 1729:3-5, 10-16, 20-23.

COUNT I FOR INFRINGEMENT OF
U.S. PATENT NO. 9,155,775 BY DEFENDANTS

60. The allegation of the preceding paragraphs 1-59 are realleged and incorporated herein by reference.

61. Upon information and belief, Amneal Pharmaceuticals LLC. currently infringes and has infringed one or more claims of the '775 patent under at least sections (a)-(c) and/or (g)

of 35 U.S.C. § 271 by the manufacture, marketing, sale, offer to sell and/or importation of the Amneal Glatiramer Acetate Product.

62. Upon information and belief, Amneal Pharmaceuticals GmbH currently infringes and has infringed one or more claims of the '775 patent under at least sections (a)-(c) and/or (g) of 35 U.S.C. § 271 by the manufacture, marketing, sale, offer to sell and/or importation of the Amneal Glatiramer Acetate Product.

63. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or importation of the Amneal Glatiramer Acetate Product.

64. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '775 patent. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '775 patent.

65. Teva will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of the Amneal Glatiramer Acetate Product. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT II FOR DECLARATORY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 9,155,775 BY DEFENDANTS**

66. The allegations of the preceding paragraphs 1-65 are realleged and incorporated herein by reference.

67. Upon information and belief, Defendants intend to manufacture, market, sell, offer to sell and/or import Defendants' Glatiramer Acetate product upon receiving FDA approval, as early as the first quarter of 2017.

68. Such conduct will constitute direct infringement of the '775 patent under 35 U.S.C. § 271(a), inducement of infringement of the '775 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and/or infringement of the '775 patent under 35 U.S.C. § 271(g).

69. As a result of the foregoing facts, there is an imminent, real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the '775 patent. Defendants' actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

70. Upon information and belief, Defendants will knowingly and willfully infringe the '775 patent.

71. Teva will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of the Amneal Glatiramer Acetate Product. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests the following relief:

- (a) a judgment that the '775 patent is infringed, not invalid, and enforceable;

(b) a judgment that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' Glatiramer Acetate Product prior to the expiration of the '775 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the '775 patent;

(c) an Order pursuant to 35 U.S.C. § 283 preliminarily and permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' Glatiramer Acetate Product, or any product or compound the use or manufacture of which infringes the '775 patent, or inducing or contributing to the infringement of the '775 patent until after the expiration of the '775 patent;

(d) an award of Teva's damages or other monetary relief to compensate Teva if Defendants engage in the commercial manufacture, use, offer to sell, sale, or marketing or distribution in, or importation into the United States of Defendants' Glatiramer Acetate Product, or any product or compound the use or manufacture of which infringes the '775 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '775 patent in accordance with 35 U.S.C. § 284;

(e) a judgment that this is an exceptional case and an award to Teva of its attorneys' fees under 35 U.S.C. § 285;

(f) a judgment that Amneal's infringement of the '775 patent is willful;

(g) an award of Teva's reasonable costs and expenses in this action; and

(h) an award of any further and additional relief to Teva as this Court deems just and proper.

Dated: January 25, 2017

Respectfully submitted,

OF COUNSEL:

By: /s/ David M. Hashmall

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