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. _____
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

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 defendants' submission of Abbreviated New Drug Application ("ANDA") No. 210601 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of BENDEKA® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL) ("BENDEKA®") 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 Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States in concert with its subsidiary, Apotex Corp.

6. On information and belief, defendant Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded

pharmaceutical products throughout the United States. Apotex Inc. and Apotex Corp. are collectively referred to herein as "Apotex."

7. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

8. On information and belief, and consistent with their practice with respect to other generic products, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit ANDA No. 210601.

9. On information and belief, Apotex Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Apotex Inc., acting in concert with Apotex Corp., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Apotex Inc., acting in concert with Apotex Corp., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

10. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including in Delaware, and including with respect to the generic product described in ANDA No. 210601.

11. On information and belief, Apotex Inc. and Apotex Corp. contemplate that upon approval of ANDA No. 210601, Apotex Inc. will manufacture the generic product described in ANDA No. 210601, which Apotex Corp. will directly or indirectly market, sell, and distribute throughout the United States, including in Delaware.

12. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 210601, Apotex Inc. and Apotex Corp. will act in concert to market, distribute, offer for sale, and sell the generic product described in ANDA No. 210601 throughout the United States and within Delaware.

13. On information and belief, following any FDA approval of ANDA No. 210601, Apotex knows and intends that the generic product described in ANDA No. 210601 will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION AND VENUE

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

15. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because Apotex, Inc. is a foreign corporation that is subject to personal jurisdiction in this Court, and Apotex Corp. is incorporated in Delaware and therefore resides there for purposes of venue.

16. 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 Apotex.

17. This Court has personal jurisdiction over Apotex Corp. because, on information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware to accept service of process. Apotex Corp. has thus consented to jurisdiction in Delaware.

18. In addition, this Court also has personal jurisdiction over Apotex Corp. and Apotex Inc. because, among other things, on information and belief: (1) Apotex Inc., acting in concert with Apotex Corp., 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. 210601 in the United States, including in Delaware; and (2) Apotex Corp. and Apotex Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell the generic product described in ANDA No. 210601 in the United States, including in Delaware, upon approval of ANDA No. 210601, and will derive substantial revenue from the use or consumption of the generic product described in ANDA No. 210601 in the State of Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). For example, Apotex's website states that "Apotex Corp. is the US Company that markets the products of Apotex, Inc." *See* http://www.apotex.com/global /about/press/20110510.asp (last visited Aug. 17, 2017). On information and belief, if ANDA No. 210601 is approved, the generic product described in ANDA No. 210601 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.

19. The Court also has personal jurisdiction over Apotex Corp. and Apotex Inc. because they have 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.

20. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hailed into court here. Upon information and belief, Apotex Inc., itself and through its subsidiary Apotex Corp., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

21. Apotex Inc. and Apotex Corp. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases. *See, e.g.*, *Senju Pharm. Co. v. Apotex, Inc. & Apotex Corp.*, C.A. No. 12-00159-SLR, D.I. 9 (D. Del. Mar. 16, 2012); *Alcon Pharm. Ltd. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-00960-SLR, D.I. 6 (D. Del. July 23, 2012); *Pfizer Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 12-00809-SLR, D.I. 18 (D. Del. Aug. 27, 2012); *UCB, Inc. v. Apotex Corp. & Apotex Inc.*, C.A. No. 13-01209-LPS, D.I. 12 (D. Del. Sept. 9, 2013); *Pfizer Inc. v. Apotex, Inc. & Apotex Corp.*, C.A. No. 13-01613-SLR, D.I. 8 (D. Del. Oct. 17, 2013); *Meda*

Pharm. Inc. v. Apotex Inc. & Apotex Corp., C.A. No. 14-1453-LPS, D.I. 93 (D. Del. Mar. 9, 2016); *Salix Pharm., Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 15-00880-GMS, D.I. 15 (D. Del. Mar. 14, 2016); *Forest Labs., LLC v. Apotex Corp. & Apotex Inc.*, C.A. No. 16-00269-GMS, D.I. 8 (D. Del. May 4, 2016); *Amgen Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-00926-GMS, D.I. 13 (D. Del. Nov. 15, 2016); *Astellas Pharma Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-00976-JFB, D.I. 17 (D. Del. Jan. 17, 2017); *Onyx Therapeutics, Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 16-01039-LPS, D.I. 14 (D. Del. Jan. 31, 2017); *Bristol-Myers Squibb Co. v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-00399-LPS, D.I. 8 (D. Del. May 4, 2017); *Bayer Healthcare LLC v. Apotex Inc. & Apotex Corp.*, C.A. No. 17-00334-LPS, D.I. 10 (D. Del. May 22, 2017).

