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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**AXSOME THERAPEUTICS, INC.,**

**Plaintiff,**

**v.**

**APOTEX INC.,**

**Defendant.**

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

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**(Filed Electronically)**

Plaintiff Axsome Therapeutics, Inc. (“Axsome” or “Plaintiff”), by its undersigned attorneys, for its Complaint against defendant Apotex Inc. (“Apotex” or “Defendant”), alleges as follows:

**Nature of the Action**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from the Defendant’s filing of its Abbreviated New Drug Application (“ANDA”) No. 220803 (“Apotex’s ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Plaintiff’s Symbravo<sup>®</sup> (meloxicam and rizatriptan) tablets prior to the expiration of United States Patent Nos. 9,821,075 (the “’075 patent”), 10,029,010 (the “’010

patent”), 10,058,614 (the “‘614 patent”), 10,137,131 (the “‘131 patent”), 10,195,278 (the “‘278 patent”), 10,265,324 (the “‘324 patent”), 10,363,312 (the “‘312 patent”), 10,369,224 (the “‘224 patent”), 10,426,839 (the “‘839 patent”), 10,463,736 (the “‘736 patent”), 10,471,014 (the “‘014 patent”), 10,471,069 (the “‘069 patent”), 10,512,692 (the “‘692 patent”), 10,512,693 (the “‘2,693 patent”), 10,517,950 (the “‘950 patent”), 10,532,101 (the “‘101 patent”), 10,537,642 (the “‘642 patent”), 10,561,664 (the “‘664 patent”), 10,583,144 (the “‘144 patent”), 10,653,777 (the “‘777 patent”), 10,688,102 (the “‘102 patent”), 10,688,185 (the “‘185 patent”), 10,695,429 (the “‘5,429 patent”), 10,695,430 (the “‘430 patent”), 10,702,535 (the “‘535 patent”), 10,702,602 (the “‘602 patent”), 10,722,583 (the “‘583 patent”), 10,729,696 (the “‘696 patent”), 10,729,697 (the “‘697 patent”), 10,729,773 (the “‘773 patent”), 10,758,617 (the “‘617 patent”), 10,758,618 (the “‘618 patent”), 10,780,165 (the “‘165 patent”), 10,780,166 (the “‘166 patent”), 10,799,588 (the “‘588 patent”), 10,821,181 (the “‘181 patent”), 10,821,182 (the “‘182 patent”), 10,894,053 (the “‘053 patent”), 10,905,693 (the “‘5,693 patent”), 10,918,722 (the “‘722 patent”), 10,933,136 (the “‘136 patent”), 10,933,137 (the “‘137 patent”), 10,940,153 (the “‘153 patent”), 10,987,358 (the “‘358 patent”), 11,013,805 (the “‘805 patent”), 11,013,806 (the “‘806 patent”), 11,020,483 (the “‘483 patent”), 11,045,549 (the “‘549 patent”), 11,135,295 (the “‘295 patent”), 11,207,328 (the “‘328 patent”), 11,219,626 (the “‘626 patent”), 11,285,213 (the “‘213 patent”), 11,331,323 (the “‘323 patent”), 11,369,684 (the “‘684 patent”), 11,426,414 (the “‘414 patent”), 11,471,464 (the “‘464 patent”), 11,471,465 (the “‘465 patent”), 11,504,429 (the “‘4,429 patent”), 11,510,927 (the “‘927 patent”), 11,571,428 (the “‘428 patent”), 11,602,563 (the “‘563 patent”), 11,607,456 (the “‘456 patent”), 11,617,755 (the “‘755 patent”), 11,617,756 (the “‘756 patent”), 11,617,791 (the “‘791 patent”), 11,628,173 (the “‘173 patent”), 11,712,441 (the “‘441 patent”), 11,738,085 (the “‘085 patent”), 11,759,522 (the “‘522 patent”), 11,801,250 (the “‘250 patent”), 11,806,354 (the “‘354

patent”), 11,826,370 (the “’370 patent”), 11,865,117 (the “’117 patent”), 12,128,052 (the “’052 patent”), and 12,370,196 (the “’196 patent”) (collectively, the “patents-in-suit”), all owned by Axsome.

### **The Parties**

2. Axsome is a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics for central nervous system (“CNS”) conditions that have limited treatment options.

3. Axsome is a corporation existing under the laws of Delaware, having a principal place of business at One World Trade Center, New York, NY 10007.

4. On information and belief, Apotex is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

### **The Patents-in-Suit**

5. On November 21, 2017, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’075 patent, entitled, “Pharmaceutical Compositions Comprising Meloxicam.” A copy of the ’075 patent is attached hereto as Exhibit 1.

6. On July 24, 2018, the USPTO duly and lawfully issued the ’010 patent, entitled, “Pharmaceutical Compositions Comprising Meloxicam.” A copy of the ’010 patent is attached hereto as Exhibit 2.

7. On August 28, 2018, the USPTO duly and lawfully issued the ’614 patent, entitled, “Pharmaceutical Compositions Comprising Meloxicam.” A copy of the ’614 patent is attached hereto as Exhibit 3.

8. On November 27, 2018, the USPTO duly and lawfully issued the '131 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '131 patent is attached hereto as Exhibit 4.

9. On February 5, 2019, the USPTO duly and lawfully issued the '278 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '278 patent is attached hereto as Exhibit 5.

10. On April 23, 2019, the USPTO duly and lawfully issued the '324 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '324 patent is attached hereto as Exhibit 6.

11. On July 30, 2019, the USPTO duly and lawfully issued the '312 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '312 patent is attached hereto as Exhibit 7.

12. On August 6, 2019, the USPTO duly and lawfully issued the '224 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '224 patent is attached hereto as Exhibit 8.

13. On October 1, 2019, the USPTO duly and lawfully issued the '839 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '839 patent is attached hereto as Exhibit 9.

14. On November 5, 2019, the USPTO duly and lawfully issued the '736 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '736 patent is attached hereto as Exhibit 10.

15. On November 12, 2019, the USPTO duly and lawfully issued the '014 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '014 patent is attached hereto as Exhibit 11.

16. On November 12, 2019, the USPTO duly and lawfully issued the '069 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '069 patent is attached hereto as Exhibit 12.

17. On December 24, 2019, the USPTO duly and lawfully issued the '692 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '692 patent is attached hereto as Exhibit 13.

18. On December 24, 2019, the USPTO duly and lawfully issued the '2,693 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '2,693 patent is attached hereto as Exhibit 14.

19. On December 31, 2019, the USPTO duly and lawfully issued the '950 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '950 patent is attached hereto as Exhibit 15.

20. On January 14, 2020, the USPTO duly and lawfully issued the '101 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '101 patent is attached hereto as Exhibit 16.

21. On January 21, 2020, the USPTO duly and lawfully issued the '642 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '642 patent is attached hereto as Exhibit 17.

