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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., INC., Plaintiffs/Counterclaim-Defendants, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and NATCO PHARMA LTD., Defendants/Counterclaim-Plaintiffs.	Civil Action No.: 09-8824 **ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS BY DEFENDANTS MYLAN PHARMACEUTICALS INC. AND MYLAN INC.**

Mylan Pharmaceuticals Inc. and Mylan Inc. ("Mylan") by its undersigned attorneys answers and responds to the Complaint of Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Inc. ("Plaintiffs") on behalf of itself and no other party, as follows:

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.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 1 and, therefore, denies those allegations.

2. Teva Pharmaceuticals 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.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 2 and, therefore, denies those allegations.

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.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 3 and, therefore, denies those allegations.

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.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 4 and, therefore, denies those allegations.

5. Upon information and belief, Mylan Pharmaceuticals is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

ANSWER: Mylan admits the allegations in paragraph 5.

6. Upon information and belief, Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

ANSWER: Mylan admits the allegations in paragraph 6.

7. Upon information and belief, Natco is an Indian company with its principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 033, India.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 7 and, therefore, denies those allegations.

8. Upon information and belief, Mylan Pharmaceuticals is doing business in the State of New York, including in this Judicial District. Mylan Pharmaceuticals 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.

ANSWER: Mylan does not contest personal jurisdiction for purposes of this lawsuit only.

9. Upon information and belief, Mylan Inc. is doing business in the State of New York, including in this Judicial District. Upon information and belief, Mylan Inc. operates offices at 405 Lexington Ave., New York, NY 10174. Mylan Inc., directly or through its subsidiaries, 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.

ANSWER: Mylan admits that Mylan Inc. operates offices at 405 Lexington Ave., New York, NY 10174. Mylan does not contest the remaining allegations of paragraph 9 for purposes of this lawsuit only.

10. Upon information and belief, Natco is doing business in the State of New York, including in this Judicial District. Natco 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 counterclaims in this Judicial District.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 10 and, therefore, denies those allegations.

JURISDICTION

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

ANSWER: Mylan denies the allegations set forth in paragraph 11, as they state a legal conclusion for which no answer is required. To the extent an answer is deemed required, Mylan Pharmaceuticals Inc. does not contest that this action for patent infringement arises under 35 U.S.C. § 271(e). Mylan Inc. denies the allegations set forth in paragraph 11.

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

ANSWER: Mylan denies the allegations set forth in paragraph 12, as they state a legal conclusion for which no answer is required. To the extent an answer is deemed required, Mylan

admits that this Court has subject matter jurisdiction over Counts I-XIV of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) for purposes of this lawsuit only.

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

ANSWER: Mylan denies the allegations set forth in paragraph 13, as they state a legal conclusion for which no answer is required. To the extent an answer is deemed required, Mylan admits that venue is proper in this Judicial District under 28 U.S.C. § 1400(b) for purposes of this lawsuit only. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 13 and, therefore, denies those allegations.

14. This Court has personal jurisdiction over Mylan Pharmaceuticals, Mylan Inc., and Natco under the New York long-arm statute, N.Y.C.P.L.R. § 301, et seq.

ANSWER: Mylan Pharmaceuticals Inc. and Mylan Inc. deny the allegations set forth in paragraph 14, as they state a legal conclusion for which no answer is required. Mylan does not contest personal jurisdiction for purposes of this lawsuit only. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 14 and, therefore, denies those allegations.

BACKGROUND

15. United States Patent No. 7,199,098 ("the '098 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 3, 2007, and expires on May 24, 2014. A true and correct copy of the '098 patent is attached as Exhibit A. Since its date of issue, Yeda has been and still is the owner of the '098 patent.

ANSWER: Mylan admits that United States Patent No. 7,199,098 ("the '098 patent") states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '098 patent is attached as Exhibit A. Mylan denies that the '098 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 3, 2007. Mylan is without sufficient knowledge or

information to form a belief as to the remaining allegations set forth in paragraph 15 and, therefore, denies those allegations.

16. Teva Ltd. is the exclusive licensee of the '098 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '098 patent and, therefore, denies those allegations.

17. United States Patent No. 6,939,539 ("the '539 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on September 6, 2005, and expires on May 24, 2014. A true and correct copy of the '539 patent is attached as Exhibit B. Since its date of issue, Yeda has been and still is the owner of the '539 patent.

