IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MOMENTA PHARMACEUTICALS, INC. Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., and TEVA NEUROSCIENCE, INC., Defendants.	C.A. No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

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Attorneys for Defendant Momenta Pharmaceuticals, Inc.

Dated: February 2, 2017

Plaintiff Momenta Pharmaceuticals, Inc. ("Momenta"), by and through its undersigned counsel, files this Complaint against Defendants 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 No. 9,155,775 ("the '775 patent"). In support of this Complaint for Declaratory Judgment, Momenta alleges as follows:

The Parties

1. Momenta Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142.

2. 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.

3. Upon information and belief, 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. 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.

Jurisdiction and Venue

5. Momenta brings this declaratory judgment action of non-infringement and invalidity of one or more claims of the '775 patent under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and 35 U.S.C. § 100 *et seq.* (including but not limited to at least 35 U.S.C. §§

102; 103; 112; 271; and 273), which are within the subject matter jurisdiction of this Court under 28 U.S.C. §§ 1331 and 1338(a).

6. 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 purported inventors of the patent.

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

8. Teva Pharmaceutical Industries, Ltd. is listed as the purported assignee on the face of the '775 patent.

9. Upon information and belief, Teva Ltd. alleges that it 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.

10. Upon information and belief, Teva USA has alleged it 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.

Prior and Pending Litigation involving Teva and Momenta

11. In 2008, Teva sued Momenta in the Southern District of New York (C.A. No. 08-cv-7611-WHP-AJP) in connection with Momenta's efforts to facilitate bringing to market (with Sandoz Inc.) a 20 mg/mL glatiramer acetate drug product that was a generic equivalent to Teva's 20 mg/mL COPAXONE® product.

12. In 2014, Teva sued Momenta in the District of Delaware (C.A. No. 14-cv-01171-GMS) in connection with Momenta's efforts to facilitate bringing to market (with Sandoz Inc.) a 40 mg/mL glatiramer acetate drug product that was a generic equivalent to Teva's 40 mg/mL COPAXONE® product.

13. Momenta is a Delaware corporation. Teva has specifically and actually threatened Momenta with litigation involving the '775 patent; has actually previously sued Momenta on the '775 patent; and as noted above has actually sued Momenta in this district in connection with several other patents involving the drug glatiramer acetate 40 mg/mL, *e.g.*, those at issue in the matter of *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.).

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, (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) Bicon Ltd., and Apotex Corp. (hereinafter "Apotex"), and (vi) Amneal Pharmaceuticals LLC and Amneal GmbH (hereinafter "Amneal").

15. More specifically, Teva filed one of those complaints in this Court on September 10, 2014, against Momenta 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 Pharm.*

USA, Inc., et al. v. Sandoz, Inc. and Momenta Pharmaceuticals, Inc., C.A. No. 1:14-cv-01171-GMS (D. Del.) (D.I. 1)).

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 Momenta and others in this Court for patent infringement of U.S. Patent No. 8,969,302 ("the '302 patent") related to Abbreviated New Drug Application ("ANDA") No. 206921 (*Teva Pharm. USA, Inc., et al. v. Doctor Reddy's Labs., Ltd., . . . Momenta Pharmaceuticals, Inc., . . . ,* C.A. No. 1:15-cv-00306-GMS (D. Del.)). On May 15, 2015 the Court consolidated C.A. No. 1:15-cv-00306-GMS (D. Del.) into *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.).

18. 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 by Sandoz Inc. and Momenta of U.S. Patent No. 9,155,776 ("the '776 patent").

19. 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.) from September 26 through October 6, 2016.

20. A Memorandum Opinion and Final Judgment was entered by this Court in *In re Copaxone 40 mg Consolidated Cases*, C.A. No. 1:14-cv-01171-GMS (D. Del.) (D.I. 294, 299) on January 30, 2017 and January 31, 2017, respectively.

21. On December 19, 2016, Teva filed another suit against DRL, Sandoz Inc., Momenta, 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 Inc. and Momenta in the U.S. District Court for the District of New Jersey, *Teva Pharm. USA, Inc., et al. v. Sandoz, Inc. and Momenta Pharmaceuticals, Inc.*, Civil Action No. 3:17-cv-00275-FLW-DEA (D.N.J.) (D.I. 1) asserting infringement of the '775 patent based on Sandoz Inc.'s intent to commercially launch its 40 mg/mL ANDA product (hereinafter "Teva's New Jersey Complaint"). Teva's New Jersey Complaint alleged 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." (Teva's New Jersey Complaint ¶ 56).

