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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. APOTEX INC., Defendant.	Civil Action No. 2:25-cv-12184-MEF-MAH **ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANT APOTEX INC.**

Defendant Apotex Inc. ("Apotex" or "Defendant") hereby answers Plaintiff Supernus Pharmaceuticals, Inc.'s ("Supernus" or "Plaintiff") Complaint and present its affirmative defenses as stated below. To the extent not admitted all allegations are denied.

NATURE OF THE ACTION

1. This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Apotex admits that the Complaint purports to state an action for patent infringement under the patent laws of the United States, pursuant to title 35 of the United States Code, involving United States Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent"; collectively, "the patents-in-suit").

THE PARTIES

2. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

3. Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, North York, Toronto, M9L 1T9, Canada.

JURISDICTION AND VENUE

4. This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, and solely for the limited purposes of this action, Apotex does not contest subject matter jurisdiction as to Plaintiff's infringement allegations.

5. This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, and solely for the limited purposes of this action, Apotex does not contest personal jurisdiction as to Plaintiff's infringement allegations.

6. This paragraph contains conclusions of law for which no response is required. The remaining allegations of this paragraph are denied.

7. This paragraph contains conclusions of law for which no response is required. The remaining allegations of this paragraph are denied.

8. Apotex admits that it prepared and filed ANDA No. 220456 (Apotex's "ANDA") seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of viloxazine extended-release capsules (100 mg, 150 mg and 200 mg) (Apotex's "ANDA Products"). Any remaining allegations of this paragraph are denied.

9. Denied.

10. Denied.

11. Denied.

12. This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, and solely for the limited purposes of this action, Apotex does not contest venue as to Plaintiff's infringement allegations.

FACTS COMMON TO ALL COUNTS

13. Apotex admits that it sent a Notification of Certification of Invalidity, Unenforceability and/or Non-infringement pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(i), (ii), (iii), and (iv)) and 21 C.F.R. § 314.95) which identified the paragraph IV certification that Apotex submitted in Apotex's ANDA (the

"Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850. Any remaining allegations of this paragraph are denied.

14. Apotex admits that the Notice Letter included an Offer of Confidential Access to the Application pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). Any remaining allegations of this paragraph are denied.

15. Denied.

16. Apotex admits that it filed its ANDA to obtain approval to engage in the commercial manufacture, use or sale of viloxazine extended-release capsules (100 mg, 150 mg and 200 mg) before the expiration of the asserted patents. Any remaining allegations of this paragraph are denied.

17. Denied.

18. Apotex admits that it filed its ANDA to obtain approval to engage in the commercial manufacture, use or sale of viloxazine extended-release capsules (100 mg, 150 mg and 200 mg). Any remaining allegations of this paragraph are denied.

19. Denied.

20. This paragraph contains conclusions of law for which no response is required.

21. Admitted.

22. Apotex admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

23. Apotex admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

24. Apotex admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

25. Apotex admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

26. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

27. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

28. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

29. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

30. Upon information and belief, Apotex admits that the USPTO issued the ’204 patent, entitled “Formulations of viloxazine” on June 7, 2016. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies them.

31. Upon information and belief, Apotex admits that the USPTO issued the '853 patent, entitled "Formulations of viloxazine" on March 28, 2017. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies them.

32. Upon information and belief, Apotex admits that the USPTO issued the '338 patent, entitled "Formulations of viloxazine" on May 30, 2017. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies them.

33. Upon information and belief, Apotex admits that the USPTO issued the '753 patent, entitled "Method of treatment of attention deficit/hyperactivity disorder (ADHD)" on May 10, 2022. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies them.

34. Upon information and belief, Apotex admits that the USPTO issued the '143 patent, entitled "Method of treatment of attention deficit/hyperactivity disorder (ADHD)" on October 4, 2022. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies them.

35. Upon information and belief, Apotex admits that the USPTO issued the '523 patent, entitled "Method of treatment of attention deficit/hyperactivity disorder (ADHD)" on October 22, 2024. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies them.

36. Apotex admits that Apotex's ANDA seeks approval to engage in the commercial manufacture, use or sale of viloxazine extended-release capsules (100 mg, 150 mg and 200 mg). Any remaining allegations of this paragraph are denied.

37. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

38. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

39. This paragraph contains conclusions of law for which no response is required.

40. Apotex admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

41. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

42. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

43. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

44. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

45. Apotex admits that it filed Apotex's ANDA and that Apotex's ANDA speaks for itself. Apotex denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Apotex's ANDA.

FIRST COUNT

46. Apotex restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

47. Admitted.

48. Admitted.

49. Admitted.

50. Admitted.

51. Denied.

52. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

53. Denied.

54. Denied.

55. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

56. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

SECOND COUNT

65. Apotex restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

66. Admitted.

67. Admitted.

68. Admitted.

69. Admitted.

70. Denied.

71. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

72. Denied.

73. Denied.

74. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

75. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

THIRD COUNT

84. Apotex restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

85. Admitted.

86. Admitted.

87. Admitted.

88. Admitted.

89. Denied.

90. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

91. Denied.

92. Denied.

93. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

94. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

FOURTH COUNT

103. Apotex restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

104. Admitted.

105. Admitted.

106. Admitted.

107. Admitted.

108. Denied.

109. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

110. Denied.

111. Denied.

112. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

113. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

FIFTH COUNT

122. Apotex restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

123. Admitted.

124. Admitted.

125. Admitted.

126. Admitted.

127. Denied.

128. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

129. Denied.

130. Denied.

131. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

132. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

133. Denied.

134. Denied.

135. Denied.

136. Denied.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

SIXTH COUNT

141. Apotex restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

142. Admitted.

143. Admitted.

144. Admitted.

145. Admitted.

146. Denied.

147. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

148. Denied.

149. Denied.

150. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

151. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

152. Denied.

153. Denied.

154. Denied.

155. Denied.

156. Denied.

157. Denied.

158. Denied.

159. Denied.

PRAYER FOR RELIEF

All allegations in Plaintiff's Complaint not expressly admitted by Apotex are hereby denied. Having answered Plaintiff's Complaint, Apotex denies Plaintiff is entitled to any of the relief requested in the Complaint or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without any admission as to burden of proof, burden of persuasion, or the truth of any of the allegations in Plaintiff's Complaint, Apotex states the following affirmative defenses. Apotex reserves the right to assert additional defenses, as warranted by the facts learned through investigation and discovery.

First Affirmative Defense
(Invalidity of U.S. Patent No. 9,358,204)

Upon information and belief, the claims of the '204 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Second Affirmative Defense
(Non-Infringement of U.S. Patent No. 9,358,204)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Apotex's ANDA No. 220456 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '204 patent.

Third Affirmative Defense
(Invalidity of U.S. Patent No. 9,603,853)

Upon information and belief, the claims of the '853 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Fourth Affirmative Defense
(Non-Infringement of U.S. Patent No. 9,603,853)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Apotex's ANDA No. 220456 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '853 patent.

Fifth Affirmative Defense
(Invalidity of U.S. Patent No. 9,662,338)

Upon information and belief, the claims of the '338 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Sixth Affirmative Defense
(Non-Infringement of U.S. Patent No. 9,662,338)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Apotex's ANDA No. 220456 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '338 patent.

Seventh Affirmative Defense
(Invalidity of U.S. Patent No. 11,324,753)

Upon information and belief, the claims of the '753 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Eighth Affirmative Defense
(Non-Infringement of U.S. Patent No. 11,324,753)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the

products that are the subject of Apotex's ANDA No. 220456 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '753 patent.

Ninth Affirmative Defense
(Invalidity of U.S. Patent No. 11,458,143)

Upon information and belief, the claims of the '143 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Tenth Affirmative Defense
(Non-Infringement of U.S. Patent No. 11,458,143)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Apotex's ANDA No. 220456 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '143 patent.

Eleventh Affirmative Defense
(Invalidity of U.S. Patent No. 12,121,523)

Upon information and belief, the claims of the '523 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Twelfth Affirmative Defense
(Non-Infringement of U.S. Patent No. 12,121,523)

Plaintiff will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject of Apotex's ANDA No. 220456 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '523 patent.

