

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

NEUROCRINE BIOSCIENCES, INC.

Plaintiff,

v.

LUPIN LIMITED, LUPIN
PHARMACEUTICALS, INC., LUPIN INC.
and LUPIN ATLANTIS HOLDINGS S.A.

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Neurocrine Biosciences, Inc. (“Neurocrine”), by way of Complaint against Defendants Lupin Limited, Lupin Pharmaceuticals, Inc. (“Lupin Pharmaceuticals”), Lupin Inc., and Lupin Atlantis Holdings S.A. (“Lupin S.A.”) (collectively “Lupin” or “Defendants”), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 8,039,627 (“the ’627 patent”), 8,357,697 (“the ’697 patent”), 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”), 10,952,997 (“the ’997 patent”) and 10,993,941 (“the ’941 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 Lupin’s filing of an Abbreviated New Drug Application (“ANDA”) No. 216064 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 Tosylate Capsule, eq. 40 mg base and eq. 80 mg base (“Lupin’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. Upon information and belief, Lupin Limited is a corporation organized under the laws of India and its principal place of business is located at 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (E), Mumbai 400 055, India.

5. Upon information and belief, Lupin Pharmaceuticals is a corporation organized under the laws of Delaware and its principal place of business is located at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202.

6. Upon information and belief, Lupin Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202.

7. Upon information and belief, Lupin S.A. is a corporation organized under the laws of Switzerland and its principal place of business is located at Landis & Gyr – Strasse 1, 6300 Zug, Switzerland.

8. Upon information and belief, Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Limited.

9. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Nanomi B.V. and Nanomi B.V. is a wholly-owned subsidiary of Lupin Limited.

10. Upon information and belief, Lupin Pharmaceuticals, Lupin Inc. and Lupin S.A. are generic pharmaceutical companies that, in coordination with each other and Lupin Limited or at the direction of Lupin Limited, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

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

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

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

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

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

16. Upon information and belief, Lupin Limited states that it “is present in the US through manufacturing, research and development, and commercial divisions for generics, complex generics, biosimilars and branded pharmaceuticals” and that its “US revenues crossed \$1 billion” in 2017-18. <https://www.lupin.com/about-us/global-presence/> (accessed July 13, 2021).

17. Upon information and belief, Lupin Limited is the holder of FDA Drug Master File No. 35246 for valbenazine tosylate.

18. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, Lupin Inc. and Lupin S.A. 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.

19. Upon information and belief, Lupin admits that it “has a strong and well-established generic presence in the United States, having entered the U.S. market in 2003 and maintaining a competitive edge in the list of top 5 generic pharmaceutical companies by prescriptions dispensed since 2010.” <https://www.lupin.com/US/about-us/> (accessed July 13, 2021). Upon information and belief, Lupin has at least five offices and a manufacturing facility in the U.S. <https://www.lupin.com/about-us/global-presence/> (accessed July 13, 2021).

20. Upon information and belief, Lupin is engaged in the submission and approval of ANDAs for the U.S. market, admitting Lupin has “received more than 250 FDA approvals and market[ed] 180 generic products” and describes itself “as one of the fastest-growing pharmaceutical companies in the U.S.” <https://www.lupin.com/US/generics/> (accessed July 13, 2021).

21. Lupin’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 Lupin’s intent to market and sell Lupin’s generic products in this judicial district.

22. Lupin 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, Lupin intends to direct sales of its generic drugs in this judicial district, among other places, once Lupin receives the requested FDA approval to market its generic products. Upon information and belief, Lupin will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

23. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, Lupin Inc. and Lupin S.A. have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 216064.

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

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Lupin Limited is incorporated in India and may be sued in any judicial district in the United States.

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

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

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

FACTUAL BACKGROUND

The NDA

29. Neurocrine is the holder of New Drug Application (“NDA”) No. 209241 for INGREZZA[®] (valbenazine) Capsules in 40, 60, and 80 mg dosage forms (“INGREZZA[®] Capsules”).