23. Teva's New Jersey Complaint further alleged that "[u]pon information and belief, [Sandoz Inc. and Momenta] 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 Inc.'s] Glatiramer Acetate Product." (Teva's New Jersey Complaint ¶ 55).

24. Momenta developed and Sandoz Inc. has commercially used, more than a year prior to January 28, 2015, the ANDA process for preparing both the Sandoz Inc. 20 mg and 40 mg/mL ANDA products.

25. After Momenta filed a motion to dismiss the New Jersey action against it for lack of personal jurisdiction, Teva dismissed its claims against Momenta, but without prejudice, and apparently solely to discourage the New Jersey district court from transferring the case to Delaware as urged by a Sandoz Inc. motion to transfer. (*See* C.A. No. 3:17-cv-00275-FLW-DEA (D.N.J.)

at D.I. 9, 10, 19). Thus, Momenta has a continuing and abiding belief of threatened and anticipated litigation against it from Teva on the '775 patent.

26. Further, 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-00007-IMK (D.I. 1)) 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." (Teva's West Virgina Complaint ¶ 76).

27. 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." (Teva's West Virgina Complaint ¶ 75).

28. 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-00345-LGS (D.I. 1)) 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." (Teva's New York Complaint ¶ 87).

29. 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 product and to meet any other requirements for FDA approval of [Synthon's] Glatiramer Acetate Product." (Teva's New York Complaint ¶ 86).

30. In December 2016, Teva sent Sandoz Inc. and Momenta a letter seeking detailed information regarding the process for manufacturing Sandoz Inc.'s ANDA 40 mg/mL product for the "purpose of assessing infringement of the '775 patent." After several rounds of correspondence; a request by Sandoz Inc. and Momenta for Teva to explain the basis for Teva's infringement accusations; and despite an offer by Sandoz Inc. and Momenta to identify areas of cooperation, Teva sued Sandoz Inc. and Momenta in New Jersey alleging infringement of the '775 patent on January 13, 2017 (C.A. No. 3:17-cv-00275-FLW-DEA (D.I. 1)).

31. Thus, 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, including against Momenta; (b) Teva's allegations in its New Jersey, West Virginia, and New York infringement complaints against Sandoz Inc. and Momenta, as well as other generic defendants such as 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 Sandoz Inc. and Momenta threatening infringement of the '775 patent based on the Sandoz Inc. product's manufacturing process, Teva has posed an immediate and real threat of litigation against Momenta.

32. Momenta, in connection with Sandoz Inc., made, and will continue to make, substantial commercial preparations in connection with the Sandoz Inc. 40 mg/mL product.

33. Upon FDA approval of Sandoz Inc.'s ANDA 206921, Momenta will be entitled to receive considerable contractually-defined profits from the marketing and selling of the Sandoz Inc. 40 mg/mL ANDA product in the United States.

34. To avoid legal uncertainty and to protect Momenta's substantial investment (and anticipated future investment) in the Sandoz Inc. 40 mg/mL ANDA product, Momenta seeks declaratory relief with respect to the '775 patent.

35. Momenta has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '775 patent.

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

37. Teva's threatening letters and prior litigations against Momenta and other defendants seeking approval to market generic glatiramer acetate products, including a glatiramer acetate 40 mg/mL product, including under the '775 patent, give rise to an actual and justiciable controversy between Momenta and Teva as to the non-infringement and invalidity of the '775 patent. Absent a declaration of non-infringement and invalidity, Teva's continued wrongful assertions of infringement related to Momenta and the Sandoz Inc. glatiramer acetate 40 mg/mL product will cause Momenta harm.

38. 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.

39. 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 40 mg Consolidated Cases*, C.A. No. 14-cv-01171-GMS (D. Del.).

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

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

41. Momenta repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

42. 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.

43. Momenta has not infringed and does not infringe—directly, contributorily, or by inducement—any valid and enforceable claim of the '775 patent, and will not infringe via the glatiramer acetate 40 mg/mL product that is the subject of the Sandoz Inc. ANDA 206921.