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

BACKGROUND

23. BENDEKA®, 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.

24. Eagle is the holder of New Drug Application No. 208194 for BENDEKA®, which has been approved by the FDA.

25. 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®

in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

26. 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® in the Orange Book.

27. 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® in the Orange Book.

28. 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® in the Orange Book.

29. 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® in the Orange Book.

30. 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® in the Orange Book.

31. 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® in the Orange Book.

32. 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® in the Orange Book.

33. 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® in the Orange Book.

34. 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® in the Orange Book.

35. 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® in the Orange Book.

36. 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® in the Orange Book.

37. 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® in the Orange Book.

38. 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®. 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® and seeks approval before expiry of a licensed patent.

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

INFRINGEMENT BY APOTEX

40. By letter dated July 7, 2017 (the “Notice Letter”), Apotex Inc. notified Cephalon and Eagle pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”) that Apotex Inc. had submitted to the FDA ANDA No. 210601, 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) multiple-dose vials ("Apotex's ANDA Product") prior to the expiration of the Orange Book patents. Upon information and belief, Apotex's ANDA Product is a drug product that is a generic version of BENDEKA®, containing the same or equivalent ingredients in the same or equivalent amounts.

41. The purpose of Apotex Inc.'s submission of ANDA No. 210601 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the Orange Book patents.

42. In the Notice Letter, Apotex Inc. also notified Cephalon and Eagle that, as part of its ANDA No. 210601, Apotex Inc. 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, Apotex Inc. submitted ANDA No. 210601 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 Apotex's ANDA Product, or alternatively, that these patents are invalid.

43. In the Notice Letter, Apotex Inc. stated that the active ingredient of Apotex's ANDA Product is bendamustine hydrochloride.

44. In the Notice Letter, Apotex Inc. stated that the proposed dosage strength of Apotex's ANDA Product is 100 mg/4 mL (25 mg/mL).

45. Upon information and belief, Apotex's ANDA Product contains propylene glycol, polyethylene glycol, and monothioglycerol in the same or equivalent amounts as BENDEKA®.

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

47. Upon information and belief, the proposed labeling for Apotex's ANDA Product recommends, instructs, and/or promotes administration of a bendamustine dose of 100 mg/m^2 to patients with chronic lymphocytic leukemia.

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

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

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

51. In an exchange of correspondence, counsel for Apotex and counsel for Teva discussed the terms of Teva's Request for Confidential Access. The parties did not agree on terms under which Teva could review, *inter alia*, Apotex's ANDA and certain portions of the Drug Master File referred to therein, and Apotex refused to produce other internal documents and data relevant to infringement.

52. 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)

53. Plaintiffs incorporate each of the preceding paragraphs 1–52 as if fully set forth herein.

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

55. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

57. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

59. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '270 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

60. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’270 patent after approval of ANDA No. 210601.

61. The foregoing actions by Apotex 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.

62. Upon information and belief, Apotex 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.

63. Unless Apotex 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)

64. Plaintiffs incorporate each of the preceding paragraphs 1–63 as if fully set forth herein.

65. Apotex Inc.’s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’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).

66. In the Notice Letter, Apotex Inc. did not contest that at least some of the claims of the ’707 patent, including claim 1, cover Apotex’s ANDA Product.

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

68. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

70. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’707 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

71. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’707 patent after approval of ANDA No. 210601.

72. The foregoing actions by Apotex 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.

73. Upon information and belief, Apotex 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.

74. Unless Apotex 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)

75. Plaintiffs incorporate each of the preceding paragraphs 1–74 as if fully set forth herein.

76. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

79. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

81. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '831 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

82. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '831 patent after approval of ANDA No. 210601.

83. The foregoing actions by Apotex 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.

84. Upon information and belief, Apotex 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.

85. Unless Apotex 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)

86. Plaintiffs incorporate each of the preceding paragraphs 1–85 as if fully set forth herein.

87. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

90. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

92. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '796 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

93. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '796 patent after approval of ANDA No. 210601.

94. The foregoing actions by Apotex 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.

95. Upon information and belief, Apotex 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.

96. Unless Apotex 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)

97. Plaintiffs incorporate each of the preceding paragraphs 1–96 as if fully set forth herein.

98. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

101. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

103. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '797 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

104. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '797 patent after approval of ANDA No. 210601.

105. The foregoing actions by Apotex 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.

106. Upon information and belief, Apotex 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.

107. Unless Apotex 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)

108. Plaintiffs incorporate each of the preceding paragraphs 1–107 as if fully set forth herein.

109. Apotex Inc.’s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’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).

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

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

112. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

114. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '908 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

115. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '908 patent after approval of ANDA No. 210601.

116. The foregoing actions by Apotex 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.

117. Upon information and belief, Apotex 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.

118. Unless Apotex 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)

119. Plaintiffs incorporate each of the preceding paragraphs 1–118 as if fully set forth herein.

120. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

123. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

125. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '568 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

126. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '568 patent after approval of ANDA No. 210601.