ANSWER: Mylan admits that United States Patent No. 6,939,539 ("the '539 patent") states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '539 patent is attached as Exhibit B. Mylan denies that the '539 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on September 6, 2005. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 17 and, therefore, denies those allegations.

18. Teva Ltd. is the exclusive licensee of the '539 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '539 patent and, therefore, denies those allegations.

19. United States Patent No. 6,054,430 ("the '430 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 25, 2000, and expires on May 24, 2014. A true and correct copy of the '430 patent is attached as Exhibit C. Since its date of issue, Yeda has been and still is the owner of the '430 patent.

ANSWER: Mylan admits that United States Patent No. 6,054,430 ("the '430 patent") states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '430 patent is attached as Exhibit C.

Mylan denies that the '430 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on April 25, 2000. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 19 and, therefore, denies those allegations.

20. Teva Ltd. is the exclusive licensee of the '430 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '430 patent and, therefore, denies those allegations.

21. United States Patent No. 6,620,847 ("the '847 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on September 16, 2003, and expires on May 24, 2014. A true and correct copy of the '847 patent is attached as Exhibit D. Since its date of issue, Yeda has been and still is the owner of the '847 patent.

ANSWER: Mylan admits that United States Patent No. 6,620,847 ("the '847 patent") states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '847 patent is attached as Exhibit D. Mylan denies that the '847 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on September 16, 2003. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 21 and, therefore, denies those allegations.

22. Teva Ltd. is the exclusive licensee of the '847 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '847 patent and, therefore, denies those allegations.

23. United States Patent No. 5,981,589 ("the '589 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on November 9, 1999, and expires on May 24, 2014. A true and correct copy of the '589 patent is attached as Exhibit E. Since its date of issue, Yeda has been and still is the owner of the '589 patent.

ANSWER: Mylan admits that United States Patent No. 5,981,589 ("the '589 patent") states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '589 patent is attached as Exhibit E. Mylan denies that the '589 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on November 9, 1999. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 23 and, therefore, denies those allegations.

24. Teva Ltd. is the exclusive licensee of the '589 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '589 patent and, therefore, denies those allegations.

25. United States Patent No. 6,342,476 ("the '476 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the United States Patent and Trademark Office on January 29, 2002, and expires on May 24, 2014. A true and correct copy of the '476 patent is attached as Exhibit F. Since its date of issue, Yeda has been and still is the owner of the '476 patent.

ANSWER: Mylan admits that United States Patent No. 6,342,476 ("the '476 patent") states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '476 patent is attached as Exhibit F. Mylan denies that the '476 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on January 29, 2002. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 25 and, therefore, denies those allegations.

26. Teva Ltd. is the exclusive licensee of the '476 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '476 patent and, therefore, denies those allegations.

27. United States Patent No. 6,362,161 ("the '161 patent"), entitled "Copolymer-1 improvements in compositions of copolymers," was duly and legally issued to Yeda by the

United States Patent and Trademark Office on March 26, 2002, and expires on May 24, 2014. A true and correct copy of the '161 patent is attached as Exhibit G. Since its date of issue, Yeda has been and still is the owner of the '161 patent.

ANSWER: Mylan admits that United States Patent No. 6,362,161 ("the '161 patent"), states on its face that it is entitled "Copolymer-1 improvements in compositions of copolymers." Mylan recognizes that what purports to be a copy of the '161 patent is attached as Exhibit G. Mylan denies that the '161 patent was duly and legally issued to Yeda by the United States Patent and Trademark Office on March 26, 2002. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 27 and, therefore, denies those allegations.

28. Teva Ltd. is the exclusive licensee of the '161 patent.

ANSWER: Mylan is without sufficient knowledge or information to form a belief that Teva Ltd. is the exclusive licensee of the '161 patent and, therefore, denies those allegations.

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

ANSWER: Mylan admits that the FDA approved a New Drug Application ("NDA") for the glatiramer acetate products, which are marketed under the trade name Copaxone®. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 29 and, therefore, denies those allegations.

30. TEVA USA is the holder of 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.

ANSWER: Mylan admits the allegations set forth in paragraph 30.

31. Upon information and belief, Mylan Pharmaceuticals 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 injection, 20 mg/mL, 1 mL syringes, purported to be generic to Teva USA's Copaxone® ("Mylan's generic glatiramer acetate product"). Upon information and belief, Mylan Pharmaceuticals filed the ANDA, assigned ANDA No. 91-646 ("the Mylan ANDA"), to obtain approval to market Mylan's generic glatiramer acetate product

before the expiration of the '098, '539, '430, '847, '589, '476, and '161 patents ("the patents in suit").

