

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

09 CV 10112

TEVA PHARMACEUTICALS USA, INC.,

TEVA PHARMACEUTICAL  
INDUSTRIES LTD.,

TEVA NEUROSCIENCE, INC.,

and

YEDA RESEARCH AND  
DEVELOPMENT CO. LTD.,

*Plaintiffs,*

v.

SANDOZ INC.,

SANDOZ INTERNATIONAL GMBH,

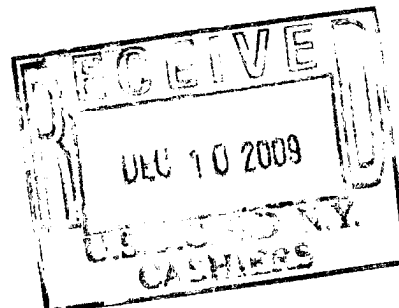
SANDOZ AG,

NOVARTIS AG,

and

MOMENTA PHARMACEUTICALS, INC.

*Defendants.*



Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co. Ltd. ("Plaintiffs"), bring this action for patent infringement and declaratory judgment against Defendants Sandoz Inc., Sandoz International GmbH, Sandoz AG, Novartis AG, and Momenta Pharmaceuticals, Inc. ("Defendants").

## THE PARTIES

1. 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.
2. 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.
3. Teva Neuroscience, Inc. ("Teva Neuroscience"), is a Delaware corporation with its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, MO 64131.
4. Yeda Research and Development Co. Ltd. ("Yeda") markets and commercializes new developments emerging from the laboratories of the Weizmann Institute of Science, and its principal place of business is at P.O. Box 95, Rehovot, 76100, Israel.
5. Upon information and belief, Sandoz Inc. is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, and is a wholly owned subsidiary of Novartis AG.
6. Upon information and belief, Sandoz Inc. is doing business in the State of New York, including in this Judicial District. Sandoz Inc. is registered to do business in New York, has designated Corporate Service Company at 80 State Street, Albany, New York, 12207-2543 for receipt of service, and maintains a place of business at 227-15 N. Conduit Avenue, Laurelton, New York 11413. Sandoz Inc. has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New York including in this Judicial District and deriving revenue from such activities, and by filing claims and counterclaims in this Judicial District.

7. Upon information and belief, Sandoz International GmbH (“Sandoz International”) is a German company with its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany, and is a wholly owned subsidiary of Novartis AG. Upon information and belief, Sandoz International has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by doing business, directly or through its subsidiaries (including Sandoz Inc.), including, among other things, by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New York including in this Judicial District, and deriving revenue from such activities.

8. Upon information and belief, Sandoz AG is a Swiss company with its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland. Upon information and belief, Sandoz AG has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by doing business, directly or through its subsidiaries, including, among other things, by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New York including in this Judicial District and deriving revenue from such activities.

9. Upon information and belief, Novartis AG is a Swiss company with its principal place of business at Lichtestrasse 35, CH-4056 Basel, Switzerland. Upon information and belief, Novartis AG has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by doing business, directly or through its subsidiaries, including, among other things, by making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New York including in

this Judicial District and deriving revenue from such activities, and by filing claims in this Judicial District.

10. Upon information and belief, Momenta Pharmaceuticals, Inc., (“Momenta”) is a Delaware corporation with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142. Upon information and belief, Momenta has engaged in continuous and systematic contacts with the State of New York and purposefully availed itself of this forum by doing business, including, among other things, soliciting business in the State of New York, including in this Judicial District.

### **JURISDICTION**

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

12. This Court has jurisdiction over Counts I-VIII 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.

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

14. This Court has personal jurisdiction over Sandoz Inc., Sandoz International, Sandoz AG, Novartis AG, and Momenta under the New York long-arm statute, N.Y.C.P.L.R. § 301, et seq.

15. Upon information and belief, Sandoz International, Sandoz AG, Novartis AG, and Momenta have acted in concert with and aided and abetted and encouraged Sandoz Inc. in the infringing activities alleged herein.

