

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS	)	
INTERNATIONAL GMBH,	)	
CEPHALON, INC., and EAGLE	)	
PHARMACEUTICALS, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN LABORATORIES LIMITED,	)	
	)	
Defendant.	)	

**COMPLAINT**

Plaintiffs Teva Pharmaceuticals International GmbH (“Teva Pharmaceuticals”), Cephalon, Inc. (“Cephalon,” and collectively with Teva Pharmaceuticals, “Teva”), and Eagle Pharmaceuticals, Inc. (“Eagle”) (collectively “Plaintiffs”), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendant’s submission of Abbreviated New Drug Application (“ANDA”) No. 210827 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of BENDEKA<sup>®</sup> (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL) (“BENDEKA<sup>®</sup>”) prior to the expiration of U.S. Patent Nos. 8,791,270 (“the ’270 patent”); 8,609,707 (“the ’707 patent”); 9,265,831 (“the ’831 patent”); 9,572,796 (“the ’796 patent”); 9,572,797 (“the ’797 patent”); 9,034,908 (“the ’908

patent”); 9,144,568 (“the ’568 patent”); 9,572,887 (“the ’887 patent”); 9,597,397 (“the ’397 patent”); 9,597,398 (“the ’398 patent”); 9,597,399 (“the ’399 patent”); 9,000,021 (“the ’021 patent”); and 9,579,384 (“the ’384 patent”) (together, “the Orange Book patents”).

### **PARTIES**

2. Plaintiff Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645 Switzerland.

3. Plaintiff Cephalon, Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

4. Plaintiff Eagle Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

5. On information and belief, defendant Mylan Laboratories Limited (“Mylan”) is a company organized and existing under the laws of India with a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad 500034, India.

### **JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, on information and belief, Mylan is a foreign company that may be sued in any judicial district in the United States in which it is subject to the Court’s personal jurisdiction. As set forth *infra*, Mylan is subject to the Court’s personal jurisdiction in this District.

8. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Mylan.

9. This Court has personal jurisdiction over Mylan because, on information and belief, Mylan has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware.

10. In addition, this Court also has personal jurisdiction over Mylan because, among other things, on information and belief: (1) Mylan has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in ANDA No. 210827 in the United States, including in Delaware; and (2) Mylan will market, distribute, offer for sale, and/or sell the generic product described in ANDA No. 210827 in the United States, including in Delaware, upon approval of ANDA No. 210827, and will derive substantial revenue from the use or consumption of the generic product described in ANDA No. 210827 in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, if ANDA No. 210827 is approved, the generic product described in ANDA No. 210827 would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

11. The Court also has personal jurisdiction over Mylan because it has committed, aided, abetted, induced, contributed to, or participated in the commission of the

tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Cephalon and Eagle, both Delaware corporations.

12. Mylan has previously consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs. *See, e.g., Cadence Pharm., Inc., et al. v. Agila Specialties Private Ltd., Inc. & Agila Specialties Inc.*, No. 14-01499-LPS, D.I. 23 (D. Del. June 19, 2015); *Cubist Pharm., Inc. v. Strides, Inc. & Agila Specialties Private Ltd.*, No. 13-01679-GMS, D.I. 8 (D. Del. Nov. 13, 2013).

13. In addition, Mylan has purposefully availed itself of this forum by asserting counterclaims in prior cases arising out of the filing of its ANDAs. *See, e.g., Javelin Pharm., Inc., et al. v. Mylan Labs. Ltd., et al.*, No. 16-00224-LPS, D.I. 15 (D. Del. June 13, 2016); *Fresenius Kabi USA, LLC, et al. v. Mylan Labs. Ltd., et al.*, No. 15-00942-LPS, D.I. 28 (D. Del. June 3, 2016); *Pfizer Inc., et al. v. Mylan Inc., Mylan Labs. Ltd. & Mylan Pharm. Inc.*, No. 15-00026-SLR-SRF, D.I. 150 (D. Del. May 17, 2016); *Millennium Pharm., Inc. v. Onco Therapies Ltd. & Agila Specialties Inc.*, No. 15-00040-GMS, D.I. 13 (D. Del. Apr. 27, 2015); *Cadence Pharm., Inc., et al. v. Agila Specialties Private Ltd., Inc. & Agila Specialties Inc.*, No. 14-01499-LPS, D.I. 23 (D. Del. June 19, 2015); *Cubist Pharm., Inc. v. Strides, Inc. & Agila Specialties Private Ltd.*, No. 13-01679-GMS, D.I. 8 (D. Del. Nov. 13, 2013).

14. Alternatively, this Court has jurisdiction over Mylan under FEDERAL RULE OF CIVIL PROCEDURE 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Mylan is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Mylan has sufficient contacts with the United States as a whole, not least through its development of generic drugs for sale in the United States, such that this Court's exercise of jurisdiction over Mylan satisfies due process at least for the reasons alleged herein.

