

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NEUROCRINE BIOSCIENCES, INC.

Plaintiff,

v.

TEVA PHARMACEUTICALS, INC., TEVA  
PHARMACEUTICALS DEVELOPMENT,  
INC., TEVA PHARMACEUTICALS USA,  
INC. and TEVA PHARMACEUTICAL  
INDUSTRIES LTD.

Defendants.

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

**COMPLAINT FOR PATENT INFRINGEMENT**

Neurocrine Biosciences, Inc. (“Neurocrine”), by way of Complaint against Defendants Teva Pharmaceuticals, Inc. (“Teva Pharmaceuticals”), Teva Pharmaceuticals Development, Inc. (“Teva Development”), Teva Pharmaceuticals USA, Inc. (“Teva USA”) and Teva Pharmaceutical Industries Ltd. (“Teva Industries”) (collectively “Teva” or “Defendants”), alleges as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,065,952 (“the ’952 patent”), 10,844,058 (“the ’058 patent”), 10,851,103 (“the ’103 patent”), 10,851,104 (“the ’104 patent”), 10,857,137 (“the ’137 patent”), 10,857,148 (“the ’148 patent”), 10,874,648 (“the ’648 patent”), 10,906,902 (“the ’902 patent”), 10,906,903 (“the ’903 patent”), 10,912,771 (“the ’771 patent”), 10,919,892 (“the ’892 patent”), 10,940,141 (“the ’141 patent”) and 10,952,997 (“the ’997 patent”) (collectively, “patents-in-suit”), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Teva’s filing of an Abbreviated New Drug Application (“ANDA”) No. 215984 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and

Drug Administration (“FDA”) approval to manufacture, use, import, offer to sell and/or sell Valbenazine Capsules, 40 mg and 80 mg (“Teva’s generic products”) before the expiration of the patents-in-suit.

### **THE PARTIES**

2. Neurocrine is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 12780 El Camino Real, San Diego, CA 92130.

3. Neurocrine is engaged in the business of researching, developing and bringing to market innovative pharmaceutical products for the treatment of neurological, endocrine and psychiatric disorders.

4. Neurocrine received a letter from Teva dated June 3, 2021 (“Teva’s Notice Letter”), purporting to include a “Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the patents-in-suit]” pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Teva’s Notice Letter defined Teva as Teva Development.

5. Upon information and belief, Teva Development was incorporated in Delaware on October 23, 2020, under File Number 3960741.

6. Upon information and belief, Teva Development filed a name amendment on June 23, 2021.

7. Upon information and belief, Teva Pharmaceuticals was incorporated in Delaware on October 23, 2020, under File Number 3960741.

8. Neurocrine, through its counsel, asked Teva to clarify whether, in light of the name change according to Delaware records, Teva’s Notice Letter is now on behalf of Teva Development, Teva Pharmaceuticals, or both entities.

9. Teva's only response was to refer Neurocrine back to Teva's Notice Letter.

10. Upon information and belief, Teva Pharmaceuticals is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

11. Upon information and belief, Teva Development is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

12. Upon information and belief, Teva USA is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054.

13. Upon information and belief, Teva Industries is a corporation organized under the laws of Israel and its principal place of business is located at 5 Basel Street, Petach Tikva, 49131, Israel.

14. Upon information and belief, Teva Pharmaceuticals is a wholly-owned subsidiary of Teva Industries.

15. Upon information and belief, Teva Development is a wholly-owned subsidiary of Teva Industries.

16. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries.

17. Upon information and belief, Teva Pharmaceuticals, Teva Development and Teva USA are generic pharmaceutical companies that, in coordination with each other and Teva Industries or at the direction of Teva Industries, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

**JURISDICTION AND VENUE**

18. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

19. This Court has personal jurisdiction over Teva Pharmaceuticals. Upon information and belief, Teva Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Pharmaceuticals directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

20. This Court has personal jurisdiction over Teva Development. Upon information and belief, Teva Development is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Development directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva Development purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

21. This Court has personal jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva USA directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

22. Upon information and belief, Teva USA states that it "is the leading generic drug

company in the United States.” <https://www.tevausa.com/about-teva/> (accessed July 7, 2021).

23. This Court has personal jurisdiction over Teva Industries. Upon information and belief, Teva Industries is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Industries directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva Industries purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva’s generic products.