### **BACKGROUND**

16. United States Patent No. 6,514,938 (“the ’938 patent”) entitled “Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use” was duly and legally issued to Yeda by the United States Patent and Trademark Office on February 4, 2003,

and expires on September 24, 2019. A true and correct copy of the '938 patent is attached as Exhibit A. Since its date of issue, Yeda has been and still is the owner of the '938 patent.

17. Teva Ltd. is the exclusive licensee of the '938 patent.

18. United States Patent No. 7,074,580 ("the '580 patent") entitled "Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use" was duly and legally issued to Yeda by the United States Patent and Trademark Office on July 11, 2006, and expires on February 22, 2020. A true and correct copy of the '580 patent is attached as Exhibit B. Since its date of issue, Yeda has been and still is the owner of the '580 patent.

19. Teva Ltd. is the exclusive licensee of the '580 patent.

20. United States Patent No. 7,163,802 ("the '802 patent") entitled "Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use" was duly and legally issued to Yeda by the United States Patent and Trademark Office on January 16, 2007, and expires on September 24, 2019. A true and correct copy of the '802 patent is attached as Exhibit C. Since its date of issue, Yeda has been and still is the owner of the '802 patent.

21. Teva Ltd. is the exclusive licensee of the '802 patent.

22. United States Patent No. 7,615,359 ("the '359 patent") entitled "Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use" was duly and legally issued to Yeda by the United States Patent and Trademark Office on November 10, 2009, and expires on September 24, 2019. A true and correct copy of the '359 patent is attached as Exhibit D. Since its date of issue, Yeda has been and still is the owner of the '359 patent.

23. Teva Ltd. is the exclusive licensee of the '359 patent. (Collectively, the '938, '580, '802, and '359 patents are referred to as the "Marker Patents.") The Marker Patents claim markers and processes for using markers (referred to here as "patented markers and processes").

24. Plaintiffs researched, developed, applied for, obtained approval of, and market the glatiramer acetate product known around the world as Copaxone®.

25. Teva USA is the holder of a New Drug Application (“NDA”) number 02-0622 approved by the United States Food and Drug Administration (“FDA”) for the use of glatiramer acetate, marketed as Copaxone®, for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis.

26. Upon information and belief, Sandoz Inc. filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. § 355(j), to obtain approval for glatiramer acetate, for injection, 20 mg/mL, 1 mL pre-filled syringes, purported to be generic to Teva USA’s Copaxone® (“Sandoz’s generic glatiramer acetate product”). Upon information and belief, Sandoz Inc. filed the ANDA, assigned ANDA No. 90-218 (“the Sandoz Inc. ANDA”), to obtain approval to market Sandoz’s generic glatiramer acetate product before the expiration of the Marker Patents.

27. Upon information and belief, Momenta worked in active concert and participation with Sandoz Inc. to develop and manufacture Sandoz’s generic glatiramer acetate product and to prepare the Sandoz Inc. ANDA. Upon information and belief, in connection with these activities, Momenta and Sandoz have made and used Teva’s patented markers and processes.

**COUNT I FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,514,938**

28. The allegations of paragraphs 1-27 are realleged and incorporated herein by reference.

29. Sandoz Inc. currently infringes and has infringed one or more claims of the ’938 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of the patented markers and processes.

30. Upon information and belief, Sandoz International, Sandoz AG, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '938 patent.

31. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '938 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that this objectively-defined risk was either known or so obvious that it should have been known to Defendants.

**COUNT II FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF  
UNITED STATES PATENT NO. 6,514,938**

32. The allegations of paragraphs 1-31 are realleged and incorporated herein by reference.

33. Upon information and belief, Defendants plan to begin making and using the patented markers in connection with the manufacture, marketing, selling, offering to sell and/or importing Sandoz Inc.'s generic glatiramer acetate product soon after FDA approval.

34. Such conduct will constitute direct infringement of one or more claims of the '938 patent under 35 U.S.C. § 271(a), inducement of infringement of the '938 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

35. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

36. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '938 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

**COUNT III FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,074,580**

37. The allegations of paragraphs 1-36 are realleged and incorporated herein by reference.

38. Sandoz Inc. currently infringes and has infringed one or more claims of the '580 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of the patented markers and processes.

39. Upon information and belief, Sandoz International, Sandoz AG, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '580 patent.

40. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '580 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that this objectively-defined risk was either known or so obvious that it should have been known to Defendants.