15. For the above reasons, it would not be unfair or unreasonable for Mylan to litigate this action in this District, and there is personal jurisdiction over Mylan here.

### **BACKGROUND**

16. BENDEKA<sup>®</sup>, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

17. Eagle is the holder of New Drug Application No. 208194 for BENDEKA<sup>®</sup>, which has been approved by the FDA.

18. The '270 patent, entitled "Bendamustine Pharmaceutical Compositions" (Exhibit A hereto), was duly and legally issued on July 29, 2014. Cephalon, Inc. is the owner and assignee of the '270 patent. The '270 patent has been listed in connection with BENDEKA<sup>®</sup> in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

19. The '707 patent, entitled "Formulations of Bendamustine" (Exhibit B hereto), was duly and legally issued on December 17, 2013. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '707 patent, subject to the exclusive license referenced herein. The '707 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

20. The '831 patent, entitled "Formulations of Bendamustine" (Exhibit C hereto), was duly and legally issued on February 23, 2016. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '831 patent, subject to the exclusive license referenced herein. The '831 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

21. The '796 patent, entitled "Formulations of Bendamustine" (Exhibit D hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '796 patent, subject to the exclusive license referenced herein. The '796 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

22. The '797 patent, entitled "Formulations of Bendamustine" (Exhibit E hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '797 patent, subject to the exclusive license referenced herein. The '797 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

23. The '908 patent, entitled "Formulations of Bendamustine" (Exhibit F hereto), was duly and legally issued on May 19, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '908 patent, subject to the exclusive license referenced herein. The '908 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

24. The '568 patent, entitled "Formulations of Bendamustine" (Exhibit G hereto), was duly and legally issued on September 29, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '568 patent, subject to the exclusive license referenced herein. The '568 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

25. The '887 patent, entitled "Formulations of Bendamustine" (Exhibit H hereto), was duly and legally issued on February 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '887 patent, subject to the exclusive license referenced herein. The '887 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

26. The '397 patent, entitled "Formulations of Bendamustine" (Exhibit I hereto), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the

owner and assignee of the '397 patent, subject to the exclusive license referenced herein. The '397 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

27. The '398 patent, entitled "Formulations of Bendamustine" (Exhibit J hereto), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '398 patent, subject to the exclusive license referenced herein. The '398 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

28. The '399 patent, entitled "Formulations of Bendamustine" (Exhibit K hereto), was duly and legally issued on March 21, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '399 patent, subject to the exclusive license referenced herein. The '399 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

29. The '021 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit L hereto), was duly and legally issued on April 7, 2015. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '021 patent, subject to the exclusive license referenced herein. The '021 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

30. The '384 patent, entitled "Method of Treating Bendamustine-Responsive Conditions in Patients Requiring Reduced Volumes for Administration" (Exhibit M hereto), was duly and legally issued on February 28, 2017. Eagle Pharmaceuticals, Inc. is the owner and assignee of the '384 patent, subject to the exclusive license referenced herein. The '384 patent has been listed in connection with BENDEKA<sup>®</sup> in the Orange Book.

31. On or around February 13, 2015, Cephalon executed an exclusive license ("the Eagle license") to, *inter alia*, the '707 patent, patent application no. 14/031,879 (which later issued as the '831 patent), patent application no. 13/838,090 (which later issued as the '908

patent), and patent application no. 13/838,267 (which later issued as the '021 patent), and all patent rights claiming priority to those patents or patent applications (which include the '796, '797, '568, '887, '397, '398, '399, and '384 patents), for the commercialization of Eagle's bendamustine hydrochloride rapid infusion product, EP-3102, which became BENDEKA<sup>®</sup>. The Eagle license provides Cephalon the right to sue for infringement of the licensed patents in the event of, *inter alia*, the filing of an ANDA that makes reference to BENDEKA<sup>®</sup> and seeks approval before expiry of a licensed patent.

32. On or around October 14, 2015, Cephalon assigned its rights in the Eagle license to Teva Pharmaceuticals.

#### **INFRINGEMENT BY MYLAN**

33. By letter dated October 30, 2017 (the "Notice Letter"), Mylan notified Teva and Eagle pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Mylan had submitted to the FDA ANDA No. 210827, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic Bendamustine Hydrochloride Injection, 100 mg /4 mL (25 mg/mL) ("Mylan's ANDA Product") prior to the expiration of the Orange Book patents. Upon information and belief, Mylan's ANDA Product is a drug product that is a generic version of BENDEKA<sup>®</sup>, containing the same or equivalent ingredients in the same or equivalent amounts.

34. The purpose of Mylan's submission of ANDA No. 210827 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the Orange Book patents.