Thirteenth Affirmative Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

Fourteenth Affirmative Defense
(Estoppel)

Plaintiff is estopped from arguing and has waived arguments that the claims of the '204 patent, the '853 patent, the '338 patent, the '753 patent, the '143 patent and the'523 patent cover the products described in ANDA No. 220456 by virtue of amendments, positions, and arguments made to the U.S. Patent and Trademark Office when obtaining the asserted patents.

Fifteenth Affirmative Defense
(Lack of Standing)

Plaintiff does not have standing to assert claims for patent infringement under 35 U.S.C. § 271(a), (b), and (c).

Sixteenth Affirmative Defense
(No Injunctive Relief)

Plaintiff may not seek injunctive relief under 35 U.S.C. §§ 274(e)(4)(B) and/or 283 against Apotex because Plaintiff's alleged damages are not irreparable and Plaintiff has an adequate remedy at law.

Seventeenth Affirmative Defense
(No Costs)

Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

Eighteenth Affirmative Defense
(No Exceptional Case)

Apotex's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Nineteenth Affirmative Defense
(Equitable Defenses)

Apotex reserves the right to amend its answer to include equitable defenses, such as disclaimer, prosecution history estoppel, unenforceability, inequitable conduct, unclean hands, laches, equitable estoppel, and/or patent misuse, if information obtained in discovery provides support for such a defense.

Twentieth Affirmative Defense
(Additional Defenses or Counterclaims)

Any additional legal or equitable defenses or counterclaims that discovery may reveal, including but not limited to, defenses of unenforceability, as well as any defenses raised by another defendant in any action involving the ’204 patent, the ’853 patent, the ’338 patent, the ’753 patent, the ’143 patent, and the’523 patent. Apotex reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

RESERVATION OF DEFENSES

Apotex hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

WHEREFORE, Apotex hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patents-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

COUNTERCLAIMS

For its counterclaims against Plaintiff/Counterclaim-Defendant Supernus Pharmaceuticals, Inc. ("Supernus" or "Counterclaim-Defendant"), Defendant/Counterclaim-Plaintiff Apotex Inc. ("Apotex" or "Counterclaim-Plaintiff") states as follows:

BACKGROUND AND PARTIES

1. This is an action for declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent") (collectively, the "Counterclaim patents-in-suit"), true and complete copies of which are attached to the Complaint as Exhibits A-F, respectively, pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the patent laws of the United States, 35 U.S.C. § 1, *et seq*.; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5)).

2. Counterclaim-Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, North York, Toronto, M9L 1T9, Canada.

3. Upon information and belief, Counterclaim-Defendant Supernus is a corporation organized and existing under the laws of Delaware, having a place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Supernus ("Counterclaim-Defendant") because, among other reasons, Supernus subjected itself to the jurisdiction of this Court by filing this action here; because, on information and belief, either directly or through agents, it transacts business in, and derive substantial revenue from, the State of Delaware.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Counterclaim-Defendant commenced the underlying action in this venue.

8. Because of Counterclaim-Defendant's Complaint against Apotex, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of U.S. Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent") (collectively, the "Counterclaim Patents-in-Suit").

FACTUAL BACKGROUND

A. FDA Approval of Brand Name Pharmaceuticals

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1),-(c)(2); 21 C.F.R. § 314.53(b)(1),-(c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

13. The FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patent.

B. FDA Approval of Brand Name Pharmaceuticals

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

16. Among other things, an ANDA must also contain a "certification" as to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

19. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

20. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id*. If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id*.

C. NDA No. 211964 and The Counterclaim Patents-In-Suit

21. According to the United States Food and Drug Administration ("FDA") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), Supernus Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 211964 for Qelbree® (viloxazine extended-release capsules (100 mg, 150 mg and 200 mg)).

22. NDA holders are required to disclose to the FDA the patent number of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

23. The Orange Book lists the '204, '853, '338, '753, '143, and '523 patents in connection with NDA No. 211964 for Qelbree® (viloxazine extended-release capsules (100 mg, 150 mg and 200 mg)).

24. On information and belief, Supernus caused the Counterclaim Patents-in-Suit to be listed in the Orange Book in connection with NDA No. 211964.