**COUNT IV FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 7,074,580**

41. The allegations of paragraphs 1-40 are realleged and incorporated herein by reference.

42. Upon information and belief, Defendants plan to begin making and using the patented markers and processes in connection with the manufacture, marketing, selling, offering to sell and/or importing Sandoz Inc.'s generic glatiramer acetate product soon after FDA approval.



43. Such conduct will constitute direct infringement of one or more claims of the '580 patent under 35 U.S.C. § 271(a), inducement of infringement of the '580 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

44. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

45. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '580 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

**COUNT V FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,163,802**

46. The allegations of paragraphs 1-45 are realleged and incorporated herein by reference.

47. Sandoz Inc. currently infringes and has infringed one or more claims of the '802 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of the patented markers and processes.

48. Upon information and belief, Sandoz International, Sandoz AG, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '802 patent.

49. Upon information and belief, Defendants' infringement continues despite knowledge of the '802 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that this objectively-defined risk was either known or so obvious that it should have been known to Defendants.

**COUNT VI FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF  
UNITED STATES PATENT NO. 7,163,802**

50. The allegations of paragraphs 1-49 are realleged and incorporated herein by reference.

51. Upon information and belief, Defendants plan to begin making and using the patented markers and processes in connection with the manufacture, marketing, selling, offering to sell and/or importing Sandoz Inc.'s generic glatiramer acetate product soon after FDA approval.

52. Such conduct will constitute direct infringement of one or more claims of the '802 patent under 35 U.S.C. § 271(a), inducement of infringement of the '802 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

53. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

54. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '802 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

**COUNT VII FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,615,359**

55. The allegations of paragraphs 1-54 are realleged and incorporated herein by reference.

56. Sandoz Inc. currently infringes and has infringed one or more claims of the '359 patent under at least sections (a)-(c) of 35 U.S.C. § 271 by the manufacture, use, offer to sell, sale or importation of the patented markers and processes.

57. Upon information and belief, Sandoz International, Sandoz AG, Novartis AG, and Momenta have, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Sandoz Inc.'s infringement of the '359 patent.

58. Upon information and belief, Defendants' infringement continues despite knowledge of the '359 patent. Upon information and belief, Defendants acted despite an objectively high likelihood that their actions constituted infringement of a valid patent, and that this objectively-defined risk was either known or so obvious that it should have been known to Defendants.

**COUNT VIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF  
UNITED STATES PATENT NO. 7,615,359**

59. The allegations of paragraphs 1-58 are realleged and incorporated herein by reference.

60. Upon information and belief, Defendants plan to begin making and using the patented markers and processes in connection with the manufacture, marketing, selling, offering to sell and/or importing Sandoz Inc.'s generic glatiramer acetate product soon after FDA approval.

61. Such conduct will constitute direct infringement of one or more claims of the '359 patent under 35 U.S.C. § 271(a), inducement of infringement of the '359 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

62. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

63. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of

the '359 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

- (a) declaring that the '938 patent is valid and enforceable;
- (b) declaring that Defendants have infringed one or more claims of the '938 patent through the importation, manufacture, use, offering to sell and/or sale of the patented markers and processes;
- (c) declaring that Defendants would infringe one or more of the claims of the '938 patent by the acts of importation, manufacture, use, offering to sell and/or sale of the patented markers and processes for use in the manufacture, use, offer to sell and/or sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (d) declaring that the '580 patent is valid and enforceable;
- (e) declaring that Defendants have infringed one or more claims of the '580 patent through the importation, manufacture, use, offering to sell and/or sale of the patented markers and processes;
- (f) declaring that Defendants would infringe one or more of the claims of the '580 patent by the acts of importation, manufacture, use, offering to sell and/or sale of the patented markers and processes for use in the manufacture, use, offer to sell and/or sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (g) declaring that the '802 patent is valid and enforceable;