35. In the Notice Letter, Mylan also notified Teva and Eagle that, as part of its ANDA No. 210827, Mylan had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA (“Paragraph IV Certification”), with respect to the Orange Book patents. Upon information and belief, Mylan submitted ANDA No. 210827 to the FDA containing a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the Orange Book patents will not be infringed by the manufacture, use, offer for sale, sale, or importation of Mylan’s ANDA Product, or alternatively, that these patents are invalid.

36. In the Notice Letter, Mylan stated that the active ingredient of Mylan’s ANDA Product is bendamustine hydrochloride.

37. In the Notice Letter, Mylan stated that the proposed dosage strength of Mylan’s ANDA Product is 25 mg/mL.

38. Upon information and belief, Mylan’s ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as BENDEKA®.

39. Upon information and belief, the proposed labeling for Mylan’s ANDA Product recommends, instructs, and/or promotes administration to patients with chronic lymphocytic leukemia.

40. Upon information and belief, the proposed labeling for Mylan’s ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m<sup>2</sup> to patients with chronic lymphocytic leukemia.

41. Upon information and belief, the proposed labeling for Mylan’s ANDA Product recommends, instructs, and/or promotes administration to patients with indolent B-cell non-Hodgkin lymphoma.

42. Upon information and belief, the proposed labeling for Mylan's ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 120 mg/m<sup>2</sup> to patients with indolent B-cell non-Hodgkin lymphoma.

43. Upon information and belief, the proposed labeling for Mylan's ANDA Product recommends, instructs, and/or promotes the administration of Mylan's ANDA product in a volume of about 50 mL or less over a 10-minute period.

44. In an exchange of correspondence, counsel for Mylan and counsel for Teva discussed the terms of Teva's Request for Confidential Access. The parties did not timely agree on terms under which Teva could review Mylan's ANDA, and Mylan refused to produce other internal documents and data relevant to infringement.

45. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

**COUNT I – INFRINGEMENT OF U.S. PATENT  
NO. 8,791,270 UNDER 35 U.S.C. § 271(e)(2)**

46. Plaintiffs incorporate each of the preceding paragraphs 1–45 as if fully set forth herein.

47. Notwithstanding Teva's Request for Confidential Access, Mylan has not provided Teva with Mylan's ANDA and other materials relevant to infringement.

48. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '270 patent was an act of infringement of the '270 patent under 35 U.S.C. § 271(e)(2)(A).

49. In the Notice Letter, Mylan did not contest that at least some of the claims of the '270 patent, including claim 7, cover Mylan's ANDA Product.

50. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '270 patent, either literally or under the doctrine of equivalents.

51. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

52. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '270 patent.

53. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '270 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

54. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '270 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '270 patent after approval of ANDA No. 210827.

55. The foregoing actions by Mylan constitute and/or will constitute infringement of the '270 patent, active inducement of infringement of the '270 patent, and contribution to the infringement by others of the '270 patent.

56. Upon information and belief, Mylan has acted with full knowledge of the '270 patent and without a reasonable basis for believing that it would not be liable for infringing

the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent.

57. Unless Mylan is enjoined from infringing the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – INFRINGEMENT OF U.S. PATENT  
NO. 8,609,707 UNDER 35 U.S.C. § 271(e)(2)**

58. Plaintiffs incorporate each of the preceding paragraphs 1–57 as if fully set forth herein.

59. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '707 patent was an act of infringement of the '707 patent under 35 U.S.C. § 271(e)(2)(A).

60. In the Notice Letter, Mylan did not contest that at least some of the claims of the '707 patent, including claim 1, cover Mylan's ANDA Product.

61. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

62. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

63. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '707 patent.

64. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '707 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

65. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '707 patent after approval of ANDA No. 210827.

66. The foregoing actions by Mylan constitute and/or will constitute infringement of the '707 patent, active inducement of infringement of the '707 patent, and contribution to the infringement by others of the '707 patent.

67. Upon information and belief, Mylan has acted with full knowledge of the '707 patent and without a reasonable basis for believing that it would not be liable for infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent.

68. Unless Mylan is enjoined from infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT III – INFRINGEMENT OF U.S. PATENT  
NO. 9,265,831 UNDER 35 U.S.C. § 271(e)(2)**

69. Plaintiffs incorporate each of the preceding paragraphs 1–68 as if fully set forth herein.

70. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Mylan's ANDA Product prior to the expiration of the '831 patent was an act of infringement of the '831 patent under 35 U.S.C. § 271(e)(2)(A).

71. In the Notice Letter, Mylan did not contest that at least some of the claims of the '831 patent, including claim 1, cover Mylan's ANDA Product.

72. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

73. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

74. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '831 patent.

75. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '831 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

76. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '831 patent after approval of ANDA No. 210827.