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

31. INGREZZA[®] 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[®] Capsules.

32. Valbenazine Capsules are marketed in the United States under the trademark INGREZZA[®].

The Patents-in-Suit

33. The United States Patent and Trademark Office (“the PTO”) issued the ’627 patent on October 18, 2011, titled “Substituted 3-isobutyl-9,10-dimethoxy-1,3,4,6,7,11b-hexahydro-2H-pyrido[2,1-a]isoquinolin-2-ol Compounds and Methods Relating Thereto.” A true and correct copy of the ’627 patent is attached as Exhibit A.

34. NBI owns the ’627 patent through assignment as recorded by the PTO at Reel 020113, Frame 0451.

35. Neurocrine filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156, and the PTO has issued a Notice of Final Determination, which is attached as Exhibit B. In Exhibit B, the PTO determined that the ’627 patent is eligible for patent term extension and stated that the period of extension has been determined to be 552 days. Accordingly, once the PTO issues the certificate of extension, the ’627 patent will expire on April 11, 2031.

36. The ’627 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 209241 for INGREZZA[®] Capsules.

37. The PTO issued the ’697 patent on January 22, 2013, titled “Substituted 3-isobutyl-9,10-dimethoxy-1,3,4,6,7,11b-hexahydro-2H-pyrido[2,1-a]isoquinolin-2-ol Compounds and Methods Relating Thereto.” A true and correct copy of the ’697 patent is attached as Exhibit C.

38. NBI owns the '697 patent through assignment as recorded by the PTO at Reel 048124, Frame 0753.

39. The '697 patent currently expires on November 8, 2027.

40. The '697 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

41. 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 D.

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

43. The '952 patent currently expires on October 28, 2036.

44. The '952 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

45. 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 E.

46. 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.

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

48. The '058 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

49. 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 F.

50. 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.

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

52. The '103 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

53. 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 G

54. 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.

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

56. The '104 patent is listed the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

57. 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 H.

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

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

60. The '137 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

61. 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 I.

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

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

64. The '148 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

65. 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 J.

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

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

68. The '648 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

69. 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-2-2-amino-3-methylbutanoate di(4-methylbenzenesulfonate)." A true and correct copy of the '902 patent is attached as Exhibit K.

70. 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.

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

72. The '902 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

73. 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 L.

74. 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.

75. The ’903 patent currently expires on December 22, 2036.

76. The ’903 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

77. 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 M.

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

79. The ’771 patent currently expires on October 10, 2037.

80. The ’771 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

81. 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 N.

82. 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.

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

84. The '892 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

85. 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 O.

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

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

88. The '141 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

89. 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 P.

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

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

92. The '997 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

93. The PTO issued the '941 patent on May 4, 2021, entitled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '941 patent is attached as Exhibit Q.

94. NBI owns the '941 patent through assignment as recorded by the PTO at Reel 053415, Frame 0390.

95. The '941 patent currently expires on October 10, 2037.

96. The '941 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA[®] Capsules.

The ANDA

97. Upon information and belief, Lupin submitted ANDA No. 216064 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 Tosylate Capsule, eq. 40 mg base and eq. 80 mg base (defined above as “Lupin’s generic products”), which are generic versions of Neurocrine’s INGREZZA[®] Capsules.

98. Neurocrine received a letter from Lupin dated June 3, 2021 (“Lupin’s Notice Letter”), purporting to include a “Notice of Paragraph IV Certification Regarding [the patents-in-suit] pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 for ANDA No. 216064.” Lupin’s Notice Letter stated that Lupin had filed ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell and/or sell Lupin’s generic products before the expiration of the patents-in-suit.

99. Lupin’s Notice Letter states that ANDA No. 216064 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 the manufacture, use or sale of Lupin’s generic products.

100. Plaintiff commenced this action within 45 days of receiving Lupin’s Notice Letter.

COUNT I

(INFRINGEMENT OF THE '627 PATENT)

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

102. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '627 patent.

103. Lupin's Notice Letter states that Lupin 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 '627 patent are invalid, unenforceable and/or will not be infringed.

104. Upon information and belief, Lupin admits infringement of at least one claim of the '627 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '627 patent.

105. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

106. Lupin has actual knowledge of the '627 patent, as evidenced by Lupin's Notice Letter.

107. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '627 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '627 patent.

108. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

109. Upon information and belief, if ANDA No. 216064 is approved, Lupin will infringe one or more claims of the '627 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Lupin'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. 216064 shall be no earlier than the expiration of the '627 patent.

110. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT II

(INFRINGEMENT OF THE '697 PATENT)

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

114. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '697 patent.

115. Lupin's Notice Letter states that Lupin 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 '697 patent are invalid, unenforceable and/or will not be infringed.

116. Upon information and belief, Lupin admits infringement of at least one claim of the '697 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '697 patent.

117. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

118. Lupin has actual knowledge of the '697 patent, as evidenced by Lupin's Notice Letter.

119. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '697 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '697 patent.

120. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

121. Upon information and belief, if ANDA No. 216064 is approved, Lupin will infringe one or more claims of the '697 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Lupin'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. 216064 shall be no earlier than the expiration of the '697 patent.

122. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '697 patent.

123. Upon information and belief, Lupin has knowledge of the '697 patent and, by its proposed package insert for Lupin's generic products, knows or should know that it will induce

direct infringement of at least one claim of the '697 patent, either literally or under the doctrine of equivalents.

124. Upon information and belief, Lupin 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 Lupin's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '697 patent.

125. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT III

(INFRINGEMENT OF THE '952 PATENT)

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

129. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '952 patent.

130. Lupin's Notice Letter states that Lupin 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.

131. Upon information and belief, Lupin admits infringement of at least one claim of the '952 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '952 patent.

132. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

134. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '952 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '952 patent.

135. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

136. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '952 patent.

137. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '952 patent.

138. Upon information and belief, Lupin has knowledge of the '952 patent and, by its proposed package insert for Lupin'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.

139. Upon information and belief, Lupin 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 Lupin'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.

140. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT IV

(INFRINGEMENT OF THE '058 PATENT)

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

144. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '058 patent.

145. Lupin's Notice Letter states that Lupin 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.

146. Upon information and belief, Lupin admits infringement of at least one claim of the '058 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '058 patent.

147. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

149. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '058 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '058 patent.

150. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

151. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '058 patent and any additional periods of exclusivity.

152. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '058 patent.

153. Upon information and belief, Lupin has knowledge of the '058 patent and, by its proposed package insert for Lupin'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.

154. Upon information and belief, Lupin 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 Lupin'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.

155. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT V

(INFRINGEMENT OF THE '103 PATENT)

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

159. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '103 patent.

160. Lupin's Notice Letter states that Lupin 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.

161. Upon information and belief, Lupin admits infringement of at least one claim of the '103 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '103 patent.

162. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

164. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '103 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '103 patent.

165. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

166. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '103 patent and any additional periods of exclusivity.

167. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '103 patent.

168. Upon information and belief, Lupin has knowledge of the '103 patent and, by its proposed package insert for Lupin'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.

169. Upon information and belief, Lupin 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 Lupin'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.

170. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT VI

(INFRINGEMENT OF THE '104 PATENT)

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

174. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '104 patent.

175. Lupin's Notice Letter states that Lupin 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.

176. Upon information and belief, Lupin admits infringement of at least one claim of the '104 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '104 patent.

177. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

179. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '104 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '104 patent.

180. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

181. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '104 patent and any additional periods of exclusivity.

182. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '104 patent.

183. Upon information and belief, Lupin has knowledge of the '104 patent and, by its proposed package insert for Lupin'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.

184. Upon information and belief, Lupin 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 Lupin'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.

185. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT VII

(INFRINGEMENT OF THE '137 PATENT)

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

189. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '137 patent.

190. Lupin's Notice Letter states that Lupin 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.

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

192. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

194. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '137 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '137 patent.

195. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

196. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '137 patent and any additional periods of exclusivity.

197. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '137 patent.

198. Upon information and belief, Lupin has knowledge of the '137 patent and, by its proposed package insert for Lupin'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.

199. Upon information and belief, Lupin 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 Lupin'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.

200. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT VIII

(INFRINGEMENT OF THE '148 PATENT)

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

204. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '148 patent.