24. Upon information and belief, Teva Industries is the holder of FDA Drug Master File No. 35290 for valbenazine tosylate.

25. Upon information and belief, Teva Pharmaceuticals, Teva Development, Teva USA and Teva Industries hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

26. Upon information and belief, Teva admits that “1 of every 9 prescriptions in the US” is filled with a Teva product. <https://www.tevapharm.com/teva-worldwide/> (accessed July 7, 2021). Upon information and belief, Teva has at least 30 locations across the U.S. and its territories. <https://businessfacilities.com/2018/07/teva-pharmaceuticals-moving-u-s-headquarters-parsippany-troy-hills-new-jersey/> (accessed July 7, 2021). Upon information and belief, Teva admits it has 100 pending first-to-file ANDAs in the U.S. and 270 product registrations pending FDA approval. [https://www.tevapharm.com/globalassets/scs-files---global/teva-infographic-files/teva\\_infographic\\_english\\_may2020.pdf](https://www.tevapharm.com/globalassets/scs-files---global/teva-infographic-files/teva_infographic_english_may2020.pdf) (accessed July 7, 2021).

27. Upon information and belief, Teva is engaged in the submission and approval of

ANDAs for the U.S. market, admitting Teva has “over 100 pending first-to-files in the U.S.” *See, e.g.,* <https://www.tevausa.com/news-and-media/press-releases/teva-wins-generic-uceris-patent-trial/> (accessed July 8, 2021).

28. Teva’s ANDA filing regarding the patents-in-suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Teva’s intent to market and sell Teva’s generic products in this judicial district.

29. Teva has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Teva intends to direct sales of its generic drugs in this judicial district, among other places, once Teva receives the requested FDA approval to market its generic products. Upon information and belief, Teva will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

30. Upon information and belief, Teva Pharmaceuticals, Teva Development, Teva USA and Teva Industries have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 215984.

31. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

32. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva Industries is incorporated in Israel and may be sued in any judicial district in the United States.

33. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva Pharmaceuticals is incorporated in the state of Delaware.

34. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva Development is incorporated in the state of Delaware.

35. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Teva USA is incorporated in the state of Delaware.

## **FACTUAL BACKGROUND**

### **The NDA**

36. Neurocrine is the holder of New Drug Application (“NDA”) No. 209241 for INGREZZA<sup>®</sup> (valbenazine) Capsules in 40, 60, and 80 mg dosage forms (“INGREZZA<sup>®</sup> Capsules”).

37. The FDA approved NDA No. 209241 on April 11, 2017.

38. INGREZZA<sup>®</sup> Capsules are prescription drugs approved for the treatment of tardive dyskinesia. Valbenazine, which is present as the tosylate salt, is the active ingredient in INGREZZA<sup>®</sup> Capsules.

39. Valbenazine Capsules are marketed in the United States under the trademark INGREZZA<sup>®</sup>.

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

40. The United States Patent and Trademark Office (“the PTO”) issued the ’952 patent on September 4, 2018, titled “Valbenazine Salts and Polymorphs Thereof.” A true and correct copy of the ’952 patent is attached as Exhibit A.

41. Neurocrine owns the ’952 patent through assignment as recorded by the PTO at Reel 041075, Frame 0820 and Reel 042510, Frame 0992.

42. The ’952 patent currently expires on October 28, 2036.

43. The '952 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

44. The PTO issued the '058 patent on November 24, 2020, titled “Valbenazine Salts and Polymorphs Thereof.” A true and correct copy of the '058 patent is attached as Exhibit B.

45. Neurocrine owns the '058 patent through assignment as recorded by the PTO at Reel 052974, Frame 0121; Reel 052974, Frame 0549 and Reel 053995, Frame 0827.

46. The '058 patent currently expires on October 28, 2036.

47. The '058 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

48. The PTO issued the '103 patent on December 1, 2020, titled “Valbenazine Salts and Polymorphs Thereof.” A true and correct copy of the '103 patent is attached as Exhibit C.

49. Neurocrine owns the '103 patent through assignment as recorded by the PTO at Reel 052974, Frame 0121; Reel 052974, Frame 0549 and Reel 053995, Frame 0827.

50. The '103 patent currently expires on October 28, 2036.

51. The '103 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

52. The PTO issued the '104 patent on December 1, 2020, titled “Valbenazine Salts and Polymorphs Thereof.” A true and correct copy of the '104 patent is attached as Exhibit D.