- (h) declaring that Defendants have infringed one or more claims of the '802 patent through the importation, manufacture, use, offering to sell and/or sale of the patented markers and processes;
- (i) declaring that Defendants would infringe one or more of the claims of the '802 patent by the acts of importation, manufacture, use, offering to sell and/or sale of the patented markers and processes for use in the manufacture, use, offer to sell and/or sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (j) declaring that the '359 patent is valid and enforceable;
- (k) declaring that Defendants have infringed one or more claims of the '359 patent through the importation, manufacture, use, offering to sell and/or sale of the patented markers and processes;
- (l) declaring that Defendants would infringe one or more of the claims of the '359 patent by the acts of importation, manufacture, use, offering to sell and/or sale of the patented markers and processes for use in the manufacture, use, offer to sell and/or sale of Sandoz's generic glatiramer acetate product prior to the expiration of said patent;
- (m) enjoining Defendants from the manufacture, use, offer to sell, sale or importation of Sandoz's generic glatiramer acetate product, in accordance with 35 U.S.C. § 283, prior to expiration of the Marker Patents;
- (n) enjoining Defendants from the manufacture, use, offer to sell, sale or importation of the patented markers and processes, in accordance with 35 U.S.C. § 283, prior to expiration of the Marker Patents;

- (o) ordering Sandoz Inc. to withdraw its ANDA No. 90-218;
- (p) enjoining Sandoz Inc. from the resubmission of ANDA No. 90-218, or any other ANDA referencing NDA 02-0622 containing data obtained by methods which infringe or have infringed any of the Marker Patents, for a time sufficient to return the parties to the status quo before infringement;
- (q) awarding Plaintiffs damages or other monetary relief in accordance with 35 U.S.C. § 284 to compensate plaintiffs for any and all manufacture, use, offer to sell, sale, or importation of Sandoz's generic glatiramer acetate product prior to the expiration of the Marker Patents;
- (r) awarding Plaintiffs increased damages, pursuant to 35 U.S.C. § 284, in an amount up to three times the amount of actual damages awarded to Plaintiffs, by reason of Defendants' willful infringement of the Marker Patents;
- (s) declaring this to be an exceptional case and awarding Plaintiffs attorney's fees under 35 U.S.C. §§ 285; and
- (t) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Dated: December 10, 2009

Respectfully submitted,

By: 

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

Teva Pharmaceuticals USA, Inc.,  
Teva Pharmaceutical Industries Ltd.,  
Teva Neuroscience, Inc., and  
Yeda Research and Development Co. Ltd.

Plaintiff,

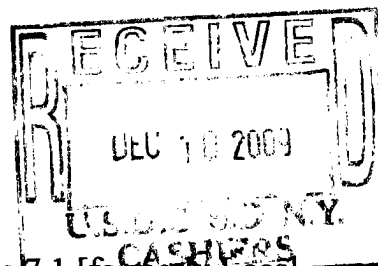
-v-

Sandoz Inc.,  
Sandoz International GmbH,  
Sandoz AG,  
Novartis AG, and  
Momenta Pharmaceuticals, Inc.

Defendant.

Case No. \_\_\_\_\_

Rule 7.1 Statement



Pursuant to Federal Rule of Civil Procedure 7.1 [formerly Local  
General Rule 1.9] and to enable District Judges and Magistrate Judges of the Court  
to evaluate possible disqualification or recusal, the undersigned counsel for  
Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. (a private non-governmental party)

certifies that the following are corporate parents, affiliates and/or subsidiaries of  
said party, which are publicly held.

The undersigned counsel hereby discloses that: (a) the parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceuticals Europe, B.V. and Teva Pharmaceutical Industries Ltd.; and (b) Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns – through the aforementioned chain – 10% or more of Teva Pharmaceuticals USA, Inc.

The undersigned counsel further discloses that: (a) Teva Pharmaceutical Industries Ltd. has no parent company; and (b) no publicly traded company owns 10% or more of Teva Pharmaceutical Industries Ltd.

The undersigned counsel further discloses that: (a) the parent companies of Teva Neuroscience, Inc. are: IVAX Corporation, Teva Pharmaceuticals USA, Inc., Orvet UK Unlimited, Teva Pharmaceuticals Europe B.V. and Teva Pharmaceutical Industries Ltd.; and (b) Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns – through the aforementioned chain – 10% or more of Teva Neuroscience, Inc.

Date: 12/10/2009

Signature of Attorney

Attorney Bar Code: EH0850