205. Lupin's Notice Letter states that Lupin 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.

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

207. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

209. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '148 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '148 patent.

210. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

211. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '148 patent and any additional periods of exclusivity.

212. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '148 patent.

213. Upon information and belief, Lupin has knowledge of the '148 patent and, by its proposed package insert for Lupin'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.

214. Upon information and belief, Lupin 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 Lupin'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.

215. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT IX

(INFRINGEMENT OF THE '648 PATENT)

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

219. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '648 patent.

220. Lupin's Notice Letter states that Lupin 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.

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

222. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

224. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '648 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '648 patent.

225. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

226. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '648 patent and any additional periods of exclusivity.

227. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '648 patent.

228. Upon information and belief, Lupin has knowledge of the '648 patent and, by its proposed package insert for Lupin'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.

229. Upon information and belief, Lupin 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 Lupin'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.

230. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT X

(INFRINGEMENT OF THE '902 PATENT)

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

234. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '902 patent.

235. Lupin's Notice Letter states that Lupin 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.

236. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

238. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '902 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '902 patent.

239. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

240. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '902 patent and any additional periods of exclusivity.

241. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT XI

(INFRINGEMENT OF THE '903 PATENT)

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

245. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '903 patent.

246. Lupin's Notice Letter states that Lupin 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.

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

248. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

250. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '903 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '903 patent.

251. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

252. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '903 patent and any additional periods of exclusivity.

253. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT XII

(INFRINGEMENT OF THE '771 PATENT)

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

257. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '771 patent.

258. Lupin's Notice Letter states that Lupin 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.

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

260. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

262. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '771 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '771 patent.

263. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

264. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '771 patent and any additional periods of exclusivity.

265. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '771 patent.

266. Upon information and belief, Lupin has knowledge of the '771 patent and, by its proposed package insert for Lupin'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.

267. Upon information and belief, Lupin 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 Lupin'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.

268. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT XIII

(INFRINGEMENT OF THE '892 PATENT)

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

272. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '892 patent.

273. Lupin's Notice Letter states that Lupin 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.

274. Upon information and belief, Lupin admits infringement of at least one claim of the '892 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '892 patent.

275. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

277. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '892 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '892 patent.

278. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

279. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '892 patent and any additional periods of exclusivity.

280. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT XIV

(INFRINGEMENT OF THE '141 PATENT)

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

284. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '141 patent.

285. Lupin's Notice Letter states that Lupin 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.

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

287. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

289. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '141 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '141 patent.

290. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

291. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '141 patent and any additional periods of exclusivity.

292. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '141 patent.

293. Upon information and belief, Lupin has knowledge of the '141 patent and, by its proposed package insert for Lupin'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.

294. Upon information and belief, Lupin 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 Lupin'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.

295. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT XV

(INFRINGEMENT OF THE '997 PATENT)

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

299. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '997 patent.

300. Lupin's Notice Letter states that Lupin 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.

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

302. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

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

304. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '997 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '997 patent.

305. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

306. Upon information and belief, if ANDA No. 216064 is approved, Lupin 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 Lupin'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. 216064 shall be no earlier than the expiration of the '997 patent and any additional periods of exclusivity.

307. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '997 patent.

308. Upon information and belief, Lupin has knowledge of the '997 patent and, by its proposed package insert for Lupin'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.

309. Upon information and belief, Lupin 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 Lupin'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.

310. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

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

COUNT XVI

(INFRINGEMENT OF THE '941 PATENT)

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

314. Upon information and belief, Lupin filed ANDA No. 216064 seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '941 patent.

315. Lupin's Notice Letter states that Lupin 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 '941 patent are invalid, unenforceable and/or will not be infringed.

316. Upon information and belief, Lupin admits infringement of at least one claim of the '941 patent because Lupin's Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '941 patent.

317. Upon information and belief, in its ANDA No. 216064, Lupin has represented to the FDA that Lupin's generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA[®] Capsules.

318. Lupin has actual knowledge of the '941 patent, as evidenced by Lupin's Notice Letter.

319. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed at least one claim of the '941 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell or sell Lupin's generic products before the expiration date of the '941 patent.