53. Neurocrine owns the '104 patent through assignment as recorded by the PTO at Reel 052974, Frame 0121; Reel 052974, Frame 0549 and Reel 053995, Frame 0827.

54. The '104 patent currently expires on October 28, 2036.

55. The '104 patent is listed the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.



56. The PTO issued the '137 patent on December 8, 2020, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '137 patent is attached as Exhibit E.

57. Neurocrine owns the '137 patent through assignment as recorded by the PTO at Reel 052974, Frame 0888.

58. The '137 patent currently expires on October 10, 2037.

59. The '137 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

60. The PTO issued the '148 patent on December 8, 2020, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '148 patent is attached as Exhibit F.

61. Neurocrine owns the '148 patent through assignment as recorded by the PTO at Reel 053415, Frame 0436.

62. The '148 patent currently expires on October 10, 2037.

63. The '148 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

64. The PTO issued the '648 patent on December 29, 2020, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '648 patent is attached as Exhibit G.

65. Neurocrine owns the '648 patent through assignment as recorded by the PTO at Reel 050397, Frame 0502 and Reel 050515, Frame 0577.

66. The '648 patent currently expires on October 10, 2037.

67. The '648 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

68. The PTO issued the '902 patent on February 2, 2021, titled "Synthetic Methods for Preparation of (S)-(2R,3R,11bR)-3-isobutyl-9,10-dimethoxy-2,3,4,6,7,11b-hexahydro-1H-pyrido[2,1-a]isoquinolin-2-yl 2-amino-3-methylbutanoate di(4-methylbenzenesulfonate)." A true and correct copy of the '902 patent is attached as Exhibit H.

69. Neurocrine owns the '902 patent through assignment as recorded by the PTO at Reel 053426, Frame 0765; Reel 053426, Frame 0633; Reel 053440, Frame 0795 and Reel 053800, Frame 0270.

70. The '902 patent currently expires on December 22, 2036.

71. The '902 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

72. The PTO issued the '903 patent on February 2, 2021, titled "Synthetic Methods for Preparation of (S)-(2R,3R,11bR)-3-isobutyl-9,10-dimethoxy-2,3,4,6,7,11b-hexahydro-1H-pyrido[2,1-a]isoquinolin-2-yl 2-amino-3-methylbutanoate di(4-methylbenzenesulfonate)." A true and correct copy of the '903 patent is attached as Exhibit I.

73. Neurocrine owns the '903 patent through assignment as recorded by the PTO at Reel 053426, Frame 0765; Reel 053426, Frame 0633; Reel 053440, Frame 0795 and Reel 053800, Frame 0270.

74. The '903 patent currently expires on December 22, 2036.

75. The '903 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

76. The PTO issued the '771 patent on February 9, 2021, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '771 patent is attached as Exhibit J.

77. Neurocrine owns the '771 patent through assignment as recorded by the PTO at Reel 054349, Frame 0110.

78. The '771 patent currently expires on October 10, 2037.

79. The '771 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

80. The PTO issued the '892 patent on February 16, 2021, entitled "Synthetic Methods for Preparation of (S)-(2R,3R,11bR)-3-isobutyl-9,10-dimethoxy-2,3,4,6,7,11b-hexahydro-1H-pyrido[2,1-a]isoquinolin-2-yl 2-amino-3-methylbutanoate di(4-methylbenzenesulfonate)." A true and correct copy of the '892 patent is attached as Exhibit K.

81. Neurocrine owns the '892 patent through assignment as recorded by the PTO at Reel 053426, Frame 0765; Reel 053426, Frame 0633; Reel 053440, Frame 0795 and Reel 053800, Frame 0270.

82. The '892 patent currently expires on December 22, 2036.

83. The '892 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

84. The PTO issued the '141 patent on March 9, 2021, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '141 patent is attached as Exhibit L.

85. Neurocrine owns the '141 patent through assignment as recorded by the PTO at Reel 053540, Frame 0438.

86. The '141 patent currently expires on August 10, 2040.

87. The '141 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

88. The PTO issued the '997 patent on March 23, 2021, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '997 patent is attached as Exhibit M.