127. The foregoing actions by Apotex 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.

128. Upon information and belief, Apotex 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.

129. Unless Apotex 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)

130. Plaintiffs incorporate each of the preceding paragraphs 1–129 as if fully set forth herein.

131. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

134. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

136. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

137. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '887 patent after approval of ANDA No. 210601.

138. The foregoing actions by Apotex 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.

139. Upon information and belief, Apotex 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.

140. Unless Apotex 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)

141. Plaintiffs incorporate each of the preceding paragraphs 1–140 as if fully set forth herein.

142. Apotex Inc.’s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’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).

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

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

145. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

147. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '397 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

148. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '397 patent after approval of ANDA No. 210601.

149. The foregoing actions by Apotex 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.

150. Upon information and belief, Apotex 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.

151. Unless Apotex 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)

152. Plaintiffs incorporate each of the preceding paragraphs 1–151 as if fully set forth herein.

153. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

156. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

158. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '398 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

159. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '398 patent after approval of ANDA No. 210601.

160. The foregoing actions by Apotex 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.

161. Upon information and belief, Apotex 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.

162. Unless Apotex 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)

163. Plaintiffs incorporate each of the preceding paragraphs 1–162 as if fully set forth herein.

164. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

167. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

169. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '399 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

170. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '399 patent after approval of ANDA No. 210601.

171. The foregoing actions by Apotex 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.

172. Upon information and belief, Apotex 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.

173. Unless Apotex 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)

174. Plaintiffs incorporate each of the preceding paragraphs 1–173 as if fully set forth herein.

175. Apotex Inc.’s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’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).

176. In the Notice Letter, Apotex Inc. did not contest that at least some of the claims of the ’021 patent, including claim 1, cover the use of Apotex’s ANDA Product as directed by Apotex’s proposed labeling.

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

178. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

180. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '021 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

181. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '021 patent after approval of ANDA No. 210601.

182. The foregoing actions by Apotex 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.

183. Upon information and belief, Apotex 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.

184. Unless Apotex 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)

185. Plaintiffs incorporate each of the preceding paragraphs 1–184 as if fully set forth herein.

186. Apotex Inc.'s submission of ANDA No. 210601 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

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

189. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

191. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '384 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

192. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '384 patent after approval of ANDA No. 210601.

193. The foregoing actions by Apotex 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.

194. Upon information and belief, Apotex 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.

195. Unless Apotex 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

196. Plaintiffs incorporate each of the preceding paragraphs 1–195 as if fully set forth herein.

197. Apotex has knowledge of the '270 patent.

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

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

200. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

202. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '270 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

203. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '270 patent after approval of ANDA No. 210601.

204. The foregoing actions by Apotex 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.

205. Upon information and belief, Apotex 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.

206. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex's manufacture, use, sale,

offer for sale, or importation into the United States of Apotex's ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the '270 patent and whether one or more claims of the '270 patent are valid.

207. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex'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.

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

209. Plaintiffs incorporate each of the preceding paragraphs 1–208 as if fully set forth herein.

210. Apotex has knowledge of the '707 patent.

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

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

213. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

215. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '707 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

216. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '707 patent after approval of ANDA No. 210601.

217. The foregoing actions by Apotex 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.

218. Upon information and belief, Apotex 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.

219. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex's manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the '707 patent and whether one or more claims of the '707 patent are valid.

220. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex'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.

221. Apotex 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

222. Plaintiffs incorporate each of the preceding paragraphs 1–221 as if fully set forth herein.

223. Apotex has knowledge of the '831 patent.

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

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

226. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

228. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’831 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

229. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’831 patent after approval of ANDA No. 210601.

230. The foregoing actions by Apotex 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.

231. Upon information and belief, Apotex 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.

232. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’831 patent and whether one or more claims of the ’831 patent are valid.

233. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

234. Apotex 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

235. Plaintiffs incorporate each of the preceding paragraphs 1–234 as if fully set forth herein.

236. Apotex has knowledge of the ’796 patent.

237. In the Notice Letter, Apotex Inc. did not contest that at least some of the claims of the ’796 patent, including claim 1, cover Apotex’s ANDA Product.

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

239. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

241. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’796 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

242. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’796 patent after approval of ANDA No. 210601.

243. The foregoing actions by Apotex 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.

244. Upon information and belief, Apotex 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.

245. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’796 patent and whether one or more claims of the ’796 patent are valid.

246. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

247. Apotex 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

248. Plaintiffs incorporate each of the preceding paragraphs 1–247 as if fully set forth herein.

249. Apotex has knowledge of the ’797 patent.

250. In the Notice Letter, Apotex Inc. did not contest that at least some of the claims of the ’797 patent, including claim 1, cover Apotex’s ANDA Product.