ANSWER: Mylan admits that Mylan Pharmaceuticals Inc. filed with the FDA an ANDA pursuant to 21 U.S.C. § 355(j) to obtain approval for glatiramer acetate injection 20 mg/mL, 1 mL syringes ("Mylan Pharmaceuticals Inc.'s glatiramer acetate product"). Mylan admits that Mylan Pharmaceuticals Inc. filed the ANDA and that the ANDA was assigned ANDA No. 91-646. Mylan further admits that Mylan Pharmaceuticals Inc. is seeking approval to market its glatiramer acetate products prior to the expiration of the '098, '539, '430, '847, '589, '476, and '161 patents ("the patents-in-suit"). Mylan denies the remaining allegations set forth in paragraph 31.

32. Upon information and belief, Mylan Pharmaceuticals also filed with the FDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the patents in suit are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Mylan's generic glatiramer acetate product.

ANSWER: Mylan admits that Mylan Pharmaceuticals Inc. also filed with the FDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the patents in suit are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Mylan Pharmaceuticals Inc.'s glatiramer acetate product. Mylan denies the remaining allegations set forth in paragraph 32.

33. Upon information and belief, Natco worked in active concert and participation with Mylan Pharmaceuticals to manufacture Mylan's generic glatiramer acetate product and to prepare the Mylan ANDA. Upon information and belief, Natco and Mylan Inc. have signed an agreement under which Mylan will market and distribute glatiramer acetate made by Natco (see e.g., http://www.natcopharma.co.in/collaborates_mylan.htm).

ANSWER: Mylan admits that Natco and Mylan Inc. have signed a license agreement relating to glatiramer acetate. Mylan denies the remaining allegations set forth in paragraph 33.

34. Mylan Pharmaceuticals caused to be sent to Teva USA, Teva Ltd., Teva Neuroscience (collectively, "Teva"), and Yeda a letter ("the Notice Letter"), dated September 16, 2009, notifying them that Mylan Pharmaceuticals had filed an ANDA for glatiramer acetate and was providing information to Teva pursuant to 21 U.S.C. §355(j)(2)(B)(ii).

ANSWER: Mylan admits the allegations set forth in paragraph 34.

COUNT I FOR INFRINGEMENT OF UNITED STATES PATENT NO. 7,199,098

35. The allegations of paragraphs 1-34 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-34 as if fully set forth herein.

36. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before expiration of the '098 patent constitutes an act of infringement of the '098 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale, or importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '098 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 36. As paragraph 36 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

37. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 37 and, therefore, denies those allegations.

COUNT II FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,939,539

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

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-37 as if fully set forth herein.

39. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '539 patent constitutes an act of infringement of the '539 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale or

importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '539 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 39. As paragraph 39 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

40. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 40 and, therefore, denies those allegations.

COUNT III FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,054,430

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

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-40 as if fully set forth herein.

42. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '430 patent constitutes an act of infringement of the '430 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '430 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 42. As paragraph 42 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

43. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 43 and, therefore, denies those allegations.

COUNT IV FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,620,847

44. The allegations of paragraphs 1-43 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-43 as if fully set forth herein.

45. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '847 patent constitutes an act of infringement of the '847 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '847 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 45. As paragraph 45 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

46. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 46 and, therefore, denies those allegations.

COUNT V FOR INFRINGEMENT OF UNITED STATES PATENT NO. 5,981,589

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

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-46 as if fully set forth herein.

48. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '589 patent constitutes an act of infringement of the '589 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '589 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 48. As paragraph 48 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

49. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 49 and, therefore, denies those allegations.

COUNT VI FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,342,476

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

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-49 as if fully set forth herein.

51. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '476 patent constitutes an act of infringement of the '476 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '476 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 51. As paragraph 51 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

52. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 52 and, therefore, denies those allegations.

COUNT VII FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,362,161

53. The allegations of paragraphs 1-52 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-52 as if fully set forth herein.