89. Neurocrine owns the '997 patent through assignment as recorded by the PTO at Reel 052974, Frame 0968.

90. The '997 patent currently expires on October 10, 2037.

91. The '997 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA<sup>®</sup> Capsules.

### **The ANDA**

92. Upon information and belief, Teva submitted ANDA No. 215984 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, import, offer to sell and/or sell in the United States Valbenazine Capsules, 40 mg and 80 mg (defined above as "Teva's generic products"), which are generic versions of Neurocrine's INGREZZA<sup>®</sup> Capsules.

93. Teva's Notice Letter purports to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the patents-in-suit]" pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95. Teva's Notice Letter stated that Teva had filed ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products before the expiration of the patents-in-suit.

94. Teva's Notice Letter states that ANDA No. 215984 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the patents-in-suit are invalid, unenforceable or will not be infringed by manufacture, use, import, offer to sell and/or sale of Teva's generic products.

95. Plaintiff commenced this action within 45 days of receiving Teva's Notice Letter.

## **COUNT I**

### **(INFRINGEMENT OF THE '952 PATENT)**

96. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

97. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '952 patent.

98. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '952 patent are invalid, unenforceable and/or will not be infringed.

99. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

100. Teva has actual knowledge of the '952 patent, as evidenced by Teva's Notice Letter.

101. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '952 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '952 patent.

102. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

103. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '952 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '952 patent.

104. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '952 patent.

105. Upon information and belief, Teva has knowledge of the '952 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '952 patent, either literally or under the doctrine of equivalents.

106. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '952 patent.

107. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

108. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

## **COUNT II**

### **(INFRINGEMENT OF THE '058 PATENT)**

110. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

111. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '058 patent.

112. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '058 patent are invalid, unenforceable and/or will not be infringed.

113. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

114. Teva has actual knowledge of the '058 patent, as evidenced by Teva's Notice Letter.

115. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '058 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '058 patent.

116. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

117. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '058 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '058 patent and any additional periods of exclusivity.

118. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '058 patent.

119. Upon information and belief, Teva has knowledge of the '058 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '058 patent, either literally or under the doctrine of equivalents.

120. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '058 patent.



121. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

122. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **COUNT III**

#### **(INFRINGEMENT OF THE '103 PATENT)**

124. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

125. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '103 patent.

126. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '103 patent are invalid, unenforceable and/or will not be infringed.

127. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

128. Teva has actual knowledge of the '103 patent, as evidenced by Teva's Notice Letter.

129. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '103 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '103 patent.

130. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

131. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '103 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '103 patent and any additional periods of exclusivity.

132. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '103 patent.

133. Upon information and belief, Teva has knowledge of the '103 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '103 patent, either literally or under the doctrine of equivalents.

134. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '103 patent.

135. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

136. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

#### **COUNT IV**

#### **(INFRINGEMENT OF THE '104 PATENT)**

138. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

139. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '104 patent.

140. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '104 patent are invalid, unenforceable and/or will not be infringed.

141. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

142. Teva has actual knowledge of the '104 patent, as evidenced by Teva's Notice Letter.

143. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '104 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '104 patent.

144. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

145. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '104 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '104 patent and any additional periods of exclusivity.

146. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '104 patent.

147. Upon information and belief, Teva has knowledge of the '104 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '104 patent, either literally or under the doctrine of equivalents.

148. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '104 patent.

149. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

150. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **COUNT V**

#### **(INFRINGEMENT OF THE '137 PATENT)**

152. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

153. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '137 patent.

154. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '137 patent are invalid, unenforceable and/or will not be infringed.

155. Upon information and belief, Teva admits infringement of at least one claim of the '137 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '137 patent.

156. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

157. Teva has actual knowledge of the '137 patent, as evidenced by Teva's Notice Letter.

158. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '137 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '137 patent.

159. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

160. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '137 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '137 patent and any additional periods of exclusivity.

161. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '137 patent.

162. Upon information and belief, Teva has knowledge of the '137 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '137 patent, either literally or under the doctrine of equivalents.

163. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an

infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '137 patent.

164. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

165. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

#### **COUNT VI**

#### **(INFRINGEMENT OF THE '148 PATENT)**

167. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

168. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '148 patent.

169. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '148 patent are invalid, unenforceable and/or will not be infringed.

170. Upon information and belief, Teva admits infringement of at least one claim of the '148 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '148 patent.

171. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

172. Teva has actual knowledge of the '148 patent, as evidenced by Teva's Notice Letter.

173. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '148 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '148 patent.

174. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

175. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '148 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '148 patent and any additional periods of exclusivity.

176. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '148 patent.



177. Upon information and belief, Teva has knowledge of the '148 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '148 patent, either literally or under the doctrine of equivalents.

178. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '148 patent.

179. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

180. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

## **COUNT VII**

### **(INFRINGEMENT OF THE '648 PATENT)**

182. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

183. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '648 patent.

184. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '648 patent are invalid, unenforceable and/or will not be infringed.

185. Upon information and belief, Teva admits infringement of at least one claim of the '648 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '648 patent.

186. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

187. Teva has actual knowledge of the '648 patent, as evidenced by Teva's Notice Letter.

188. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '648 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '648 patent.

189. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

190. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '648 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '648 patent and any additional periods of exclusivity.

191. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '648 patent.

192. Upon information and belief, Teva has knowledge of the '648 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '648 patent, either literally or under the doctrine of equivalents.

193. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '648 patent.

194. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

195. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **COUNT VIII**

#### **(INFRINGEMENT OF THE '902 PATENT)**

197. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

198. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '902 patent.

199. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '902 patent are invalid, unenforceable and/or will not be infringed.

200. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

201. Teva has actual knowledge of the '902 patent, as evidenced by Teva's Notice Letter.

202. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '902 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '902 patent.

203. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

204. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe at least one claim of the '902 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '902 patent and any additional periods of exclusivity.

205. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

206. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **COUNT IX**

#### **(INFRINGEMENT OF THE '903 PATENT)**

208. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

209. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '903 patent.

210. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '903 patent are invalid, unenforceable and/or will not be infringed.

211. Upon information and belief, Teva admits infringement of at least one claim of the '903 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '903 patent.

212. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

213. Teva has actual knowledge of the '903 patent, as evidenced by Teva's Notice Letter.

214. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '903 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '903 patent.

215. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

216. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe at least one claim of the '903 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '903 patent and any additional periods of exclusivity.

217. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

218. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **COUNT X**

#### **(INFRINGEMENT OF THE '771 PATENT)**

220. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

221. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '771 patent.

222. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '771 patent are invalid, unenforceable and/or will not be infringed.

223. Upon information and belief, Teva admits infringement of at least one claim of the '771 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '771 patent.

224. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

225. Teva has actual knowledge of the '771 patent, as evidenced by Teva's Notice Letter.

226. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '771 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '771 patent.

227. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

228. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '771 patent under § 271(a), either literally or under the doctrine of

equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '771 patent and any additional periods of exclusivity.

229. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '771 patent.

230. Upon information and belief, Teva has knowledge of the '771 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '771 patent, either literally or under the doctrine of equivalents.

231. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '771 patent.

232. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

233. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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



**COUNT XI**

**(INFRINGEMENT OF THE '892 PATENT)**

235. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

236. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '892 patent.

237. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '892 patent are invalid, unenforceable and/or will not be infringed.

238. Upon information and belief, Teva admits infringement of at least one claim of the '892 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '892 patent. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

239. Teva has actual knowledge of the '892 patent, as evidenced by Teva's Notice Letter.

240. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '892 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '892 patent.

241. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

242. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe at least one claim of the '892 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '892 patent and any additional periods of exclusivity.

243. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

244. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

## **COUNT XII**

### **(INFRINGEMENT OF THE '141 PATENT)**

246. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

247. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '141 patent.

248. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '141 patent are invalid, unenforceable and/or will not be infringed.

249. Upon information and belief, Teva admits infringement of at least one claim of the '141 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '141 patent.

250. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

251. Teva has actual knowledge of the '141 patent, as evidenced by Teva's Notice Letter.

252. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '141 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '141 patent.

253. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

254. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '141 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '141 patent and any additional periods of exclusivity.

255. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '141 patent.

256. Upon information and belief, Teva has knowledge of the '141 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '141 patent, either literally or under the doctrine of equivalents.

257. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '141 patent.

258. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

259. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **COUNT XIII**

#### **(INFRINGEMENT OF THE '997 PATENT)**

261. Plaintiff realleges, and incorporates fully herein, each preceding paragraph.

262. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '997 patent.

263. Teva's Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '997 patent are invalid, unenforceable and/or will not be infringed.

264. Upon information and belief, Teva admits infringement of at least one claim of the '997 patent because Teva's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '997 patent.

265. Upon information and belief, in its ANDA No. 215984, Teva has represented to the FDA that Teva's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA<sup>®</sup> Capsules.