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

252. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

254. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’797 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

255. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’797 patent after approval of ANDA No. 210601.

256. The foregoing actions by Apotex 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.

257. Upon information and belief, Apotex 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.

258. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’797 patent and whether one or more claims of the ’797 patent are valid.

259. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

260. Apotex 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

261. Plaintiffs incorporate each of the preceding paragraphs 1–260 as if fully set forth herein.

262. Apotex has knowledge of the ’908 patent.

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

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

265. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product immediately and imminently upon FDA approval of ANDA No. 210601.

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

267. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’908 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

268. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’908 patent after approval of ANDA No. 210601.

269. The foregoing actions by Apotex 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.

270. Upon information and belief, Apotex 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.

271. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’908 patent and whether one or more claims of the ’908 patent are valid.

272. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

273. Apotex 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

274. Plaintiffs incorporate each of the preceding paragraphs 1–273 as if fully set forth herein.

275. Apotex has knowledge of the ’568 patent.

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

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

278. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

280. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’568 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

281. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’568 patent after approval of ANDA No. 210601.

282. The foregoing actions by Apotex 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.

283. Upon information and belief, Apotex 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.

284. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’568 patent and whether one or more claims of the ’568 patent are valid.

285. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

286. Apotex 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

287. Plaintiffs incorporate each of the preceding paragraphs 1–286 as if fully set forth herein.

288. Apotex has knowledge of the ’887 patent.

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

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

291. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

293. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '887 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

294. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the '887 patent after approval of ANDA No. 210601.

295. The foregoing actions by Apotex 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.

296. Upon information and belief, Apotex 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.

297. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex's manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the '887 patent and whether one or more claims of the '887 patent are valid.

298. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex'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.

299. Apotex 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

300. Plaintiffs incorporate each of the preceding paragraphs 1–299 as if fully set forth herein.

301. Apotex has knowledge of the ’397 patent.

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

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

304. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

306. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’397 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

307. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’397 patent after approval of ANDA No. 210601.

308. The foregoing actions by Apotex 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.

309. Upon information and belief, Apotex 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.

310. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’397 patent and whether one or more claims of the ’397 patent are valid.

311. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

312. Apotex 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

313. Plaintiffs incorporate each of the preceding paragraphs 1–312 as if fully set forth herein.

314. Apotex has knowledge of the ’398 patent.

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

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

317. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

319. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’398 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

320. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’398 patent after approval of ANDA No. 210601.

321. The foregoing actions by Apotex 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.

322. Upon information and belief, Apotex 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.

323. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’398 patent and whether one or more claims of the ’398 patent are valid.

324. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

325. Apotex 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

326. Plaintiffs incorporate each of the preceding paragraphs 1–325 as if fully set forth herein.

327. Apotex has knowledge of the ’399 patent.

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

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

330. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

332. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’399 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

333. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’399 patent after approval of ANDA No. 210601.

334. The foregoing actions by Apotex 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.

335. Upon information and belief, Apotex 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.

336. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’399 patent and whether one or more claims of the ’399 patent are valid.

337. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

338. Apotex 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

339. Plaintiffs incorporate each of the preceding paragraphs 1–338 as if fully set forth herein.

340. Apotex has knowledge of the ’021 patent.

341. In the Notice Letter, Apotex Inc. did not contest that at least some of the claims of the ’021 patent, including claim 1, cover the use of Apotex’s ANDA Product as directed by Apotex’s proposed labeling.

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

343. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

345. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’021 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

346. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’021 patent after approval of ANDA No. 210601.

347. The foregoing actions by Apotex 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.

348. Upon information and belief, Apotex 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.

349. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’021 patent and whether one or more claims of the ’021 patent are valid.

350. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

351. Apotex 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

352. Plaintiffs incorporate each of the preceding paragraphs 1–351 as if fully set forth herein.

353. Apotex has knowledge of the ’384 patent.

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

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

356. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex’s ANDA Product with its proposed labeling upon FDA approval of ANDA No. 210601.

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

358. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’384 patent when ANDA No. 210601 is approved, and plans and intends to, and will, do so after approval.

359. Upon information and belief, Apotex 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, Apotex plans and intends to, and will, contribute to infringement of the ’384 patent after approval of ANDA No. 210601.

360. The foregoing actions by Apotex 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.

361. Upon information and belief, Apotex 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.

362. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Apotex regarding whether Apotex’s manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Product with its proposed labeling according to ANDA No. 210601 will infringe one or more claims of the ’384 patent and whether one or more claims of the ’384 patent are valid.

363. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Apotex’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.

364. Apotex 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 Apotex 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 Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex’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 Apotex, their 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 Apotex’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 Apotex'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 Apotex engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Apotex'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 Apotex 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.

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