22. On February 18, 2020, the USPTO duly and lawfully issued the '664 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '664 patent is attached hereto as Exhibit 18.

23. On March 10, 2020, the USPTO duly and lawfully issued the '144 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '144 patent is attached hereto as Exhibit 19.

24. On May 19, 2020, the USPTO duly and lawfully issued the '777 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '777 patent is attached hereto as Exhibit 20.

25. On June 23, 2020, the USPTO duly and lawfully issued the '102 patent, entitled, "Combination Treatment for Migraine and Other Pain." A copy of the '102 patent is attached hereto as Exhibit 21.

26. On June 23, 2020, the USPTO duly and lawfully issued the '185 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '185 patent is attached hereto as Exhibit 22.

27. On June 30, 2020, the USPTO duly and lawfully issued the '5,429 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '5,429 patent is attached hereto as Exhibit 23.

28. On June 30, 2020, the USPTO duly and lawfully issued the '430 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '430 patent is attached hereto as Exhibit 24.

29. On July 7, 2020, the USPTO duly and lawfully issued the '535 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '535 patent is attached hereto as Exhibit 25.

30. On July 7, 2020, the USPTO duly and lawfully issued the '602 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '602 patent is attached hereto as Exhibit 26.

31. On July 28, 2020, the USPTO duly and lawfully issued the '583 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '583 patent is attached hereto as Exhibit 27.

32. On August 4, 2020, the USPTO duly and lawfully issued the '696 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '696 patent is attached hereto as Exhibit 28.

33. On August 4, 2020, the USPTO duly and lawfully issued the '697 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '697 patent is attached hereto as Exhibit 29.

34. On August 4, 2020, the USPTO duly and lawfully issued the '773 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '773 patent is attached hereto as Exhibit 30.

35. On September 1, 2020, the USPTO duly and lawfully issued the '617 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '617 patent is attached hereto as Exhibit 31.

36. On September 1, 2020, the USPTO duly and lawfully issued the '618 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '618 patent is attached hereto as Exhibit 32.

37. On September 22, 2020, the USPTO duly and lawfully issued the '165 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '165 patent is attached hereto as Exhibit 33.

38. On September 22, 2020, the USPTO duly and lawfully issued the '166 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '166 patent is attached hereto as Exhibit 34.

39. On October 13, 2020, the USPTO duly and lawfully issued the '588 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '588 patent is attached hereto as Exhibit 35.

40. On November 3, 2020, the USPTO duly and lawfully issued the '181 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '181 patent is attached hereto as Exhibit 36.

41. On November 3, 2020, the USPTO duly and lawfully issued the '182 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '182 patent is attached hereto as Exhibit 37.

42. On January 19, 2021, the USPTO duly and lawfully issued the '053 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '053 patent is attached hereto as Exhibit 38.



43. On February 2, 2021, the USPTO duly and lawfully issued the '5,693 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '5,693 patent is attached hereto as Exhibit 39.

44. On February 16, 2021, the USPTO duly and lawfully issued the '722 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '722 patent is attached hereto as Exhibit 40.

45. On March 2, 2021, the USPTO duly and lawfully issued the '136 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '136 patent is attached hereto as Exhibit 41.

46. On March 2, 2021, the USPTO duly and lawfully issued the '137 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '137 patent is attached hereto as Exhibit 42.

47. On March 9, 2021, the USPTO duly and lawfully issued the '153 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '153 patent is attached hereto as Exhibit 43.

48. On April 27, 2021, the USPTO duly and lawfully issued the '358 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '358 patent is attached hereto as Exhibit 44.

49. On May 25, 2021, the USPTO duly and lawfully issued the '805 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '805 patent is attached hereto as Exhibit 45.

50. On May 25, 2021, the USPTO duly and lawfully issued the '806 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '806 patent is attached hereto as Exhibit 46.

51. On June 1, 2021, the USPTO duly and lawfully issued the '483 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '483 patent is attached hereto as Exhibit 47.

52. On June 29, 2021, the USPTO duly and lawfully issued the '549 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '549 patent is attached hereto as Exhibit 48.

53. On October 5, 2021, the USPTO duly and lawfully issued the '295 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '295 patent is attached hereto as Exhibit 49.

54. On December 28, 2021, the USPTO duly and lawfully issued the '328 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '328 patent is attached hereto as Exhibit 50.

55. On January 11, 2022, the USPTO duly and lawfully issued the '626 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '626 patent is attached hereto as Exhibit 51.

56. On March 29, 2022, the USPTO duly and lawfully issued the '213 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '213 patent is attached hereto as Exhibit 52.

57. On May 17, 2022, the USPTO duly and lawfully issued the '323 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '323 patent is attached hereto as Exhibit 53.

58. On June 28, 2022, the USPTO duly and lawfully issued the '684 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '684 patent is attached hereto as Exhibit 54.

59. On August 30, 2022, the USPTO duly and lawfully issued the '414 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '414 patent is attached hereto as Exhibit 55.

60. On October 18, 2022, the USPTO duly and lawfully issued the '464 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '464 patent is attached hereto as Exhibit 56.

61. On October 18, 2022, the USPTO duly and lawfully issued the '465 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '465 patent is attached hereto as Exhibit 57.

62. On November 22, 2022, the USPTO duly and lawfully issued the '4,429 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '4,429 patent is attached hereto as Exhibit 58.

63. On November 29, 2022, the USPTO duly and lawfully issued the '927 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '927 patent is attached hereto as Exhibit 59.

64. On February 7, 2023, the USPTO duly and lawfully issued the '428 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '428 patent is attached hereto as Exhibit 60.

65. On March 14, 2023, the USPTO duly and lawfully issued the '563 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '563 patent is attached hereto as Exhibit 61.

66. On March 21, 2023, the USPTO duly and lawfully issued the '456 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '456 patent is attached hereto as Exhibit 62.

67. On April 4, 2023, the USPTO duly and lawfully issued the '755 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '755 patent is attached hereto as Exhibit 63.

68. On April 4, 2023, the USPTO duly and lawfully issued the '756 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '756 patent is attached hereto as Exhibit 64.

69. On April 4, 2023, the USPTO duly and lawfully issued the '791 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '791 patent is attached hereto as Exhibit 65.

70. On April 18, 2023, the USPTO duly and lawfully issued the '173 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '173 patent is attached hereto as Exhibit 66.

71. On August 1, 2023, the USPTO duly and lawfully issued the '441 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '441 patent is attached hereto as Exhibit 67.

72. On August 29, 2023, the USPTO duly and lawfully issued the '085 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '085 patent is attached hereto as Exhibit 68.

73. On September 19, 2023, the USPTO duly and lawfully issued the '522 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '522 patent is attached hereto as Exhibit 69.