54. Under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals' submission to the FDA of its ANDA No. 91-646 to obtain approval for Mylan's generic glatiramer acetate product before the expiration of the '161 patent constitutes an act of infringement of the '161 patent, and if approved, Mylan Pharmaceuticals' commercial manufacture, use, offer to sell, sale or importation of Mylan's generic glatiramer acetate product would infringe one or more claims of the '161 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

ANSWER: Mylan Pharmaceuticals Inc. denies the allegations set forth in paragraph 54. As paragraph 54 contains no allegations as to Mylan Inc., no answer is required as to Mylan Inc.

55. Upon information and belief, Natco has, under 35 U.S.C. § 271(b), acted in concert, actively supporting, participating in, encouraging, and inducing Mylan Pharmaceuticals' filing of ANDA No. 91-646 for glatiramer acetate, and in the preparation to sell, in the United States, pharmaceutical products containing glatiramer acetate.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 55 and, therefore, denies those allegations.

COUNT VIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 7,199,098

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

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-55 as if fully set forth herein.

57. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 57 and, therefore, denies those allegations.

58. Such conduct will constitute direct infringement of one or more claims of the '098 patent under 35 U.S.C. § 271(a), inducement of infringement of the '098 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 58.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 59.

60. 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 '098 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 60.

COUNT IX FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,939,539

61. The allegations of paragraphs 1-60 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-60 as if fully set forth herein.

62. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 62 and, therefore, denies those allegations.

63. Such conduct will constitute direct infringement of one or more claims of the '539 patent under 35 U.S.C. § 271(a), inducement of infringement of the '539 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 63.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 64.

65. 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 '539 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 65.

COUNT X FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,054,430

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

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-65 as if fully set forth herein.

67. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 67 and, therefore, denies those allegations.

68. Such conduct will constitute direct infringement of one or more claims of the '430 patent under 35 U.S.C. § 271(a), inducement of infringement of the '430 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 68.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 69.

70. 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 '430 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 70.

COUNT XI FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,620,847

71. The allegations of paragraphs 1-70 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-70 as if fully set forth herein.

72. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 72 and, therefore, denies those allegations.

73. Such conduct will constitute direct infringement of one or more claims of the '847 patent under 35 U.S.C. § 271(a), inducement of infringement of the '847 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 73.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 74.

75. 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 '847 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 75.

COUNT XII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 5,981,589

76. The allegations of paragraphs 1-75 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-75 as if fully set forth herein.

77. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 77 and, therefore, denies those allegations.

78. Such conduct will constitute direct infringement of one or more claims of the '589 patent under 35 U.S.C. § 271(a), inducement of infringement of the '589 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 78.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 79.

80. 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 '589 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 80.

COUNT XIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,342,476

81. The allegations of paragraphs 1-80 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-80 as if fully set forth herein.

82. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 82 and, therefore, denies those allegations.

83. Such conduct will constitute direct infringement of one or more claims of the '476 patent under 35 U.S.C. § 271(a), inducement of infringement of the '476 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 83.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 84.

85 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 '476 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 85.

COUNT XIV FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,362,161

86. The allegations of paragraphs 1-85 are realleged and incorporated herein by reference.

ANSWER: Mylan incorporates its foregoing responses to paragraphs 1-85 as if fully set forth herein.

87. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Mylan's generic glatiramer acetate product soon after FDA approval.

ANSWER: Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 87and, therefore, denies those allegations.

88. Such conduct will constitute direct infringement of one or more claims of the '161 patent under 35 U.S.C. § 271(a), inducement of infringement of the '161 patent under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

ANSWER: Mylan denies the allegations of set forth in paragraph 88.

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

ANSWER: Mylan denies the allegations of set forth in paragraph 89.

90. 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 '161 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Mylan denies the allegations of set forth in paragraph 90.

SEPARATE DEFENSES

FIRST AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 7,199,098

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '098 patent.

SECOND AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 6,939,539

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '539 patent.

THIRD AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 6,054,430

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '430 patent.

FOURTH AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 6,620,847

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '847 patent.

FIFTH AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 5,981,589

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '589 patent.

SIXTH AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 6,342,476

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '476 patent.

SEVENTH AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 6,362,161

Mylan has not infringed and is not infringing, directly or indirectly, any valid claim of the '161 patent.

EIGHTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 7,199,098

The claims of the '098 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

NINTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,939,539

The claims of the '539 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

TENTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,054,430

The claims of the '430 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

ELEVENTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,620,847

The claims of the '847 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

TWELFTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 5,981,589

The claims of the '589 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

THIRTEENTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,342,476

The claims of the '476 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

FOURTEENTH AFFIRMATIVE DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,362,161

The claims of the '161 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and/or 112.