320. Upon information and belief, if ANDA No. 216064 is approved, Lupin intends to and will manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States.

321. Upon information and belief, if ANDA No. 216064 is approved, Lupin will infringe one or more claims of the '941 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Lupin'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. 216064 shall be no earlier than the expiration of the '941 patent.

322. Upon information and belief, Lupin knows, should know and intends that physicians will prescribe and patients will take Lupin's generic products for which approval is sought in ANDA No. 216064, and therefore will infringe at least one claim of the '941 patent.

323. Upon information and belief, Lupin has knowledge of the '941 patent and, by its proposed package insert for Lupin's generic products, knows or should know that it will induce direct infringement of at least one claim of the '941 patent, either literally or under the doctrine of equivalents.

324. Upon information and belief, Lupin 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 Lupin's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '941 patent.

325. Upon information and belief, Lupin's actions relating to Lupin's ANDA No. 216064 complained of herein were done by and for the benefit of Lupin.

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

327. 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 Lupin has infringed at least one claim of the '627 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '627 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin's generic products before the expiration of the '627 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '627 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 Lupin's generic products shall be no earlier than the expiration date of the '627 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 Lupin and all persons acting in concert with Lupin from manufacturing, using, offering for sale or selling Lupin's generic products within the United States, or importing Lupin's generic products into the United States, until the expiration of the '627 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 Lupin and all persons acting in concert with Lupin from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '627 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 Lupin has infringed at least one claim of the '697 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '697 patent;

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

'697 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '697 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 Lupin's generic products shall be no earlier than the expiration date of the '697 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 Lupin and all persons acting in concert with Lupin from manufacturing, using, offering for sale or selling Lupin's generic products within the United States, or importing Lupin's generic products into the United States, until the expiration of the '697 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 Lupin and all persons acting in concert with Lupin from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '697 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 Lupin has infringed at least one claim of the '952 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '952 patent;

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

M. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

O. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

P. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '058 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '058 patent;

Q. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

R. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

T. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

U. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '103 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '103 patent;

V. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

W. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

Y. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

Z. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '104 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '104 patent;

AA. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

BB. The issuance of an order that the effective date of any FDA approval of Lupin'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);

CC. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from manufacturing, using, offering for sale or selling

Lupin's generic products within the United States, or importing Lupin'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;

DD. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

EE. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '137 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '137 patent;

FF. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

GG. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

II. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

JJ. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '148 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '148 patent;

KK. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

LL. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

NN. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

OO. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '648 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '648 patent;

PP. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

QQ. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

SS. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

TT. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '902 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '902 patent;

UU. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

VV. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

XX. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

YY. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '903 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '903 patent;

ZZ. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

AAA. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

CCC. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

DDD. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '771 patent through Lupin's submission of ANDA No. 216064 to the FDA

seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '771 patent;

EEE. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

FFF. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

HHH. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

III. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '892 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '892 patent;

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

KKK. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

MMM. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

NNN. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '141 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '141 patent;

OOO. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

PPP. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

RRR. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

SSS. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '997 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '997 patent;

TTT. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin'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);

UUU. The issuance of an order that the effective date of any FDA approval of Lupin'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);

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

WWW. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin 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;

XXX. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Lupin has infringed at least one claim of the '941 patent through Lupin's submission of ANDA No. 216064 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Lupin's generic products in the United States before the expiration of the '941 patent;

YYY. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Lupin's making, using, offering to sell, selling or importing of Lupin's generic products before the expiration of the '941 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '941 patent under 35 U.S.C. § 271(a), (b) and/or (c);

ZZZ. The issuance of an order that the effective date of any FDA approval of Lupin's generic products shall be no earlier than the expiration date of the '941 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);

AAAA. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from manufacturing, using, offering for sale or selling Lupin's generic products within the United States, or importing Lupin's generic products into the United States, until the expiration of the '941 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

BBBB. The entry of a preliminary and/or permanent injunction, enjoining Lupin and all persons acting in concert with Lupin from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '941 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

CCCC. 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);

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

EEEE. 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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