The '204 Patent

25. Upon information and belief, the United States Patent and Trademark Office ("USPTO") issued the '204 patent, titled "Formulations of viloxazine," on or about June 7, 2016.

26. Upon information and belief, Counterclaim Defendant Supernus is the assignee of the '204 patent, and upon information and belief, a copy of the '204 patent is attached as Exhibit A to the Complaint.

The '853 Patent

27. Upon information and belief, the USPTO issued the '853 patent, titled "Formulations of viloxazine," on or about March 28, 2017.

28. Upon information and belief, Counterclaim Defendant Supernus is the assignee of the ’853 patent, and upon information and belief, a copy of the ’853 patent is attached as Exhibit B to the Complaint.

The ’338 Patent

29. Upon information and belief, the USPTO issued the ’338 patent, titled “Formulations of viloxazine,” on or about May 30, 2017.

30. Upon information and belief, Counterclaim Defendant Supernus is the assignee of the ’338 patent, and upon information and belief, a copy of the ’338 patent is attached as Exhibit C to the Complaint.

The ’753 Patent

31. Upon information and belief, the USPTO issued the ’753 patent, titled “Method of treatment of attention deficit/hyperactivity disorder (ADHD),” on or about May 10, 2022.

32. Upon information and belief, Counterclaim Defendant Supernus is the assignee of the ’753 patent, and upon information and belief, a copy of the ’753 patent is attached as Exhibit D to the Complaint.

The ’143 Patent

33. Upon information and belief, the USPTO issued the ’143 patent, titled “Method of treatment of attention deficit/hyperactivity disorder (ADHD),” on or about October 4, 2022.

34. Upon information and belief, Counterclaim Defendant Supernus is the assignee of the ’143 patent, and upon information and belief, a copy of the ’143 patent is attached as Exhibit E to the Complaint.

The ’523 Patent

35. Upon information and belief, the USPTO issued the '523 patent, titled "Method of treatment of attention deficit/hyperactivity disorder (ADHD)," on or about October 22, 2022.

36. Upon information and belief, Counterclaim Defendant Supernus is the assignee of the '523 patent, and upon information and belief, a copy of the '523 patent is attached as Exhibit F to the Complaint.

D. Apotex's ANDA No. 220456

37. Apotex filed Abbreviated New Drug Application ("ANDA") No. 220456 ("Apotex's ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval for viloxazine extended-release capsules (100 mg, 150 mg and 200 mg) ("Apotex's ANDA Products") prior to expiration of the Counterclaim Patents-In-Suit.

38. Apotex's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that, in Apotex's opinion and to the best of its knowledge, Apotex's ANDA Products would not infringe any valid claim of the Counterclaim Patents-In-Suit.

39. Pursuant to 21 U.S.C. § 355(j)(2)(B), Apotex sent, or caused to be sent, to Counterclaim-Defendant a letter dated May 22, 2025, detailing the legal and factual bases for its Paragraph IV certification that Apotex's ANDA would not infringe any valid claim of the Counterclaim patents-in-suit (the "detailed statement"), detailing multiple bases for Apotex's certification as to each claim of the Counterclaim patents-in-suit, and including an Offer of Confidential Access in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow Counterclaim-Defendant to inspect relevant portions of Apotex's ANDA.

40. Counterclaim-Defendant refused the terms and conditions of Apotex's Offer of Confidential Access.

41. Counterclaim-Defendant initiated the present litigation by filing a complaint against Apotex on June 26, 2025, alleging that Apotex's ANDA infringes one or more claims of the '204, '853, '338, '753, '143 patent, and '523 patents.

42. Counterclaim-Defendant did not review Apotex's ANDA in the instant action prior to filing suit.

43. Counterclaim-Defendant did not perform a prefiling infringement investigation of Apotex's ANDA products.

44. As a consequence of the foregoing, there is an actual and justiciable controversy between Counterclaim-Defendant and Apotex as to whether Apotex's ANDA infringes the Counterclaim Patents-In-Suit, or whether the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products would infringe the Counterclaim Patents-In-Suit.

COUNT I

(Declaratory Judgment of Invalidity of the '204 Patent)

45. Apotex restates and realleges each of the foregoing paragraphs 1-44 of the Counterclaims as if fully set forth herein.

46. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '204 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Products would infringe the '204 patent.

47. As evidenced by Counterclaim Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between

Apotex and Counterclaim Defendant regarding the validity of the claims of the '204 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

48. The claims of the '204 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

49. Apotex is entitled to a judicial determination that the claims of the '204 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT II

(Declaratory Judgment of Non-Infringement of the '204 Patent)

50. Apotex restates and realleges each of the foregoing paragraphs 1-49 of the Counterclaims as if fully set forth herein.

51. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '204 patent and that the manufacture, use, offer for sale, sale or importation of Apotex's ANDA Products would infringe the '204 patent.

52. As evidenced by Counterclaim-Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim-Defendant regarding the infringement of the claims of the '204 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

53. The manufacture, use, offer for sale, sale, and/or import of Apotex's ANDA Products would not infringe any valid or enforceable claim of the '204 patent, either directly or indirectly.

54. Apotex incorporates by reference Apotex's Notice Letter, which contains exemplary and nonlimiting explanations that no valid or enforceable claim of the '204 patent is infringed by Apotex's ANDA or Apotex's ANDA Products.

55. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by Apotex of their proposed ANDA Products pursuant to ANDA No. 220456 will not infringe, directly or indirectly, any valid claim of the '204 patent under any provision of 35 U.S.C. § 271.

56. Apotex is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '204 patent.

COUNT III

(Declaratory Judgment of Invalidity of the '853 Patent)

57. Apotex restates and realleges each of the foregoing paragraphs 1-57 of the Counterclaims as if fully set forth herein.

58. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '853 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Products would infringe the '853 patent.

59. As evidenced by Counterclaim Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim Defendant regarding the validity of the claims of the '853 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

60. The claims of the ’853 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

61. Apotex is entitled to a judicial determination that the claims of the ’853 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT IV

(Declaratory Judgment of Non-Infringement of the ’853 Patent)

62. Apotex restates and realleges each of the foregoing paragraphs 1-61 of the Counterclaims as if fully set forth herein.

63. Counterclaim-Defendant alleges that Apotex’s filing of ANDA No. 220456 infringes the ’853 patent and that the manufacture, use, offer for sale, sale or importation of Apotex’s ANDA Products would infringe the ’853 patent.

64. As evidenced by Counterclaim-Defendant’s Complaint and Apotex’s Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim-Defendant regarding the infringement of the claims of the ’853 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

65. The manufacture, use, offer for sale, sale, and/or import of Apotex’s ANDA Products would not infringe any valid or enforceable claim of the ’853 patent, either directly or indirectly.

66. Apotex incorporates by reference Apotex’s Notice Letter, which contains exemplary and nonlimiting explanations that no valid or enforceable claim of the ’853 patent is infringed by Apotex’s ANDA or Apotex’s ANDA Products.

67. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by Apotex of their proposed ANDA Products pursuant to ANDA No. 220456 will not infringe, directly or indirectly, any valid claim of the '853 patent under any provision of 35 U.S.C. § 271.

68. Apotex is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '853 patent.

COUNT V

(Declaratory Judgment of Invalidity of the '338 Patent)

69. Apotex restates and realleges each of the foregoing paragraphs 1-68 of the Counterclaims as if fully set forth herein.

70. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '338 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Products would infringe the '338 patent.

71. As evidenced by Counterclaim Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim Defendant regarding the validity of the claims of the '338 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

72. The claims of the '338 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

73. Apotex is entitled to a judicial determination that the claims of the '338 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT VI

(Declaratory Judgment of Non-Infringement of the '338 Patent)

74. Apotex restates and realleges each of the foregoing paragraphs 1-73 of the Counterclaims as if fully set forth herein.

75. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '338 patent and that the manufacture, use, offer for sale, sale or importation of Apotex's ANDA Products would infringe the '338 patent.

76. As evidenced by Counterclaim-Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim-Defendant regarding the infringement of the claims of the '338 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

77. The manufacture, use, offer for sale, sale, and/or import of Apotex's ANDA Products would not infringe any valid or enforceable claim of the '338 patent, either directly or indirectly.