FIFTEENTH AFFIRMATIVE DEFENSE – FAILURE TO STATE A CLAIM

The Complaint fails to state a claim upon which relief can be granted.

SIXTEENTH AFFIRMATIVE DEFENSE – RESERVATION OF RIGHTS

Mylan's asserted affirmative defenses are based on information publicly available and accessible to Mylan at this time. Mylan's investigation of its defenses will continue throughout discovery in this matter and Mylan reserves the right to supplement and/or amend these defenses.

COUNTERCLAIMS

For their counterclaims against Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. and Yeda Research and Development Co., Inc. ("Teva"), Mylan Pharmaceuticals Inc. and Mylan Inc. ("Mylan") state as follows:

PARTIES

1. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505.

2. Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

3. Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc.

4. Mylan Pharmaceuticals Inc. filed with the FDA an ANDA pursuant to 21 U.S.C. § 355(j) to obtain approval for glatiramer acetate injection 20 mg/mL, 1 mL syringes and that ANDA was assigned ANDA No. 91-646, herein referred to as "Mylan Pharmaceuticals Inc.'s glatiramer acetate product".

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

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

7. Upon information and belief, Teva Neuroscience, Inc. ("Teva Neuroscience"), is a Delaware corporation, having its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, MO 64131.

8. Upon information and belief, Yeda Research and Development Co. Ltd. ("Yeda") is an Israeli company, having its principal place of business is at P.O. Box 95, Rehovot, 76100, Israel.

JURISDICTION AND VENUE

9. The Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

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

11. Teva is subject to personal jurisdiction in this District by commencing and continuing to prosecute this action; because a substantial part of the events giving rise to Mylan's Counterclaims occurred in this district; and Teva is found or transacts business in this district.

FIRST COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 7,199,098

12. Paragraphs 1-11 of the Counterclaim are incorporated as if fully set forth herein.

13. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '098 patent.

14. Unless Teva is enjoined, Mylan believes the Plaintiffs will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '098 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

15. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '098 patent and from interfering with Mylan's business.

16. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '098 patent.

SECOND COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 6,939,539

17. Paragraphs 1-16 of the Counterclaim are incorporated as if fully set forth herein.

18. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '539 patent.

19. Unless Teva is enjoined, Mylan believes the Teva will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '539 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

20. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '539 patent, and from interfering with Mylan's business.

21. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '539 patent.

THIRD COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 6,054,430

22. Paragraphs 1-21 of the Counterclaim are incorporated as if fully set forth herein.

23. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '430 patent.

24. Unless Teva is enjoined, Mylan believes the Teva will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '430 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

25. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '430 patent, and from interfering with Mylan's business.

26. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '430 patent.

FOURTH COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 6,620,847

27. Paragraphs 1-26 of the Counterclaim are incorporated as if fully set forth herein.

28. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '847 patent.

29. Unless Teva is enjoined, Mylan believes the Teva will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '847 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

30. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '430 patent, and from interfering with Mylan's business.

31. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '847 patent.

FIFTH COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 5,981,589

32. Paragraphs 1-31 of the Counterclaim are incorporated as if fully set forth herein.

33. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '589 patent.

34. Unless Teva is enjoined, Mylan believes the Teva will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '589 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

35. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '589 patent, and from interfering with Mylan's business.

36. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '589 patent.

SIXTH COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 6,342,476

37. Paragraphs 1-36 of the Counterclaim are incorporated as if fully set forth herein.

38. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '476 patent.

39. Unless Teva is enjoined, Mylan believes the Teva will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '476 patent, and will

continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

40. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '476 patent, and from interfering with Mylan's business.

41. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '476 patent.

SEVENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF UNITED STATES PATENT NO. 6,362,161

42. Paragraphs 1-41 of the Counterclaim are incorporated as if fully set forth herein.

43. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '161 patent.

44. Unless Teva is enjoined, Mylan believes the Teva will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '161 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

45. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '161 patent, and from interfering with Mylan's business.

46. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed, directly or indirectly, any valid claim of the '161 patent.

EIGHTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 7,199,098

47. Paragraphs 1-46 of the Counterclaim are incorporated as if fully set forth herein.

48. The claims of the '098 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

49. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '098 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and it manufacture, use, offer for sale and sale.

50. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '098 patent, and from interfering with Mylan's business.

51. Mylan is entitled to declaratory judgment that the claims of the '098 patent are invalid.

NINTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 6,939,539

52. Paragraphs 1-51 of the Counterclaim are incorporated as if fully set forth herein.

53. The claims of the '539 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

54. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '539 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

55. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '539 patent, and from interfering with Mylan's business.

56. Mylan is entitled to declaratory judgment that the claims of the '539 patent are invalid.

TENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 6,054,430

57. Paragraphs 1-56 of the Counterclaim are incorporated as if fully set forth herein.

58. The claims of the '430 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

59. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '430 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

60. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '430 patent, and from interfering with Mylan's business.

61. Mylan is entitled to declaratory judgment that the claims of the '430 patent are invalid.

ELEVENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 6,620,847

62. Paragraphs 1-61 of the Counterclaim are incorporated as if fully set forth herein.

63. The claims of the '847 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

64. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '847 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

65. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '847 patent, and from interfering with Mylan's business.

66. Mylan is entitled to declaratory judgment that the claims of the '847 patent are invalid.

TWELFTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 5,981,589

67. Paragraphs 1-66 of the Counterclaim are incorporated as if fully set forth herein.

68. The claims of the '589 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

69. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '589 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

70. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '589 patent, and from interfering with Mylan's business.

71. Mylan is entitled to declaratory judgment that the claims of the '589 patent are invalid.

THIRTEEN COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 6,342,476

72. Paragraphs 1-71 of the Counterclaim are incorporated as if fully set forth herein.

73. The claims of the '476 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

74. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '476

patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

75. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '476 patent, and from interfering with Mylan's business.

76. Mylan is entitled to declaratory judgment that the claims of the '476 patent are invalid.

FOURTEENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF UNITED STATES PATENT NO. 6,362,161

77. Paragraphs 1-76 of the Counterclaim are incorporated as if fully set forth herein.

78. The claims of the '161 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

79. Unless Teva is enjoined, Mylan believes that they will continue to assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '161 patent, and will continue to interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

80. Mylan will be irreparably harmed if Teva is not enjoined from continuing to assert the '161 patent, and from interfering with Mylan's business.

81. Mylan is entitled to declaratory judgment that the claims of the '161 patent are invalid.

FIFTEENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 5,800,808

82. Paragraphs 1-81 of the Counterclaim are incorporated as if fully set forth herein.

83. The 5,800,808 patent ("the '808 patent") is titled, "Copolymer-1 Improvements in Compositions of Copolymers."

84. The '808 patent was issued to Yeda Research and Development Co., Inc. on September 1, 1998.

85. Upon information and belief, the '808 patent is scheduled to expire on September 1, 2015.

86. Upon information and belief, Teva is the exclusive licensee of the '808 patent.

87. Upon information and belief, the '808 patent on its face claims priority to U.S. Patent Application (U.S. Patent Application No. 08/248,037, which is abandoned), which is the same as the '098, '539, '430, '847, '589, '476, and '161 patents.

88. The specification of the '808 patent is nearly identical to the specifications of the '098, '539, '430, '847, '589, '476, and '161 patents.

89. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '808 patent.

90. Upon information and belief, Teva is holding the '808 patent in reserve in order to file a future patent infringement suit and to further delay Mylan's entry into the United States market for glatiramer acetate. This is contrary to the intent of the Hatch-Waxman Act, which encourages the timely resolution of all patent disputes and the early filing of patent litigation by NDA holders against ANDA holders.

91. Unless Teva is enjoined, Mylan believes the Teva will assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '808 patent and will interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

92. There exists an actual controversy between Mylan and Teva whether Mylan Pharmaceuticals Inc.'s glatiramer acetate product infringes the '808 patent, and a judicial declaration of noninfringement is necessary and proper at this time.

93. Mylan will be irreparably harmed if Teva is not enjoined from asserting the '808 patent, and from interfering with Mylan's business.

94. Mylan is entitled to a declaratory judgment that Mylan Pharmaceuticals Inc.'s glatiramer acetate product does not infringe, directly or indirectly, any valid claim of the '808 patent.

SIXTEENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 6,048,898

95. Paragraphs 1-94 of the Counterclaim are incorporated as if fully set forth herein.

96. The 6,048,898 patent ("the '898 patent") is titled, "Copolymer-1 Improvements in Compositions of Copolymers."

97. The '898 patent was issued to Yeda Research and Development Co., Inc. on April 11, 2000.

98. Upon information and belief, the '898 patent is scheduled to expire on May 24, 2014.

99. Upon information and belief, Teva is the exclusive licensee of the '898 patent.

100. Upon information and belief, the '898 patent on its face claims priority to U.S. Patent Application (U.S. Patent Application No. 08/248,037, which is abandoned), which is the same as the '098, '539, '430, '847, '589, '476, and '161 patents.

101. The specification of the '898 patent is nearly identical to the specifications of the '098, '539, '430, '847, '589, '476, and '161 patents.

102. Mylan Pharmaceuticals Inc.'s glatiramer acetate product has not infringed and is not infringing, directly or indirectly, any valid claim of the '898 patent.

103. Upon information and belief, Teva is holding the '898 patent in reserve in order to file a future patent infringement suit and to further delay Mylan's entry into the United States market for glatiramer acetate. This is contrary to the intent of the Hatch-Waxman Act, which encourages the timely resolution of all patent disputes and the early filing of patent litigation by NDA holders against ANDA holders.

104. Unless Teva is enjoined, Mylan believes the Teva will assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '898 patent and will interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

105. There exists an actual controversy between Mylan and Teva whether Mylan Pharmaceuticals Inc.'s glatiramer acetate product infringes the '898 patent, and a judicial declaration of noninfringement is necessary and proper at this time.

106. Mylan will be irreparably harmed if Teva is not enjoined from asserting the '898 patent, and from interfering with Mylan's business.

107. Mylan is entitled to a declaratory judgment that Mylan has not infringed, directly or indirectly, any valid claim of the '898 patent.

SEVENTEENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 5,800,808

108. Paragraphs 1-107 of the Counterclaim are incorporated as if fully set forth herein.

109. The claims of the '808 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

110. Unless Teva is enjoined, Mylan believes the Teva will assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing the '808 patent and will interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

111. Mylan will be irreparably harmed Teva is not enjoined from continuing to assert the '808 patent, and from interfering with Mylan's business.

112. Mylan is entitled to declaratory judgment that the claims of the '808 patent are invalid.

EIGHTEENTH COUNTERCLAIM – DECLARATORY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 6,048,898

113. Paragraphs 1-112 of the Counterclaim are incorporated as if fully set forth herein.

114. The claims of the '898 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

115. Unless Teva is enjoined, Mylan believes the Teva will assert that Mylan Pharmaceuticals Inc.'s glatiramer acetate product is infringing valid claims of the '898 patent and will interfere with Mylan's business with respect to Mylan Pharmaceuticals Inc.'s glatiramer acetate product and its manufacture, use, offer for sale and sale.

116. Mylan will be irreparably harmed Teva is not enjoined from continuing to assert the '898 patent, and from interfering with Mylan's business.

117. Mylan is entitled to declaratory judgment that the claims of the '898 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Mylan respectfully request that this Court enter judgment:

a. dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;

b. declaring that Mylan Pharmaceuticals Inc.'s glatiramer acetate product does not infringe, directly or indirectly, any valid claim of the '098, '539, '430, '847, '589, '476, and '161 patents;

c. declaring that the '098, '539, '430, '847, '589, '476, and '161 patents are invalid;

d. declaring that Mylan Pharmaceuticals Inc.'s glatiramer acetate product does not infringe, directly or indirectly, any valid claim of the '808 and '898 patents;

e. declaring that the '808 and '898 patents are invalid;

f. enjoining the Plaintiffs, their respective officers, employees, agents, representatives, attorneys and others acting on their behalf, from representing to anyone, either directly or indirectly, that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has infringed, is infringing or will infringe, directly or indirectly, the '098, '539, '430, '847, '589, '476, and '161 patents;

g. enjoining the counterclaim-defendants , their respective officers, employees, agents, representatives, attorneys and others acting on their behalf, from representing to anyone, either directly or indirectly, that Mylan Pharmaceuticals Inc.'s glatiramer acetate product has infringed, is infringing or will infringe, directly or indirectly, the '808 and '898 patents;

h. awarding Mylan its costs;

i. declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Mylan its attorneys' fees; and

j. awarding to Mylan such further relief as this Court may deem necessary, just and proper.

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