77. The foregoing actions by Mylan constitute and/or will constitute infringement of the '831 patent, active inducement of infringement of the '831 patent, and contribution to the infringement by others of the '831 patent.

78. Upon information and belief, Mylan has acted with full knowledge of the '831 patent and without a reasonable basis for believing that it would not be liable for infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent.

79. Unless Mylan is enjoined from infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IV – INFRINGEMENT OF U.S. PATENT  
NO. 9,572,796 UNDER 35 U.S.C. § 271(e)(2)**

80. Plaintiffs incorporate each of the preceding paragraphs 1–79 as if fully set forth herein.

81. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '796 patent was an act of infringement of the '796 patent under 35 U.S.C. § 271(e)(2)(A).

82. In the Notice Letter, Mylan did not contest that at least some of the claims of the '796 patent, including claim 1, cover Mylan's ANDA Product.

83. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

84. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

85. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '796 patent.

86. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '796 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

87. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '796 patent after approval of ANDA No. 210827.

88. The foregoing actions by Mylan constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and contribution to the infringement by others of the '796 patent.

89. Upon information and belief, Mylan has acted with full knowledge of the '796 patent and without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent.



90. Unless Mylan is enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT V – INFRINGEMENT OF U.S. PATENT  
NO. 9,572,797 UNDER 35 U.S.C. § 271(e)(2)**

91. Plaintiffs incorporate each of the preceding paragraphs 1–90 as if fully set forth herein.

92. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '797 patent was an act of infringement of the '797 patent under 35 U.S.C. § 271(e)(2)(A).

93. In the Notice Letter, Mylan did not contest that at least some of the claims of the '797 patent, including claim 1, cover Mylan's ANDA Product.

94. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

95. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

96. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '797 patent.

97. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '797 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

98. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '797 patent after approval of ANDA No. 210827.

99. The foregoing actions by Mylan constitute and/or will constitute infringement of the '797 patent, active inducement of infringement of the '797 patent, and contribution to the infringement by others of the '797 patent.

100. Upon information and belief, Mylan has acted with full knowledge of the '797 patent and without a reasonable basis for believing that it would not be liable for infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent.

101. Unless Mylan is enjoined from infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VI – INFRINGEMENT OF U.S. PATENT  
NO. 9,034,908 UNDER 35 U.S.C. § 271(e)(2)**

102. Plaintiffs incorporate each of the preceding paragraphs 1–101 as if fully set forth herein.

103. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Mylan's ANDA Product prior to the expiration of the '908 patent was an act of infringement of the '908 patent under 35 U.S.C. § 271(e)(2)(A).

104. In the Notice Letter, Mylan did not contest that at least some of the claims of the '908 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

105. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

106. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

107. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '908 patent.

108. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '908 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

109. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '908 patent after approval of ANDA No. 210827.

110. The foregoing actions by Mylan constitute and/or will constitute infringement of the '908 patent, active inducement of infringement of the '908 patent, and contribution to the infringement by others of the '908 patent.

111. Upon information and belief, Mylan has acted with full knowledge of the '908 patent and without a reasonable basis for believing that it would not be liable for infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent.

112. Unless Mylan is enjoined from infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VII – INFRINGEMENT OF U.S. PATENT  
NO. 9,144,568 UNDER 35 U.S.C. § 271(e)(2)**

113. Plaintiffs incorporate each of the preceding paragraphs 1–112 as if fully set forth herein.

114. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '568 patent was an act of infringement of the '568 patent under 35 U.S.C. § 271(e)(2)(A).

115. In the Notice Letter, Mylan did not contest that at least some of the claims of the '568 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

116. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '568 patent, either literally or under the doctrine of equivalents.

117. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

118. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '568 patent.

119. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '568 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

120. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '568 patent after approval of ANDA No. 210827.

121. The foregoing actions by Mylan constitute and/or will constitute infringement of the '568 patent, active inducement of infringement of the '568 patent, and contribution to the infringement by others of the '568 patent.

122. Upon information and belief, Mylan has acted with full knowledge of the '568 patent and without a reasonable basis for believing that it would not be liable for infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent.

123. Unless Mylan is enjoined from infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VIII – INFRINGEMENT OF U.S. PATENT  
NO. 9,572,887 UNDER 35 U.S.C. § 271(e)(2)**

124. Plaintiffs incorporate each of the preceding paragraphs 1–123 as if fully set forth herein.

125. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '887 patent was an act of infringement of the '887 patent under 35 U.S.C. § 271(e)(2)(A).

126. In the Notice Letter, Mylan did not contest that at least some of the claims of the '887 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

127. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

128. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

129. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '887 patent.

130. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

131. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '887 patent after approval of ANDA No. 210827.