78. Apotex incorporates by reference Apotex's Notice Letter, which contains exemplary and nonlimiting explanations that no valid or enforceable claim of the '338 patent is infringed by Apotex's ANDA or Apotex's ANDA Products.

79. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by

Apotex of their proposed ANDA Products pursuant to ANDA No. 220456 will not infringe, directly or indirectly, any valid claim of the '338 patent under any provision of 35 U.S.C. § 271.

80. Apotex is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '338 patent.

COUNT VII

(Declaratory Judgment of Invalidity of the '753 Patent)

81. Apotex restates and realleges each of the foregoing paragraphs 1-80 of the Counterclaims as if fully set forth herein.

82. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '753 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Products would infringe the '753 patent.

83. As evidenced by Counterclaim Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim Defendant regarding the validity of the claims of the '753 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

84. In accordance with 21 U.S.C. § 355(j)(2)(B), Apotex's Notice Letter included a detailed statement of factual and legal bases for why the claims of the '753 patent are invalid. Apotex incorporates by reference Apotex's Notice Letter.

85. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Apotex's Notice Letter, the claims of the '753 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

86. Apotex is entitled to a judicial determination that the claims of the '753 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT VIII

(Declaratory Judgment of Non-Infringement of the '753 Patent)

87. Apotex restates and realleges each of the foregoing paragraphs 1-86 of the Counterclaims as if fully set forth herein.

88. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '753 patent and that the manufacture, use, offer for sale, sale or importation of Apotex's ANDA Products would infringe the '753 patent.

89. As evidenced by Counterclaim-Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim-Defendant regarding the infringement of the claims of the '753 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

90. The manufacture, use, offer for sale, sale, and/or import of Apotex's ANDA Products would not infringe any valid or enforceable claim of the '753 patent, either directly or indirectly.

91. Apotex incorporates by reference Apotex's Notice Letter, which contains exemplary and nonlimiting explanations that no valid or enforceable claim of the '753 patent is infringed by Apotex's ANDA or Apotex's ANDA Products.

92. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by

Apotex of their proposed ANDA Products pursuant to ANDA No. 220456 will not infringe, directly or indirectly, any valid claim of the '753 patent under any provision of 35 U.S.C. § 271.

93. Apotex is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '753 patent.

COUNT IX

(Declaratory Judgment of Invalidity of the '143 Patent)

94. Apotex restates and realleges each of the foregoing paragraphs 1-93 of the Counterclaims as if fully set forth herein.

95. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '143 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Products would infringe the '143 patent.

96. As evidenced by Counterclaim Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim Defendant regarding the validity of the claims of the '143 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

97. In accordance with 21 U.S.C. § 355(j)(2)(B), Apotex's Notice Letter included a detailed statement of factual and legal bases for why the claims of the '143 patent are invalid. Apotex incorporates by reference Apotex's Notice Letter.

98. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Apotex's Notice Letter, the claims of the '143 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

99. Apotex is entitled to a judicial determination that the claims of the '143 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT X

(Declaratory Judgment of Non-Infringement of the '143 Patent)

100. Apotex restates and realleges each of the foregoing paragraphs 1-99 of the Counterclaims as if fully set forth herein.

101. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '143 patent and that the manufacture, use, offer for sale, sale or importation of Apotex's ANDA Products would infringe the '143 patent.

102. As evidenced by Counterclaim-Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim-Defendant regarding the infringement of the claims of the '143 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

103. The manufacture, use, offer for sale, sale, and/or import of Apotex's ANDA Products would not infringe any valid or enforceable claim of the '143 patent, either directly or indirectly.

104. Apotex incorporates by reference Apotex's Notice Letter, which contains exemplary and nonlimiting explanations that no valid or enforceable claim of the '143 patent is infringed by Apotex's ANDA or Apotex's ANDA Products.

105. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by

Apotex of their proposed ANDA Products pursuant to ANDA No. 220456 will not infringe, directly or indirectly, any valid claim of the '143 patent under any provision of 35 U.S.C. § 271.

106. Apotex is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '143 patent.

COUNT XI

(Declaratory Judgment of Invalidity of the '523 Patent)

107. Apotex restates and realleges each of the foregoing paragraphs 1-106 of the Counterclaims as if fully set forth herein.

108. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '523 patent and that the manufacture, use, offer for sale, sale or importation of the proposed ANDA Products would infringe the '523 patent.

109. As evidenced by Counterclaim Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim Defendant regarding the validity of the claims of the '523 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

110. In accordance with 21 U.S.C. § 355(j)(2)(B), Apotex's Notice Letter included a detailed statement of factual and legal bases for why the claims of the '523 patent are invalid. Apotex incorporates by reference Apotex's Notice Letter.

111. Based at least upon the facts and the reasons set forth in the detailed statement accompanying Apotex's Notice Letter, the claims of the '523 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

112. Apotex is entitled to a judicial determination that the claims of the '523 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT XII

(Declaratory Judgment of Non-Infringement of the '523 Patent)

113. Apotex restates and realleges each of the foregoing paragraphs 1-112 of the Counterclaims as if fully set forth herein.

114. Counterclaim-Defendant alleges that Apotex's filing of ANDA No. 220456 infringes the '523 patent and that the manufacture, use, offer for sale, sale or importation of Apotex's ANDA Products would infringe the '523 patent.

115. As evidenced by Counterclaim-Defendant's Complaint and Apotex's Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Apotex and Counterclaim-Defendant regarding the infringement of the claims of the '523 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

116. The manufacture, use, offer for sale, sale, and/or import of Apotex's ANDA Products would not infringe any valid or enforceable claim of the '523 patent, either directly or indirectly.

117. Apotex incorporates by reference Apotex's Notice Letter, which contains exemplary and nonlimiting explanations that no valid or enforceable claim of the '523 patent is infringed by Apotex's ANDA or Apotex's ANDA Products.

118. Based at least upon the facts and the reasons set forth in the detailed statement accompanying the Notice Letter, the manufacture, use, sale, offer for sale, and/or importation by

Apotex of their proposed ANDA Products pursuant to ANDA No. 220456 will not infringe, directly or indirectly, any valid claim of the '523 patent under any provision of 35 U.S.C. § 271.

119. Apotex is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '523 patent.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests that this Court enter a judgment in its favor and against Counterclaim Defendants as follows:

a. Declaring that the filing of Apotex's ANDA did not infringe any valid and enforceable claim of the Counterclaim Patents-In-Suit;

b. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products described in Apotex's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and enforceable claim of the Counterclaim Patents-In-Suit either literally or under the doctrine of equivalents;

c. Declaring that the claims of the '204 patent are invalid or unenforceable;

d. Declaring that the claims of the '853 patent are invalid or unenforceable;

e. Declaring that the claims of the '338 patent are invalid or unenforceable;

f. Declaring that the claims of the '753 patent are invalid or unenforceable;

g. Declaring that the claims of the '143 patent are invalid or unenforceable;

h. Declaring that the claims of the '523 patent are invalid or unenforceable;

i. Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Apotex;

j. Denying Plaintiff/Counterclaim Defendant any of the relief requested in the Complaint;

k. Declaring this case exceptional in favor of Apotex pursuant to 35 U.S.C. § 285;

l. Awarding costs and attorneys' fees to Apotex; and,

m. Awarding Apotex such other and further relief the Court may deem just and proper.

Respectfully submitted,

Dated: September 19, 2025

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Attorneys for Defendants/Counterclaim-Plaintiffs Apotex Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

On behalf of Defendant/Counterclaim-Plaintiff Apotex Inc., I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of other civil actions pending in any Court or of any pending arbitration or administrative proceeding.

Dated: September 19, 2025

By: /s/ Rebekah Conroy

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Attorneys for Defendants/Counterclaim-Plaintiffs Apotex Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendant/Counterclaim-Plaintiff Apotex Inc. hereby certifies that as a result of the nature of Defendant/Counterclaim-Plaintiff's cause of action, as asserted in its counterclaims, this action is not appropriate for compulsory arbitration.

Dated: September 19, 2025

By: /s/ Rebekah Conroy

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Attorneys for Defendants/Counterclaim-Plaintiffs Apotex Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the September 19, 2025, I filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notice of electronic filing to all the registered users.

By: /s/ Rebekah Conroy
Rebekah Conroy