266. Teva has actual knowledge of the '997 patent, as evidenced by Teva's Notice Letter.

267. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '997 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '997 patent.

268. Upon information and belief, if ANDA No. 215984 is approved, Teva intends to and will manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States.

269. Upon information and belief, if ANDA No. 215984 is approved, Teva will infringe one or more claims of the '997 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval

of ANDA No. 215984 shall be no earlier than the expiration of the '997 patent and any additional periods of exclusivity.

270. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '997 patent.

271. Upon information and belief, Teva has knowledge of the '997 patent and, by its proposed package insert for Teva's generic products, knows or should know that it will induce direct infringement of at least one claim of the '997 patent, either literally or under the doctrine of equivalents.

272. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '997 patent.

273. Upon information and belief, Teva's actions relating to Teva's ANDA No. 215984 complained of herein were done by and for the benefit of Teva.

274. Plaintiff will be irreparably harmed by Teva's infringing activities unless this Court enjoins those activities.

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

### **REQUEST FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '952 patent through Teva's submission of ANDA No. 215984 to the FDA

seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '952 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '952 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '952 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '952 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '952 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '952 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '058 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '058 patent;

G. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '058 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '058 patent under 35 U.S.C. § 271(a), (b) and/or (c);

H. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '058 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

I. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '058 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

J. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '058 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '103 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '103 patent;

L. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the



'103 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '103 patent under 35 U.S.C. § 271(a), (b) and/or (c);

M. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '103 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

N. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '103 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

O. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '103 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

P. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '104 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '104 patent;

Q. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '104 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '104 patent under 35 U.S.C. § 271(a), (b) and/or (c);

R. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '104 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

S. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '104 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

T. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '104 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

U. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '137 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '137 patent;

V. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '137 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '137 patent under 35 U.S.C. § 271(a), (b) and/or (c);

W. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '137 patent and any additional

periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

X. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '137 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Y. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '137 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

Z. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '148 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '148 patent;

AA. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '148 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '148 patent under 35 U.S.C. § 271(a), (b) and/or (c);

BB. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '148 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

CC. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '148 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

DD. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '148 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

EE. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '648 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '648 patent;

FF. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '648 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '648 patent under 35 U.S.C. § 271(a), (b) and/or (c);

GG. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '648 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

HH. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United

States, until the expiration of the '648 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

II. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '648 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

JJ. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '902 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '902 patent;

KK. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '902 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '902 patent under 35 U.S.C. § 271(a), (b) and/or (c);

LL. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '902 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

MM. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '902 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

NN. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '902 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

OO. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '903 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '903 patent;

PP. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '903 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '903 patent under 35 U.S.C. § 271(a), (b) and/or (c);

QQ. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '903 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

RR. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '903 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

SS. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '903 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

TT. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '771 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '771 patent;

UU. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '771 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '771 patent under 35 U.S.C. § 271(a), (b) and/or (c);

VV. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '771 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

WW. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '771 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

XX. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '771 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

YY. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '892 patent through Teva's submission of ANDA No. 215984 to the FDA

seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '892 patent;

ZZ. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '892 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '892 patent under 35 U.S.C. § 271(a), (b) and/or (c);

AAA. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '892 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

BBB. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '892 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

CCC. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '892 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

DDD. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '141 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '141 patent;



EEE. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the '141 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '141 patent under 35 U.S.C. § 271(a), (b) and/or (c);

FFF. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '141 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

GGG. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '141 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

HHH. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '141 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

III. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '997 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '997 patent;

JJJ. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Teva's making, using, offering to sell, selling or importing of Teva's generic products before the expiration of the

'997 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '997 patent under 35 U.S.C. § 271(a), (b) and/or (c);

KKK. The issuance of an order that the effective date of any FDA approval of Teva's generic products shall be no earlier than the expiration date of the '997 patent and any additional periods of exclusivity, or any such later date as the Court may determine, in accordance with 35 U.S.C. § 271(e)(4)(A);

LLL. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '997 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

MMM. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '997 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

NNN. The issuance of a declaration that this is an exceptional case and an award to Plaintiff of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

OOO. An award to Plaintiff of any further appropriate relief under 35 U.S.C. § 271(e)(4);  
and

PPP. An award to Plaintiff of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

*/s/ Steven J. Balick*

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Dated: July 16, 2021

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