74. On October 31, 2023, the USPTO duly and lawfully issued the '250 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '250 patent is attached hereto as Exhibit 70.

75. On November 7, 2023, the USPTO duly and lawfully issued the '354 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '354 patent is attached hereto as Exhibit 71.

76. On November 28, 2023, the USPTO duly and lawfully issued the '370 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '370 patent is attached hereto as Exhibit 72.

77. On January 9, 2024, the USPTO duly and lawfully issued the '117 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '117 patent is attached hereto as Exhibit 73.

78. On October 29, 2024, the USPTO duly and lawfully issued the '052 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '052 patent is attached hereto as Exhibit 74.

79. On July 29, 2025, the USPTO duly and lawfully issued the '196 patent, entitled, "Pharmaceutical Compositions Comprising Meloxicam." A copy of the '196 patent is attached hereto as Exhibit 75.

### **The Symbravo® Drug Product**

80. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for meloxicam and rizatriptan tablets ("NDA No. 215431"), which is sold under the trade name Symbravo®. Symbravo® is a combination of meloxicam and rizatriptan approved for the acute treatment of migraine with or without aura in adults. The claims of the patents-in-suit cover, *inter alia*, the pharmaceutical composition of Symbravo® and methods of using Symbravo®.

81. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Symbravo®.

### **Jurisdiction and Venue**

82. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

83. This Court has personal jurisdiction over Apotex by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

84. On information and belief, Apotex purposefully has conducted and continues to conduct business in this Judicial District.

85. On information and belief, Apotex is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

86. This Court has personal jurisdiction over Apotex pursuant to Federal Rule of Civil Procedure 4(k)(2), including because (a) Axsome's claims arise under federal law; (b) Apotex is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex has sufficient contacts with the United States as a whole, including, without limitation, preparing and submitting pharmaceutical drug applications to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical drug products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex satisfies due process.

87. On information and belief, this Judicial District will be a destination for the generic version of Plaintiff's meloxicam and rizatriptan tablets for which Apotex seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 220803 ("Apotex's Proposed Product").

88. On information and belief, Apotex intends to benefit directly if its ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Apotex's Proposed Product.

89. Apotex has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g., Incyte Corp., et al. v. Apotex Inc.*, No. 25-4044 (D.N.J.); *Novo Nordisk Inc., et al. v. Apotex Inc.*, No. 24-9729 (D.N.J.); *Jazz Pharms. Research UK Limited f/k/a GW Research Limited v. Apotex Inc., et al.*, No. 24-7550 (D.N.J.); *Incyte Corp., et al. v. Apotex Inc.*, No. 24-4366 (D.N.J.); *GW Research*

*Ltd. v. Teva Pharms., Inc., et al.*, No. 23-3914 (D.N.J.); *Amgen Inc. v. Apotex Inc.*, No. 22-3827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc., et al.*, No. 20-7870 (D.N.J.); *Boehringer Ingelheim Pharms., Inc., et al. v. Apotex Inc., et al.*, No. 18-11350 (D.N.J.); *Patheon Softgels Inc. v. Apotex Inc., et al.*, No. 17-13819 (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc., et al.*, No. 17-5399 (D.N.J.).

90. Venue is proper in this Judicial District for Apotex pursuant to 28 U.S.C. §§ 1391 and/or 1400(b), including, for example, because Apotex is a company organized and existing under the laws of Canada and may be sued in any judicial district.

#### **Acts Giving Rise To This Suit**

91. Pursuant to Section 505 of the FFDCA, Apotex filed ANDA No. 220803 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Apotex's Proposed Product, before the patents-in-suit expire.

92. On information and belief, in connection with the filing of Apotex's ANDA as described above, Apotex provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Apotex's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Apotex's ANDA.

93. No earlier than August 15, 2025, Apotex sent written notice of Apotex's Paragraph IV Certification ("Apotex's Notice Letter") to Axsome. According to Apotex's Notice Letter, Apotex filed an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product before the expiration of certain patents listed in the Orange Book with respect to Symbravo<sup>®</sup>.



94. Apotex's Notice Letter alleges that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Apotex's ANDA.

95. On information and belief, following FDA approval of Apotex's ANDA, unless enjoined by the Court, Apotex will make, use, offer to sell, or sell Apotex's Proposed Product throughout the United States, or import such a generic product into the United States.

**Count I: Infringement of the '075 Patent by Apotex**

96. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

97. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '075 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

98. A justiciable controversy exists between the parties hereto as to the infringement of the '075 patent.

99. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '075 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

100. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '075 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of

Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '075 patent and knowledge that its acts are encouraging infringement.

101. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '075 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '075 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

102. Failure to enjoin Apotex's infringement of the '075 patent will substantially and irreparably damage Plaintiff.

103. Plaintiff does not have an adequate remedy at law.

104. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count II: Infringement of the '010 Patent by Apotex**

105. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

106. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '010 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

107. A justiciable controversy exists between the parties hereto as to the infringement of the '010 patent.

108. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '010 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

109. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '010 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '010 patent and knowledge that its acts are encouraging infringement.

110. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '010 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '010 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

111. Failure to enjoin Apotex's infringement of the '010 patent will substantially and irreparably damage Plaintiff.

112. Plaintiff does not have an adequate remedy at law.

113. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count III: Infringement of the '614 Patent by Apotex**

114. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

115. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '614 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

116. A justiciable controversy exists between the parties hereto as to the infringement of the '614 patent.

117. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '614 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

118. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '614 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '614 patent and knowledge that its acts are encouraging infringement.

119. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '614 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '614 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

120. Failure to enjoin Apotex's infringement of the '614 patent will substantially and irreparably damage Plaintiff.

121. Plaintiff does not have an adequate remedy at law.

122. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count IV: Infringement of the '131 Patent by Apotex**

123. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

124. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '131 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

125. A justiciable controversy exists between the parties hereto as to the infringement of the '131 patent.

126. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '131 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

127. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '131 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '131 patent and knowledge that its acts are encouraging infringement.

128. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '131 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '131 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

129. Failure to enjoin Apotex's infringement of the '131 patent will substantially and irreparably damage Plaintiff.

130. Plaintiff does not have an adequate remedy at law.

131. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count V: Infringement of the '278 Patent by Apotex**

132. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

133. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '278 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

134. A justiciable controversy exists between the parties hereto as to the infringement of the '278 patent.

135. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '278 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

136. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '278 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '278 patent and knowledge that its acts are encouraging infringement.

137. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '278 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '278 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

138. Failure to enjoin Apotex's infringement of the '278 patent will substantially and irreparably damage Plaintiff.

139. Plaintiff does not have an adequate remedy at law.

140. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count VI: Infringement of the '324 Patent by Apotex**

141. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

142. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '324 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

143. A justiciable controversy exists between the parties hereto as to the infringement of the '324 patent.

144. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '324 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

145. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '324 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '324 patent and knowledge that its acts are encouraging infringement.

146. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '324 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '324 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

147. Failure to enjoin Apotex's infringement of the '324 patent will substantially and irreparably damage Plaintiff.

148. Plaintiff does not have an adequate remedy at law.

149. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count VII: Infringement of the '312 Patent by Apotex**

150. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

151. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '312 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

152. A justiciable controversy exists between the parties hereto as to the infringement of the '312 patent.

153. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '312 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

154. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '312 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '312 patent and knowledge that its acts are encouraging infringement.

155. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '312 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '312 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

156. Failure to enjoin Apotex's infringement of the '312 patent will substantially and irreparably damage Plaintiff.

157. Plaintiff does not have an adequate remedy at law.

158. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count VIII: Infringement of the '224 Patent by Apotex**

159. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

160. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '224 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

161. A justiciable controversy exists between the parties hereto as to the infringement of the '224 patent.

162. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '224 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

163. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '224 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '224 patent and knowledge that its acts are encouraging infringement.

164. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '224 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '224 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

165. Failure to enjoin Apotex's infringement of the '224 patent will substantially and irreparably damage Plaintiff.

166. Plaintiff does not have an adequate remedy at law.

167. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count IX: Infringement of the '839 Patent by Apotex**

168. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

169. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '839 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

170. A justiciable controversy exists between the parties hereto as to the infringement of the '839 patent.

171. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '839 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

172. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '839 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '839 patent and knowledge that its acts are encouraging infringement.

173. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '839 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '839 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

174. Failure to enjoin Apotex's infringement of the '839 patent will substantially and irreparably damage Plaintiff.

175. Plaintiff does not have an adequate remedy at law.

176. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count X: Infringement of the '736 Patent by Apotex**

177. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

178. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '736 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

179. A justiciable controversy exists between the parties hereto as to the infringement of the '736 patent.

180. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '736 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

181. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '736 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '736 patent and knowledge that its acts are encouraging infringement.

182. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '736 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '736 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

183. Failure to enjoin Apotex's infringement of the '736 patent will substantially and irreparably damage Plaintiff.

184. Plaintiff does not have an adequate remedy at law.

185. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XI: Infringement of the '014 Patent by Apotex**

186. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

187. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '014 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

188. A justiciable controversy exists between the parties hereto as to the infringement of the '014 patent.

189. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '014 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

190. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '014 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '014 patent and knowledge that its acts are encouraging infringement.

191. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '014 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '014 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

192. Failure to enjoin Apotex's infringement of the '014 patent will substantially and irreparably damage Plaintiff.

193. Plaintiff does not have an adequate remedy at law.

194. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XII: Infringement of the '069 Patent by Apotex**

195. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

196. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '069 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

197. A justiciable controversy exists between the parties hereto as to the infringement of the '069 patent.

198. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '069 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

199. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '069 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '069 patent and knowledge that its acts are encouraging infringement.

200. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '069 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '069 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

201. Failure to enjoin Apotex's infringement of the '069 patent will substantially and irreparably damage Plaintiff.

202. Plaintiff does not have an adequate remedy at law.

203. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XIII: Infringement of the '692 Patent by Apotex**

204. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

205. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '692 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

206. A justiciable controversy exists between the parties hereto as to the infringement of the '692 patent.

207. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '692 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

208. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '692 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '692 patent and knowledge that its acts are encouraging infringement.

209. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '692 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '692 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

210. Failure to enjoin Apotex's infringement of the '692 patent will substantially and irreparably damage Plaintiff.

211. Plaintiff does not have an adequate remedy at law.

212. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XIV: Infringement of the '2,693 Patent by Apotex**

213. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

214. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '2,693 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

215. A justiciable controversy exists between the parties hereto as to the infringement of the '2,693 patent.

216. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '2,693 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

217. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '2,693 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '2,693 patent and knowledge that its acts are encouraging infringement.

218. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '2,693 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '2,693 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

219. Failure to enjoin Apotex's infringement of the '2,693 patent will substantially and irreparably damage Plaintiff.

220. Plaintiff does not have an adequate remedy at law.

221. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XV: Infringement of the '950 Patent by Apotex**

222. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

223. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '950 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

224. A justiciable controversy exists between the parties hereto as to the infringement of the '950 patent.

225. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '950 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

226. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '950 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '950 patent and knowledge that its acts are encouraging infringement.

227. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '950 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '950 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

228. Failure to enjoin Apotex's infringement of the '950 patent will substantially and irreparably damage Plaintiff.

229. Plaintiff does not have an adequate remedy at law.

230. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XVI: Infringement of the '101 Patent by Apotex**

231. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

232. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '101 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

233. A justiciable controversy exists between the parties hereto as to the infringement of the '101 patent.

234. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '101 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

235. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '101 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '101 patent and knowledge that its acts are encouraging infringement.

236. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '101 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '101 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

237. Failure to enjoin Apotex's infringement of the '101 patent will substantially and irreparably damage Plaintiff.

238. Plaintiff does not have an adequate remedy at law.

239. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XVII: Infringement of the '642 Patent by Apotex**

240. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

241. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '642 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

242. A justiciable controversy exists between the parties hereto as to the infringement of the '642 patent.

243. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '642 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

244. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '642 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '642 patent and knowledge that its acts are encouraging infringement.

245. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '642 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '642 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

246. Failure to enjoin Apotex's infringement of the '642 patent will substantially and irreparably damage Plaintiff.

247. Plaintiff does not have an adequate remedy at law.

248. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XVIII: Infringement of the '664 Patent by Apotex**

249. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

250. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '664 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

251. A justiciable controversy exists between the parties hereto as to the infringement of the '664 patent.

252. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '664 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

253. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '664 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '664 patent and knowledge that its acts are encouraging infringement.

254. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '664 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '664 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

255. Failure to enjoin Apotex's infringement of the '664 patent will substantially and irreparably damage Plaintiff.

256. Plaintiff does not have an adequate remedy at law.

257. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XIX: Infringement of the '144 Patent by Apotex**

258. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

259. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '144 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

260. A justiciable controversy exists between the parties hereto as to the infringement of the '144 patent.

261. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '144 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

262. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '144 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '144 patent and knowledge that its acts are encouraging infringement.

263. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '144 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '144 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

264. Failure to enjoin Apotex's infringement of the '144 patent will substantially and irreparably damage Plaintiff.

265. Plaintiff does not have an adequate remedy at law.

266. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XX: Infringement of the '777 Patent by Apotex**

267. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

268. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '777 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

269. A justiciable controversy exists between the parties hereto as to the infringement of the '777 patent.

270. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '777 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

271. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '777 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '777 patent and knowledge that its acts are encouraging infringement.

272. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '777 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '777 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

273. Failure to enjoin Apotex's infringement of the '777 patent will substantially and irreparably damage Plaintiff.

274. Plaintiff does not have an adequate remedy at law.

275. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXI: Infringement of the '102 Patent by Apotex**

276. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

277. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '102 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

278. A justiciable controversy exists between the parties hereto as to the infringement of the '102 patent.

279. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '102 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

280. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '102 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '102 patent and knowledge that its acts are encouraging infringement.

281. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '102 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '102 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

282. Failure to enjoin Apotex's infringement of the '102 patent will substantially and irreparably damage Plaintiff.

283. Plaintiff does not have an adequate remedy at law.

284. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXII: Infringement of the '185 Patent by Apotex**

285. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

286. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '185 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

287. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.

288. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '185 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

289. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '185 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '185 patent and knowledge that its acts are encouraging infringement.

290. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '185 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '185 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

291. Failure to enjoin Apotex's infringement of the '185 patent will substantially and irreparably damage Plaintiff.

292. Plaintiff does not have an adequate remedy at law.

293. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXIII: Infringement of the '5,429 Patent by Apotex**

294. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

295. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '5,429 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

296. A justiciable controversy exists between the parties hereto as to the infringement of the '5,429 patent.

297. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '5,429 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

298. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '5,429 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '5,429 patent and knowledge that its acts are encouraging infringement.

299. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '5,429 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '5,429 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

300. Failure to enjoin Apotex's infringement of the '5,429 patent will substantially and irreparably damage Plaintiff.

301. Plaintiff does not have an adequate remedy at law.

302. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXIV: Infringement of the '430 Patent by Apotex**

303. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

304. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '430 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

305. A justiciable controversy exists between the parties hereto as to the infringement of the '430 patent.

306. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '430 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

307. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '430 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '430 patent and knowledge that its acts are encouraging infringement.

308. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '430 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '430 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

309. Failure to enjoin Apotex's infringement of the '430 patent will substantially and irreparably damage Plaintiff.

310. Plaintiff does not have an adequate remedy at law.

311. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXV: Infringement of the '535 Patent by Apotex**

312. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

313. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '535 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

314. A justiciable controversy exists between the parties hereto as to the infringement of the '535 patent.

315. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '535 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

316. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '535 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '535 patent and knowledge that its acts are encouraging infringement.

317. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '535 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '535 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

318. Failure to enjoin Apotex's infringement of the '535 patent will substantially and irreparably damage Plaintiff.

319. Plaintiff does not have an adequate remedy at law.

320. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXVI: Infringement of the '602 Patent by Apotex**

321. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

322. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '602 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

323. A justiciable controversy exists between the parties hereto as to the infringement of the '602 patent.

324. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '602 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

325. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '602 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '602 patent and knowledge that its acts are encouraging infringement.

326. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '602 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '602 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

327. Failure to enjoin Apotex's infringement of the '602 patent will substantially and irreparably damage Plaintiff.

328. Plaintiff does not have an adequate remedy at law.

329. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXVII: Infringement of the '583 Patent by Apotex**

330. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

331. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '583 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

332. A justiciable controversy exists between the parties hereto as to the infringement of the '583 patent.

333. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '583 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

334. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '583 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '583 patent and knowledge that its acts are encouraging infringement.

335. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '583 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '583 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

336. Failure to enjoin Apotex's infringement of the '583 patent will substantially and irreparably damage Plaintiff.

337. Plaintiff does not have an adequate remedy at law.

338. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXVIII: Infringement of the '696 Patent by Apotex**

339. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

340. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '696 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

341. A justiciable controversy exists between the parties hereto as to the infringement of the '696 patent.

342. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '696 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

343. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '696 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '696 patent and knowledge that its acts are encouraging infringement.

344. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '696 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '696 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

345. Failure to enjoin Apotex's infringement of the '696 patent will substantially and irreparably damage Plaintiff.

346. Plaintiff does not have an adequate remedy at law.

347. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXIX: Infringement of the '697 Patent by Apotex**

348. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

349. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '697 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

350. A justiciable controversy exists between the parties hereto as to the infringement of the '697 patent.

351. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '697 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

352. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '697 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '697 patent and knowledge that its acts are encouraging infringement.

353. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '697 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '697 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

354. Failure to enjoin Apotex's infringement of the '697 patent will substantially and irreparably damage Plaintiff.

355. Plaintiff does not have an adequate remedy at law.

356. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXX: Infringement of the '773 Patent by Apotex**

357. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

358. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '773 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

359. A justiciable controversy exists between the parties hereto as to the infringement of the '773 patent.

360. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '773 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

361. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '773 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '773 patent and knowledge that its acts are encouraging infringement.

362. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '773 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '773 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

363. Failure to enjoin Apotex's infringement of the '773 patent will substantially and irreparably damage Plaintiff.

364. Plaintiff does not have an adequate remedy at law.

365. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXI: Infringement of the '617 Patent by Apotex**

366. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

367. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '617 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

368. A justiciable controversy exists between the parties hereto as to the infringement of the '617 patent.

369. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '617 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

370. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '617 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '617 patent and knowledge that its acts are encouraging infringement.

371. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '617 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '617 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

372. Failure to enjoin Apotex's infringement of the '617 patent will substantially and irreparably damage Plaintiff.

373. Plaintiff does not have an adequate remedy at law.

374. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXII: Infringement of the '618 Patent by Apotex**

375. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

376. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '618 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

377. A justiciable controversy exists between the parties hereto as to the infringement of the '618 patent.

378. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '618 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

379. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '618 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '618 patent and knowledge that its acts are encouraging infringement.

380. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '618 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '618 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

381. Failure to enjoin Apotex's infringement of the '618 patent will substantially and irreparably damage Plaintiff.

382. Plaintiff does not have an adequate remedy at law.

383. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXIII: Infringement of the '165 Patent by Apotex**

384. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

385. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '165 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

386. A justiciable controversy exists between the parties hereto as to the infringement of the '165 patent.

387. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '165 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

388. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '165 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '165 patent and knowledge that its acts are encouraging infringement.

389. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '165 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '165 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

390. Failure to enjoin Apotex's infringement of the '165 patent will substantially and irreparably damage Plaintiff.

391. Plaintiff does not have an adequate remedy at law.

392. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXIV: Infringement of the '166 Patent by Apotex**

393. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

394. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '166 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

395. A justiciable controversy exists between the parties hereto as to the infringement of the '166 patent.

396. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '166 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

397. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '166 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '166 patent and knowledge that its acts are encouraging infringement.

398. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '166 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '166 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

399. Failure to enjoin Apotex's infringement of the '166 patent will substantially and irreparably damage Plaintiff.

400. Plaintiff does not have an adequate remedy at law.

401. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXV: Infringement of the '588 Patent by Apotex**

402. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

403. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '588 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

404. A justiciable controversy exists between the parties hereto as to the infringement of the '588 patent.

405. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '588 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

406. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '588 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '588 patent and knowledge that its acts are encouraging infringement.

407. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '588 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '588 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

408. Failure to enjoin Apotex's infringement of the '588 patent will substantially and irreparably damage Plaintiff.

409. Plaintiff does not have an adequate remedy at law.

410. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXVI: Infringement of the '181 Patent by Apotex**

411. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

412. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '181 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

413. A justiciable controversy exists between the parties hereto as to the infringement of the '181 patent.

414. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '181 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

415. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '181 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '181 patent and knowledge that its acts are encouraging infringement.

416. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '181 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '181 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

417. Failure to enjoin Apotex's infringement of the '181 patent will substantially and irreparably damage Plaintiff.

418. Plaintiff does not have an adequate remedy at law.

419. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXVII: Infringement of the '182 Patent by Apotex**

420. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

421. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '182 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

422. A justiciable controversy exists between the parties hereto as to the infringement of the '182 patent.

423. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '182 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

424. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '182 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '182 patent and knowledge that its acts are encouraging infringement.

425. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '182 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '182 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

426. Failure to enjoin Apotex's infringement of the '182 patent will substantially and irreparably damage Plaintiff.

427. Plaintiff does not have an adequate remedy at law.

428. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXVIII: Infringement of the '053 Patent by Apotex**

429. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

430. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '053 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

431. A justiciable controversy exists between the parties hereto as to the infringement of the '053 patent.

432. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '053 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

433. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '053 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '053 patent and knowledge that its acts are encouraging infringement.

434. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '053 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '053 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

435. Failure to enjoin Apotex's infringement of the '053 patent will substantially and irreparably damage Plaintiff.

436. Plaintiff does not have an adequate remedy at law.

437. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XXXIX: Infringement of the '5,693 Patent by Apotex**

438. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

439. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '5,693 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

440. A justiciable controversy exists between the parties hereto as to the infringement of the '5,693 patent.

441. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '5,693 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

442. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '5,693 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '5,693 patent and knowledge that its acts are encouraging infringement.

443. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '5,693 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '5,693 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

444. Failure to enjoin Apotex's infringement of the '5,693 patent will substantially and irreparably damage Plaintiff.

445. Plaintiff does not have an adequate remedy at law.

446. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XL: Infringement of the '722 Patent by Apotex**

447. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

448. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '722 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

449. A justiciable controversy exists between the parties hereto as to the infringement of the '722 patent.

450. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '722 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

451. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '722 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '722 patent and knowledge that its acts are encouraging infringement.

452. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '722 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '722 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

453. Failure to enjoin Apotex's infringement of the '722 patent will substantially and irreparably damage Plaintiff.

454. Plaintiff does not have an adequate remedy at law.

455. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLI: Infringement of the '136 Patent by Apotex**

456. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

457. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '136 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

458. A justiciable controversy exists between the parties hereto as to the infringement of the '136 patent.

459. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '136 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

460. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '136 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '136 patent and knowledge that its acts are encouraging infringement.

461. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '136 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '136 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

462. Failure to enjoin Apotex's infringement of the '136 patent will substantially and irreparably damage Plaintiff.

463. Plaintiff does not have an adequate remedy at law.

464. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLII: Infringement of the '137 Patent by Apotex**

465. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

466. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '137 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

467. A justiciable controversy exists between the parties hereto as to the infringement of the '137 patent.

468. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '137 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

469. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '137 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '137 patent and knowledge that its acts are encouraging infringement.

470. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '137 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '137 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

471. Failure to enjoin Apotex's infringement of the '137 patent will substantially and irreparably damage Plaintiff.

472. Plaintiff does not have an adequate remedy at law.

473. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLIII: Infringement of the '153 Patent by Apotex**

474. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

475. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '153 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

476. A justiciable controversy exists between the parties hereto as to the infringement of the '153 patent.

477. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '153 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

478. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '153 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '153 patent and knowledge that its acts are encouraging infringement.

479. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '153 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '153 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

480. Failure to enjoin Apotex's infringement of the '153 patent will substantially and irreparably damage Plaintiff.

481. Plaintiff does not have an adequate remedy at law.

482. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLIV: Infringement of the '358 Patent by Apotex**

483. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

484. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '358 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

485. A justiciable controversy exists between the parties hereto as to the infringement of the '358 patent.

486. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '358 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

487. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '358 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '358 patent and knowledge that its acts are encouraging infringement.

488. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '358 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '358 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

489. Failure to enjoin Apotex's infringement of the '358 patent will substantially and irreparably damage Plaintiff.

490. Plaintiff does not have an adequate remedy at law.

491. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLV: Infringement of the '805 Patent by Apotex**

492. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

493. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '805 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

494. A justiciable controversy exists between the parties hereto as to the infringement of the '805 patent.

495. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '805 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

496. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '805 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '805 patent and knowledge that its acts are encouraging infringement.

497. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '805 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '805 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

498. Failure to enjoin Apotex's infringement of the '805 patent will substantially and irreparably damage Plaintiff.

499. Plaintiff does not have an adequate remedy at law.

500. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLVI: Infringement of the '806 Patent by Apotex**

501. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

502. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '806 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

503. A justiciable controversy exists between the parties hereto as to the infringement of the '806 patent.

504. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '806 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

505. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '806 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '806 patent and knowledge that its acts are encouraging infringement.

506. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '806 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '806 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

507. Failure to enjoin Apotex's infringement of the '806 patent will substantially and irreparably damage Plaintiff.

508. Plaintiff does not have an adequate remedy at law.

509. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLVII: Infringement of the '483 Patent by Apotex**

510. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

511. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '483 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

512. A justiciable controversy exists between the parties hereto as to the infringement of the '483 patent.

513. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '483 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

514. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '483 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '483 patent and knowledge that its acts are encouraging infringement.

515. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '483 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '483 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

516. Failure to enjoin Apotex's infringement of the '483 patent will substantially and irreparably damage Plaintiff.

517. Plaintiff does not have an adequate remedy at law.

518. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLVIII: Infringement of the '549 Patent by Apotex**

519. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

520. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '549 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

521. A justiciable controversy exists between the parties hereto as to the infringement of the '549 patent.

522. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '549 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

523. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '549 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '549 patent and knowledge that its acts are encouraging infringement.

524. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '549 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '549 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

525. Failure to enjoin Apotex's infringement of the '549 patent will substantially and irreparably damage Plaintiff.

526. Plaintiff does not have an adequate remedy at law.

527. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count XLIX: Infringement of the '295 Patent by Apotex**

528. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

529. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '295 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

530. A justiciable controversy exists between the parties hereto as to the infringement of the '295 patent.

531. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '295 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

532. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '295 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '295 patent and knowledge that its acts are encouraging infringement.

533. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '295 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '295 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

534. Failure to enjoin Apotex's infringement of the '295 patent will substantially and irreparably damage Plaintiff.

535. Plaintiff does not have an adequate remedy at law.

536. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count L: Infringement of the '328 Patent by Apotex**

537. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

538. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '328 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

539. A justiciable controversy exists between the parties hereto as to the infringement of the '328 patent.

540. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '328 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

541. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '328 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '328 patent and knowledge that its acts are encouraging infringement.

542. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '328 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '328 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

543. Failure to enjoin Apotex's infringement of the '328 patent will substantially and irreparably damage Plaintiff.

544. Plaintiff does not have an adequate remedy at law.

545. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LI: Infringement of the '626 Patent by Apotex**

546. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

547. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '626 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

548. A justiciable controversy exists between the parties hereto as to the infringement of the '626 patent.

549. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '626 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

550. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '626 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '626 patent and knowledge that its acts are encouraging infringement.

551. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '626 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '626 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

552. Failure to enjoin Apotex's infringement of the '626 patent will substantially and irreparably damage Plaintiff.

553. Plaintiff does not have an adequate remedy at law.

554. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LII: Infringement of the '213 Patent by Apotex**

555. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

556. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '213 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

557. A justiciable controversy exists between the parties hereto as to the infringement of the '213 patent.

558. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '213 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

559. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '213 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '213 patent and knowledge that its acts are encouraging infringement.

560. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '213 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '213 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

561. Failure to enjoin Apotex's infringement of the '213 patent will substantially and irreparably damage Plaintiff.

562. Plaintiff does not have an adequate remedy at law.

563. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LIII: Infringement of the '323 Patent by Apotex**

564. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

565. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '323 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

566. A justiciable controversy exists between the parties hereto as to the infringement of the '323 patent.

567. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '323 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

568. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '323 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '323 patent and knowledge that its acts are encouraging infringement.

569. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '323 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '323 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

570. Failure to enjoin Apotex's infringement of the '323 patent will substantially and irreparably damage Plaintiff.

571. Plaintiff does not have an adequate remedy at law.

572. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LIV: Infringement of the '684 Patent by Apotex**

573. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

574. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '684 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

575. A justiciable controversy exists between the parties hereto as to the infringement of the '684 patent.

576. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '684 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

577. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '684 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '684 patent and knowledge that its acts are encouraging infringement.

578. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '684 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '684 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

579. Failure to enjoin Apotex's infringement of the '684 patent will substantially and irreparably damage Plaintiff.

580. Plaintiff does not have an adequate remedy at law.

581. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LV: Infringement of the '414 Patent by Apotex**

582. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

583. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '414 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

584. A justiciable controversy exists between the parties hereto as to the infringement of the '414 patent.

585. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '414 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

586. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '414 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '414 patent and knowledge that its acts are encouraging infringement.

587. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '414 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '414 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

588. Failure to enjoin Apotex's infringement of the '414 patent will substantially and irreparably damage Plaintiff.

589. Plaintiff does not have an adequate remedy at law.

590. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LVI: Infringement of the '464 Patent by Apotex**

591. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

592. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '464 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

593. A justiciable controversy exists between the parties hereto as to the infringement of the '464 patent.

594. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '464 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

595. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '464 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '464 patent and knowledge that its acts are encouraging infringement.

596. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '464 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '464 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

597. Failure to enjoin Apotex's infringement of the '464 patent will substantially and irreparably damage Plaintiff.

598. Plaintiff does not have an adequate remedy at law.

599. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LVII: Infringement of the '465 Patent by Apotex**

600. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

601. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '465 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

602. A justiciable controversy exists between the parties hereto as to the infringement of the '465 patent.

603. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '465 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

604. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '465 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '465 patent and knowledge that its acts are encouraging infringement.

605. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '465 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '465 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

606. Failure to enjoin Apotex's infringement of the '465 patent will substantially and irreparably damage Plaintiff.

607. Plaintiff does not have an adequate remedy at law.

608. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LVIII: Infringement of the '4,429 Patent by Apotex**

609. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

610. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '4,429 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

611. A justiciable controversy exists between the parties hereto as to the infringement of the '4,429 patent.

612. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '4,429 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

613. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '4,429 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '4,429 patent and knowledge that its acts are encouraging infringement.

614. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '4,429 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '4,429 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

615. Failure to enjoin Apotex's infringement of the '4,429 patent will substantially and irreparably damage Plaintiff.

616. Plaintiff does not have an adequate remedy at law.

617. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LIX: Infringement of the '927 Patent by Apotex**

618. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

619. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '927 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

620. A justiciable controversy exists between the parties hereto as to the infringement of the '927 patent.

621. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '927 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

622. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '927 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '927 patent and knowledge that its acts are encouraging infringement.

623. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '927 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '927 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

624. Failure to enjoin Apotex's infringement of the '927 patent will substantially and irreparably damage Plaintiff.

625. Plaintiff does not have an adequate remedy at law.

626. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LX: Infringement of the '428 Patent by Apotex**

627. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

628. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '428 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

629. A justiciable controversy exists between the parties hereto as to the infringement of the '428 patent.

630. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '428 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

631. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '428 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '428 patent and knowledge that its acts are encouraging infringement.

632. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '428 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '428 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

633. Failure to enjoin Apotex's infringement of the '428 patent will substantially and irreparably damage Plaintiff.

634. Plaintiff does not have an adequate remedy at law.

635. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXI: Infringement of the '563 Patent by Apotex**

636. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

637. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '563 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

638. A justiciable controversy exists between the parties hereto as to the infringement of the '563 patent.

639. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '563 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

640. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '563 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '563 patent and knowledge that its acts are encouraging infringement.

641. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '563 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '563 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

642. Failure to enjoin Apotex's infringement of the '563 patent will substantially and irreparably damage Plaintiff.

643. Plaintiff does not have an adequate remedy at law.

644. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXII: Infringement of the '456 Patent by Apotex**

645. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

646. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '456 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

647. A justiciable controversy exists between the parties hereto as to the infringement of the '456 patent.

648. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '456 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

649. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '456 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '456 patent and knowledge that its acts are encouraging infringement.

650. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '456 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '456 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

651. Failure to enjoin Apotex's infringement of the '456 patent will substantially and irreparably damage Plaintiff.

652. Plaintiff does not have an adequate remedy at law.

653. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXIII: Infringement of the '755 Patent by Apotex**

654. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

655. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '755 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

656. A justiciable controversy exists between the parties hereto as to the infringement of the '755 patent.

657. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '755 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

658. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '755 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '755 patent and knowledge that its acts are encouraging infringement.

659. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '755 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '755 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

660. Failure to enjoin Apotex's infringement of the '755 patent will substantially and irreparably damage Plaintiff.

661. Plaintiff does not have an adequate remedy at law.

662. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXIV: Infringement of the '756 Patent by Apotex**

663. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

664. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '756 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

665. A justiciable controversy exists between the parties hereto as to the infringement of the '756 patent.

666. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '756 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

667. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '756 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '756 patent and knowledge that its acts are encouraging infringement.

668. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '756 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '756 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

669. Failure to enjoin Apotex's infringement of the '756 patent will substantially and irreparably damage Plaintiff.

670. Plaintiff does not have an adequate remedy at law.

671. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXV: Infringement of the '791 Patent by Apotex**

672. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

673. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '791 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

674. A justiciable controversy exists between the parties hereto as to the infringement of the '791 patent.

675. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '791 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

676. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '791 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '791 patent and knowledge that its acts are encouraging infringement.

677. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '791 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '791 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

678. Failure to enjoin Apotex's infringement of the '791 patent will substantially and irreparably damage Plaintiff.

679. Plaintiff does not have an adequate remedy at law.

680. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXVI: Infringement of the '173 Patent by Apotex**

681. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

682. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '173 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

683. A justiciable controversy exists between the parties hereto as to the infringement of the '173 patent.

684. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '173 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

685. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '173 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '173 patent and knowledge that its acts are encouraging infringement.

686. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '173 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '173 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

687. Failure to enjoin Apotex's infringement of the '173 patent will substantially and irreparably damage Plaintiff.

688. Plaintiff does not have an adequate remedy at law.

689. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXVII: Infringement of the '441 Patent by Apotex**

690. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

691. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '441 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

692. A justiciable controversy exists between the parties hereto as to the infringement of the '441 patent.

693. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '441 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

694. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '441 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '441 patent and knowledge that its acts are encouraging infringement.

695. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '441 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '441 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

696. Failure to enjoin Apotex's infringement of the '441 patent will substantially and irreparably damage Plaintiff.

697. Plaintiff does not have an adequate remedy at law.

698. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXVIII: Infringement of the '085 Patent by Apotex**

699. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

700. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '085 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

701. A justiciable controversy exists between the parties hereto as to the infringement of the '085 patent.

702. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '085 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

703. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '085 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '085 patent and knowledge that its acts are encouraging infringement.

704. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '085 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '085 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

705. Failure to enjoin Apotex's infringement of the '085 patent will substantially and irreparably damage Plaintiff.

706. Plaintiff does not have an adequate remedy at law.

707. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXIX: Infringement of the '522 Patent by Apotex**

708. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

709. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '522 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

710. A justiciable controversy exists between the parties hereto as to the infringement of the '522 patent.

711. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '522 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

712. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '522 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '522 patent and knowledge that its acts are encouraging infringement.

713. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '522 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '522 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

714. Failure to enjoin Apotex's infringement of the '522 patent will substantially and irreparably damage Plaintiff.

715. Plaintiff does not have an adequate remedy at law.

716. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXX: Infringement of the '250 Patent by Apotex**

717. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

718. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '250 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

719. A justiciable controversy exists between the parties hereto as to the infringement of the '250 patent.

720. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '250 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

721. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '250 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '250 patent and knowledge that its acts are encouraging infringement.

722. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '250 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '250 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

723. Failure to enjoin Apotex's infringement of the '250 patent will substantially and irreparably damage Plaintiff.

724. Plaintiff does not have an adequate remedy at law.

725. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXXI: Infringement of the '354 Patent by Apotex**

726. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

727. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '354 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

728. A justiciable controversy exists between the parties hereto as to the infringement of the '354 patent.

729. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '354 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

730. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '354 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '354 patent and knowledge that its acts are encouraging infringement.

731. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '354 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '354 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

732. Failure to enjoin Apotex's infringement of the '354 patent will substantially and irreparably damage Plaintiff.

733. Plaintiff does not have an adequate remedy at law.

734. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXXII: Infringement of the '370 Patent by Apotex**

735. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

736. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '370 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

737. A justiciable controversy exists between the parties hereto as to the infringement of the '370 patent.

738. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '370 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

739. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '370 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '370 patent and knowledge that its acts are encouraging infringement.

740. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '370 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that



Apotex's Proposed Product is designed for a use that infringes one or more claims of the '370 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

741. Failure to enjoin Apotex's infringement of the '370 patent will substantially and irreparably damage Plaintiff.

742. Plaintiff does not have an adequate remedy at law.

743. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXXIII: Infringement of the '117 Patent by Apotex**

744. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

745. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '117 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

746. A justiciable controversy exists between the parties hereto as to the infringement of the '117 patent.

747. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '117 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

748. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '117 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's

Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '117 patent and knowledge that its acts are encouraging infringement.

749. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '117 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '117 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

750. Failure to enjoin Apotex's infringement of the '117 patent will substantially and irreparably damage Plaintiff.

751. Plaintiff does not have an adequate remedy at law.

752. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXXIV: Infringement of the '052 Patent by Apotex**

753. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

754. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '052 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

755. A justiciable controversy exists between the parties hereto as to the infringement of the '052 patent.

756. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '052 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

757. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '052 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '052 patent and knowledge that its acts are encouraging infringement.

758. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '052 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that Apotex's Proposed Product is designed for a use that infringes one or more claims of the '052 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

759. Failure to enjoin Apotex's infringement of the '052 patent will substantially and irreparably damage Plaintiff.

760. Plaintiff does not have an adequate remedy at law.

761. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

**Count LXXV: Infringement of the '196 Patent by Apotex**

762. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

763. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '196 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

764. A justiciable controversy exists between the parties hereto as to the infringement of the '196 patent.

765. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '196 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

766. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '196 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '196 patent and knowledge that its acts are encouraging infringement.

767. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '196 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '196 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

768. Failure to enjoin Apotex's infringement of the '196 patent will substantially and irreparably damage Plaintiff.

769. Plaintiff does not have an adequate remedy at law.

770. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A Judgment that Apotex infringed one or more claims of each of the patents-in-suit by submitting ANDA No. 220803;

(B) A Judgment that Apotex has infringed the patents-in-suit by submitting ANDA No. 220803, and that Apotex's making, using, offering to sell, selling, or importing Apotex's Proposed Product will infringe one or more claims of each of the patents-in-suit;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 220803 be a date no earlier than the later of the expiration of each of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Apotex and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Apotex's Proposed Product until after the expiration of each of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Apotex, its officers, agents, attorneys, and employees, and those acting in privity or

concert with them, from practicing any of the subject matter claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of each of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Apotex's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit;

(G) To the extent that Apotex has committed any acts with respect to the subject matter claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiff damages for such acts;

(H) If Apotex engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Apotex's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiff resulting from such infringement, together with interest;

(I) A Judgment declaring that each of the patents-in-suit remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiff its attorneys' fees, costs, and expenses incurred in this action; and

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

Dated: September 26, 2025

By: s/ Charles M. Lizza

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1**

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is not related to any other matter currently pending in this Judicial District.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 26, 2025

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