132. The foregoing actions by Mylan constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

133. Upon information and belief, Mylan has acted with full knowledge of the '887 patent and without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

134. Unless Mylan is enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IX – INFRINGEMENT OF U.S. PATENT  
NO. 9,597,397 UNDER 35 U.S.C. § 271(e)(2)**

135. Plaintiffs incorporate each of the preceding paragraphs 1–134 as if fully set forth herein.

136. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Mylan's ANDA Product prior to the expiration of the '397 patent was an act of infringement of the '397 patent under 35 U.S.C. § 271(e)(2)(A).

137. In the Notice Letter, Mylan did not contest that at least some of the claims of the '397 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

138. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '397 patent, either literally or under the doctrine of equivalents.

139. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

140. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '397 patent.

141. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '397 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

142. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '397 patent after approval of ANDA No. 210827.



143. The foregoing actions by Mylan constitute and/or will constitute infringement of the '397 patent, active inducement of infringement of the '397 patent, and contribution to the infringement by others of the '397 patent.

144. Upon information and belief, Mylan has acted with full knowledge of the '397 patent and without a reasonable basis for believing that it would not be liable for infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent.

145. Unless Mylan is enjoined from infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT X – INFRINGEMENT OF U.S. PATENT  
NO. 9,597,398 UNDER 35 U.S.C. § 271(e)(2)**

146. Plaintiffs incorporate each of the preceding paragraphs 1–145 as if fully set forth herein.

147. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '398 patent was an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

148. In the Notice Letter, Mylan did not contest that at least some of the claims of the '398 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

149. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '398 patent, either literally or under the doctrine of equivalents.

150. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

151. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '398 patent.

152. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '398 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

153. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '398 patent after approval of ANDA No. 210827.

154. The foregoing actions by Mylan constitute and/or will constitute infringement of the '398 patent, active inducement of infringement of the '398 patent, and contribution to the infringement by others of the '398 patent.

155. Upon information and belief, Mylan has acted with full knowledge of the '398 patent and without a reasonable basis for believing that it would not be liable for infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent.

156. Unless Mylan is enjoined from infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XI – INFRINGEMENT OF U.S. PATENT  
NO. 9,597,399 UNDER 35 U.S.C. § 271(e)(2)**

157. Plaintiffs incorporate each of the preceding paragraphs 1–156 as if fully set forth herein.

158. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '399 patent was an act of infringement of the '399 patent under 35 U.S.C. § 271(e)(2)(A).

159. In the Notice Letter, Mylan did not contest that at least some of the claims of the '399 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

160. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '399 patent, either literally or under the doctrine of equivalents.

161. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

162. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '399 patent.

163. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '399 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

164. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '399 patent after approval of ANDA No. 210827.

165. The foregoing actions by Mylan constitute and/or will constitute infringement of the '399 patent, active inducement of infringement of the '399 patent, and contribution to the infringement by others of the '399 patent.

166. Upon information and belief, Mylan has acted with full knowledge of the '399 patent and without a reasonable basis for believing that it would not be liable for infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent.

167. Unless Mylan is enjoined from infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XII – INFRINGEMENT OF U.S. PATENT  
NO. 9,000,021 UNDER 35 U.S.C. § 271(e)(2)**

168. Plaintiffs incorporate each of the preceding paragraphs 1–167 as if fully set forth herein.

169. Notwithstanding Teva's Request for Confidential Access, Mylan has not provided Teva with Mylan's ANDA and other materials relevant to infringement.

170. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '021 patent was an act of infringement of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

171. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '021 patent, either literally or under the doctrine of equivalents.

172. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

173. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '021 patent.

174. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '021 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

175. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '021 patent after approval of ANDA No. 210827.

176. The foregoing actions by Mylan constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contribution to the infringement by others of the '021 patent.

177. Upon information and belief, Mylan has acted with full knowledge of the '021 patent and without a reasonable basis for believing that it would not be liable for infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

178. Unless Mylan is enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIII – INFRINGEMENT OF U.S. PATENT  
NO. 9,579,384 UNDER 35 U.S.C. § 271(e)(2)**

179. Plaintiffs incorporate each of the preceding paragraphs 1–178 as if fully set forth herein.

180. Mylan's submission of ANDA No. 210827 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '384 patent was an act of infringement of the '384 patent under 35 U.S.C. § 271(e)(2)(A).

181. In the Notice Letter, Mylan did not contest that at least some of the claims of the '384 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

182. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '384 patent, either literally or under the doctrine of equivalents.

183. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

184. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '384 patent.

185. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '384 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

186. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '384 patent after approval of ANDA No. 210827.

187. The foregoing actions by Mylan constitute and/or will constitute infringement of the '384 patent, active inducement of infringement of the '384 patent, and contribution to the infringement by others of the '384 patent.