44. Momenta 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 Non-infringement of the '775 patent–Fair Use Defense)

45. Momenta repeats and incorporates by reference paragraphs 1-40 of its Complaint.

46. The America Invents Act ("AIA") became effective on September 16, 2011; through it, Congress expressly expanded the scope of the "prior user" defense to process patent infringement, which is found in 35 U.S.C. § 273, to include manufacturing processes.[1] Not only

[1] "The [America Invents] Act broadened the subject matter of the defense [beyond just business method patents] to protect businesses from having to disclose internal processes and technologies." *dunnhumby USA, LLC v. emnos USA Corp.*, Case No. 13-cv-00399, Dkt. 106, at 4 (N.D. Ill. June 27, 2014); *see also, e.g.*, 157 Cong. Rec. H4483 (daily ed. June 23, 2011) (statement of Rep. Smith) ("The prior-use defense . . . will protect American manufacturers from having to patent the hundreds or thousands of processes they already use in their plants."); 157 Cong. Rec. S5426 (daily ed. Sept. 8, 2011) (statements of Sen. Blunt and Sen. Leahy) (discussing that "the prior user rights

were the scope of protected processes expanded, but Congress expressly provided that processes presented in documents submitted for "premarketing regulatory review" (*i.e.*, FDA submissions) are "commercial use" for purposes of the defense. 35 U.S.C. § 273(c).

47. The '775 patent on its face identifies a filing date of January 28, 2015.

48. Momenta developed the process used to prepare its glatiramer acetate 20 and 40 mg/mL sterile formulations ("GA20" and "GA40", respectively) at least as of 2012.

49. The Sandoz ANDA filtration process was established for exhibit and commercial-scale batches and presented for pre-marketing regulatory review at least by December, 2012, which is more than one year before January 28, 2015 filing date of the '775 patent. The filtration process itself was first used in batches actually commercially sold in the United States.

50. This Sandoz ANDA process in place circa 2013—including the commercial-scale process—is the same one Teva accuses of infringement today. Moreover, as noted above, Teva's New Jersey Complaint alleged that Sandoz Inc. and Momenta "must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent," because "processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL." (Teva's New Jersey Complaint ¶¶ 55, 56). If such Teva infringement allegations were to be accepted as true, then the prior process is eligible for the prior use defense.

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provided under section 5 of H.R. 1249 will allow developers of innovative technologies to keep internally used technologies in-house without publication in a patent"); 157 Cong. Rec. S5430 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl) ("The prior-commercial-use defense provides relief to U.S. manufacturers . . . [by] allowing them to make long-term use of a manufacturing process without having to give it away to competitors or run the risk that it will be patented out from under them.").

51. Neither Sandoz Inc. nor Momenta were aware of the particular methodology that Teva used to prepare Teva's commercial formulations, or aware of the '775 patent application at the time those processes were developed. Nor did Sandoz Inc. or Momenta derive its methodology from Teva. Rather, in good faith, Momenta and Sandoz Inc. independently developed the process for preparing a sterile filtrate of GA20 or GA40, and used it commercially. Such commercial use (including as defined by 35 U.S.C. § 273(c)(1)), likewise involved arm's length commercial transfers on or before January 28, 2014.

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

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

53. Momenta repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

54. 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.

55. Upon information and belief, such defenses include (and particularly to the extent that the '775 patent's process is not limited to a limited scope as Teva represented to the USPTO), but are not limited to, that the '775 patent lacks utility across the full scope of what is claimed and/or is inoperable across the full scope of what it is claimed; is invalid for prior use and/or being on sale; would have been obvious to the person of ordinary skill in the art; includes claims with claim terms that are indefinite; encompasses subject matter for which there is no written description support; and the full scope of the claims is not fully enabled (at least for encompassing embodiments that lack operability).

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

FOURTH COUNT
(No injunctive remedy for the '775 patent)

57. Momenta repeats and incorporates by reference each of the foregoing paragraphs of its Complaint.

58. Neither the patent holder nor its exclusive licensee will in fact experience any harm from any Sandoz Inc. sales of the GA40 product that has nexus to the '775 patent claims.

59. Teva has unacceptably delayed in asserting the '775 patent.

60. Teva cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

61. Teva is not entitled to any injunctive remedy of any kind.

PRAYERS FOR RELIEF

WHEREFORE, Momenta prays:

A. That this Court find and declare that the making, using, selling, offering for sale, marketing, or importation of Sandoz Inc.'s GA40 mg/mL ANDA product, and any actions by Momenta relating thereto, does not and will not directly or indirectly infringe, or induce or contribute to the infringement of, any valid claim of the '775 patent;

B. That this Court find and declare that Sandoz Inc. and Momenta are permitted to use their pre-existing ANDA process conditions to prepare GA40 under the fair use provisions of 35 U.S.C. § 273;

C. That this Court find and declare that the '775 patent and all of its claims are invalid;

D. 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 Momenta, Sandoz Inc., or their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of the Sandoz Inc./Momenta GA40 product, or charging them either orally or in writing with infringement of the '775 patent;

E. That this Court award Momenta all of its costs for this action;

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

G. That this Court grant Momenta such other and further relief as the Court deems just and proper.

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