188. Upon information and belief, Mylan has acted with full knowledge of the '384 patent and without a reasonable basis for believing that it would not be liable for infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent.

189. Unless Mylan is enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIV – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,791,270**

190. Plaintiffs incorporate each of the preceding paragraphs 1–189 as if fully set forth herein.

191. Notwithstanding Teva's Request for Confidential Access, Mylan has not provided Teva with Mylan's ANDA and other materials relevant to infringement.

192. Mylan has knowledge of the '270 patent.

193. In the Notice Letter, Mylan did not contest that at least some of the claims of the '270 patent, including claim 7, cover Mylan's ANDA Product.

194. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '270 patent, either literally or under the doctrine of equivalents.

195. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

196. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '270 patent.

197. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '270 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.



198. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '270 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '270 patent after approval of ANDA No. 210827.

199. The foregoing actions by Mylan constitute and/or will constitute infringement of the '270 patent, active inducement of infringement of the '270 patent, and contribution to the infringement by others of the '270 patent.

200. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the '270 patent.

201. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '270 patent and whether one or more claims of the '270 patent are valid.

202. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '270 patent and that the claims of the '270 patent are valid.

203. Mylan should be enjoined from infringing the '270 patent, actively inducing infringement of the '270 patent, and contributing to the infringement by others of the

'770 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XV – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,609,707**

204. Plaintiffs incorporate each of the preceding paragraphs 1–203 as if fully set forth herein.

205. Mylan has knowledge of the '707 patent.

206. In the Notice Letter, Mylan did not contest that at least some of the claims of the '707 patent, including claim 1, cover Mylan's ANDA Product.

207. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '707 patent, either literally or under the doctrine of equivalents.

208. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

209. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '707 patent.

210. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '707 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

211. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '707 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '707 patent after approval of ANDA No. 210827.

212. The foregoing actions by Mylan constitute and/or will constitute infringement of the '707 patent, active inducement of infringement of the '707 patent, and contribution to the infringement by others of the '707 patent.

213. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent.

214. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '707 patent and whether one or more claims of the '707 patent are valid.

215. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '707 patent and that the claims of the '707 patent are valid.

216. Mylan should be enjoined from infringing the '707 patent, actively inducing infringement of the '707 patent, and contributing to the infringement by others of the '707 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XVI – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,265,831**

217. Plaintiffs incorporate each of the preceding paragraphs 1–216 as if fully set forth herein.

218. Mylan has knowledge of the '831 patent.

219. In the Notice Letter, Mylan did not contest that at least some of the claims of the '831 patent, including claim 1, cover Mylan's ANDA Product.

220. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '831 patent, either literally or under the doctrine of equivalents.

221. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

222. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '831 patent.

223. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '831 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

224. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '831 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '831 patent after approval of ANDA No. 210827.

225. The foregoing actions by Mylan constitute and/or will constitute infringement of the '831 patent, active inducement of infringement of the '831 patent, and contribution to the infringement by others of the '831 patent.

226. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent.

227. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '831 patent and whether one or more claims of the '831 patent are valid.

228. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '831 patent and that the claims of the '831 patent are valid.

229. Mylan should be enjoined from infringing the '831 patent, actively inducing infringement of the '831 patent, and contributing to the infringement by others of the '831 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XVII – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,572,796**

230. Plaintiffs incorporate each of the preceding paragraphs 1–229 as if fully set forth herein.

231. Mylan has knowledge of the '796 patent.

232. In the Notice Letter, Mylan did not contest that at least some of the claims of the '796 patent, including claim 1, cover Mylan's ANDA Product.

233. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '796 patent, either literally or under the doctrine of equivalents.

234. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

235. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '796 patent.

236. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '796 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

237. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '796 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '796 patent after approval of ANDA No. 210827.

238. The foregoing actions by Mylan constitute and/or will constitute infringement of the '796 patent, active inducement of infringement of the '796 patent, and contribution to the infringement by others of the '796 patent.

239. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent.

240. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '796 patent and whether one or more claims of the '796 patent are valid.

241. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '796 patent and that the claims of the '796 patent are valid.

242. Mylan should be enjoined from infringing the '796 patent, actively inducing infringement of the '796 patent, and contributing to the infringement by others of the '796 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XVIII – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,572,797**

243. Plaintiffs incorporate each of the preceding paragraphs 1–242 as if fully set forth herein.

244. Mylan has knowledge of the '797 patent.

245. In the Notice Letter, Mylan did not contest that at least some of the claims of the '797 patent, including claim 1, cover Mylan's ANDA Product.

246. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '797 patent, either literally or under the doctrine of equivalents.

247. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

248. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '797 patent.

249. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '797 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

250. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '797 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '797 patent after approval of ANDA No. 210827.

251. The foregoing actions by Mylan constitute and/or will constitute infringement of the '797 patent, active inducement of infringement of the '797 patent, and contribution to the infringement by others of the '797 patent.

252. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '797 patent, actively inducing



infringement of the '797 patent, and contributing to the infringement by others of the '797 patent.

253. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '797 patent and whether one or more claims of the '797 patent are valid.

254. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '797 patent and that the claims of the '797 patent are valid.

255. Mylan should be enjoined from infringing the '797 patent, actively inducing infringement of the '797 patent, and contributing to the infringement by others of the '797 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIX – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,034,908**

256. Plaintiffs incorporate each of the preceding paragraphs 1–255 as if fully set forth herein.

257. Mylan has knowledge of the '908 patent.

258. In the Notice Letter, Mylan did not contest that at least some of the claims of the '908 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

259. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

260. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210827.

261. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '908 patent.

262. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '908 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

263. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '908 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '908 patent after approval of ANDA No. 210827.

264. The foregoing actions by Mylan constitute and/or will constitute infringement of the '908 patent, active inducement of infringement of the '908 patent, and contribution to the infringement by others of the '908 patent.

265. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '908 patent, actively inducing

infringement of the '908 patent, and contributing to the infringement by others of the '908 patent.

266. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '908 patent and whether one or more claims of the '908 patent are valid.

267. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '908 patent and that the claims of the '908 patent are valid.

268. Mylan should be enjoined from infringing the '908 patent, actively inducing infringement of the '908 patent, and contributing to the infringement by others of the '908 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XX – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,144,568**

269. Plaintiffs incorporate each of the preceding paragraphs 1–268 as if fully set forth herein.

270. Mylan has knowledge of the '568 patent.

271. In the Notice Letter, Mylan did not contest that at least some of the claims of the '568 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

272. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '568 patent, either literally or under the doctrine of equivalents.

273. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

274. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '568 patent.

275. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '568 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

276. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '568 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '568 patent after approval of ANDA No. 210827.

277. The foregoing actions by Mylan constitute and/or will constitute infringement of the '568 patent, active inducement of infringement of the '568 patent, and contribution to the infringement by others of the '568 patent.

278. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '568 patent, actively inducing

infringement of the '568 patent, and contributing to the infringement by others of the '568 patent.

279. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '568 patent and whether one or more claims of the '568 patent are valid.

280. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '568 patent and that the claims of the '568 patent are valid.

281. Mylan should be enjoined from infringing the '568 patent, actively inducing infringement of the '568 patent, and contributing to the infringement by others of the '568 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXI – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,572,887**

282. Plaintiffs incorporate each of the preceding paragraphs 1–281 as if fully set forth herein.

283. Mylan has knowledge of the '887 patent.

284. In the Notice Letter, Mylan did not contest that at least some of the claims of the '887 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

285. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '887 patent, either literally or under the doctrine of equivalents.

286. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

287. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '887 patent.

288. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

289. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '887 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '887 patent after approval of ANDA No. 210827.

290. The foregoing actions by Mylan constitute and/or will constitute infringement of the '887 patent, active inducement of infringement of the '887 patent, and contribution to the infringement by others of the '887 patent.

291. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '887 patent, actively inducing

infringement of the '887 patent, and contributing to the infringement by others of the '887 patent.

292. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '887 patent and whether one or more claims of the '887 patent are valid.

293. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '887 patent and that the claims of the '887 patent are valid.

294. Mylan should be enjoined from infringing the '887 patent, actively inducing infringement of the '887 patent, and contributing to the infringement by others of the '887 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXII – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,597,397**

295. Plaintiffs incorporate each of the preceding paragraphs 1–294 as if fully set forth herein.

296. Mylan has knowledge of the '397 patent.

297. In the Notice Letter, Mylan did not contest that at least some of the claims of the '397 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

298. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '397 patent, either literally or under the doctrine of equivalents.

299. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

300. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '397 patent.

301. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '397 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

302. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '397 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '397 patent after approval of ANDA No. 210827.

303. The foregoing actions by Mylan constitute and/or will constitute infringement of the '397 patent, active inducement of infringement of the '397 patent, and contribution to the infringement by others of the '397 patent.

304. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '397 patent, actively inducing



infringement of the '397 patent, and contributing to the infringement by others of the '397 patent.

305. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '397 patent and whether one or more claims of the '397 patent are valid.

306. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '397 patent and that the claims of the '397 patent are valid.

307. Mylan should be enjoined from infringing the '397 patent, actively inducing infringement of the '397 patent, and contributing to the infringement by others of the '397 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXIII – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,597,398**

308. Plaintiffs incorporate each of the preceding paragraphs 1–307 as if fully set forth herein.

309. Mylan has knowledge of the '398 patent.

310. In the Notice Letter, Mylan did not contest that at least some of the claims of the '398 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

311. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '398 patent, either literally or under the doctrine of equivalents.

312. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

313. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '398 patent.

314. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '398 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

315. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '398 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '398 patent after approval of ANDA No. 210827.

316. The foregoing actions by Mylan constitute and/or will constitute infringement of the '398 patent, active inducement of infringement of the '398 patent, and contribution to the infringement by others of the '398 patent.

317. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '398 patent, actively inducing

infringement of the '398 patent, and contributing to the infringement by others of the '398 patent.

318. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '398 patent and whether one or more claims of the '398 patent are valid.

319. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '398 patent and that the claims of the '398 patent are valid.

320. Mylan should be enjoined from infringing the '398 patent, actively inducing infringement of the '398 patent, and contributing to the infringement by others of the '398 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXIV – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,597,399**

321. Plaintiffs incorporate each of the preceding paragraphs 1–320 as if fully set forth herein.

322. Mylan has knowledge of the '399 patent.

323. In the Notice Letter, Mylan did not contest that at least some of the claims of the '399 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

324. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '399 patent, either literally or under the doctrine of equivalents.

325. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

326. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '399 patent.

327. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '399 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

328. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '399 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '399 patent after approval of ANDA No. 210827.

329. The foregoing actions by Mylan constitute and/or will constitute infringement of the '399 patent, active inducement of infringement of the '399 patent, and contribution to the infringement by others of the '399 patent.

330. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '399 patent, actively inducing

infringement of the '399 patent, and contributing to the infringement by others of the '399 patent.

331. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '399 patent and whether one or more claims of the '399 patent are valid.

332. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '399 patent and that the claims of the '399 patent are valid.

333. Mylan should be enjoined from infringing the '399 patent, actively inducing infringement of the '399 patent, and contributing to the infringement by others of the '399 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXV – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,000,021**

334. Plaintiffs incorporate each of the preceding paragraphs 1–333 as if fully set forth herein.

335. Notwithstanding Teva's Request for Confidential Access, Mylan has not provided Teva with Mylan's ANDA and other materials relevant to infringement.

336. Mylan has knowledge of the '021 patent.

337. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '021 patent, either literally or under the doctrine of equivalents.

338. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

339. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '021 patent.

340. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '021 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

341. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '021 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '021 patent after approval of ANDA No. 210827.

342. The foregoing actions by Mylan constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contribution to the infringement by others of the '021 patent.

343. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '021 patent, actively inducing

infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

344. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '021 patent and whether one or more claims of the '021 patent are valid.

345. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '021 patent and that the claims of the '021 patent are valid.

346. Mylan should be enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XXVI – DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 9,579,384**

347. Plaintiffs incorporate each of the preceding paragraphs 1–346 as if fully set forth herein.

348. Mylan has knowledge of the '384 patent.

349. In the Notice Letter, Mylan did not contest that at least some of the claims of the '384 patent, including claim 1, cover the use of Mylan's ANDA Product as directed by Mylan's proposed labeling.

350. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '384 patent, either literally or under the doctrine of equivalents.

351. Upon information and belief, Mylan will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210827.

352. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '384 patent.

353. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '384 patent when ANDA No. 210827 is approved, and plans and intends to, and will, do so after approval.

354. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '384 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '384 patent after approval of ANDA No. 210827.

355. The foregoing actions by Mylan constitute and/or will constitute infringement of the '384 patent, active inducement of infringement of the '384 patent, and contribution to the infringement by others of the '384 patent.

356. Upon information and belief, Mylan has acted without a reasonable basis for believing that it would not be liable for infringing the '384 patent, actively inducing



infringement of the '384 patent, and contributing to the infringement by others of the '384 patent.

357. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Mylan regarding whether Mylan's manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product with its proposed labeling according to ANDA No. 210827 will infringe one or more claims of the '384 patent and whether one or more claims of the '384 patent are valid.

358. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Mylan's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '384 patent and that the claims of the '384 patent are valid.

359. Mylan should be enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and contributing to the infringement by others of the '384 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Mylan has infringed, will infringe, and will induce and contribute to infringement of the '270 patent, the '707 patent, the '831 patent, the '796 patent, the '797 patent, the '908 patent, the '568 patent, the '887 patent, the '397 patent, the '398 patent, the '399 patent, the '021 patent, and the '384 patent (the "patents-in-suit").

(b) A judgment that the patents-in-suit are valid and enforceable;

(c) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market,

distribute, or import Mylan's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the patents-in-suit, be not earlier than the latest of the expiration dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283 enjoining Mylan, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the patents-in-suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the patents-in-suit, prior to the expiration date of the patents-in-suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the patents-in-suit;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Mylan engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Mylan's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the patents-in-suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration

dates of the patents-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A declaration that this case against Mylan is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) An award of Plaintiffs' costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

*/s/ Karen E. Keller*

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