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

NEUROCRINE BIOSCIENCES, INC. Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC., ZYDUS WORLDWIDE DMCC, ZYDUS HEALTHCARE (USA) LLC and CADILA HEALTHCARE LIMITED Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Neurocrine Biosciences, Inc. ("Neurocrine"), by way of Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus Pharmaceuticals"), Zydus Worldwide DMCC ("Zydus Worldwide"), Zydus Healthcare (USA) LLC ("Zydus Healthcare") and Cadila Healthcare Limited d/b/a Zydus Cadila ("Zydus Cadila") (collectively "Zydus" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,993,941 ("the '941 patent"), 11,026,931 ("the '931 patent"), 11,026,939 ("the '939 patent") and 11,040,029 ("the '029 patent") (collectively "the 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 Zydus' filing of an Abbreviated New Drug Application ("ANDA") No. 216137 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and/or sell Valbenazine Capsules, 40 mg and 80 mg ("Zydus' generic products") before the expiration of the patents-in-suit.

2. Neurocrine filed separate actions involving the same ANDA No. 216137 in this Court and the District of Delaware for patent infringement of U.S. Patent Nos. 10,065,952 ("the '952 patent"), 10,844,058 ("the '058 patent"), 10,851,103 ("the '103 patent"), 10,851,104 ("the '104 patent"), 10,857,137 ("the '137 patent"), 10,857,148 ("the '148 patent"), 10,874,648 ("the '648 patent"), 10,906,902 ("the '902 patent"), 10,906,903 ("the '903 patent"), 10,912,771 ("the '771 patent"), 10,919,892 ("the '892 patent"), 10,940,141 ("the '141 patent") and 10,952,997 ("the '997 patent") (collectively "First Suit Patents") in *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, No. 2:21-cv-14447-KM-JSA (D.N.J. filed July 30, 2021) and *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:21-cv-01118-MN (D. Del. filed July 30, 2021) (collectively "the First Suits").

3. The First Suits were filed in response to a letter from Zydus dated June 15, 2021 ("Zydus' First Notice Letter"), purporting to include an exhibit titled "Zydus's Detailed Factual and Legal Bases in Support of its Paragraph IV Certification for Valbenazine Capsules, 40 mg and 80 mg." Zydus' First Notice Letter stated that Zydus had filed ANDA No. 216137, seeking

approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products before the expiration of the First Suit Patents. The First Suits included counts of infringement of the First Suit Patents.

4. This complaint is filed in response to a new, second letter from Zydus dated September 16, 2021 ("Zydus' Second Notice Letter"), purporting to include an exhibit titled "Zydus's Detailed Factual and Legal Bases in Support of its Paragraph IV Certification for Valbenazine Capsules, 40 mg and 80 mg." Zydus' Second Notice Letter stated that Zydus had filed ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products before the expiration of the patents-in-suit.

THE PARTIES

5. 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.

6. 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.

7. Upon information and belief, Zydus Pharmaceuticals is a corporation organized under the laws of New Jersey and its principal place of business is located at 73 Route 31 N., Pennington, New Jersey 08534.

8. Upon information and belief, Zydus Worldwide is a corporation organized under the laws of the United Arab Emirates and its principal place of business is located at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

9. Upon information and belief, Zydus Healthcare is a company organized under the laws of the state of Delaware and its principal place of business is located at 73 Route 31 N., Pennington, NJ, 08534-3601.

10. Upon information and belief, Zydus Cadila is a corporation organized under the laws of the Republic of India and its principal place of business is located at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gandhinagar GJ 382481 IN.

11. Upon information and belief, Zydus Pharmaceuticals is a subsidiary of Zydus Cadila.

12. Upon information and belief, Zydus Worldwide is a subsidiary of Zydus Cadila.

13. Upon information and belief, Zydus Healthcare is a subsidiary of Zydus Cadila.

JURISDICTION AND VENUE

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

15. Plaintiff believes this case belongs in Delaware but is concurrently filing a case in this district out of an abundance of caution.

16. This Court has personal jurisdiction over Zydus Pharmaceuticals because, upon information and belief, Zydus Pharmaceuticals directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

17. This Court has personal jurisdiction over Zydus Worldwide because, upon information and belief, Zydus Worldwide directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

18. Upon information and belief, Zydus Worldwide is the holder of ANDA No. 216137.

19. This Court has personal jurisdiction over Zydus Healthcare because, upon information and belief, Zydus Healthcare directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

20. This Court has personal jurisdiction over Zydus Cadila because, upon information and belief, Zydus Cadila directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

21. Upon information and belief, Zydus Pharmaceuticals, Zydus Worldwide, Zydus Healthcare and Zydus Cadila 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.

22. Upon information and belief, Zydus Pharmaceuticals, Zydus Worldwide, Zydus Healthcare and Zydus Cadila have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 216137.

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

24. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Worldwide is incorporated in the United Arab Emirates and may be sued in any judicial district in the United States.

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Pharmaceuticals is incorporated in the state of New Jersey.

26. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because, upon information and belief, Zydus Healthcare's principal place of business is located in New Jersey.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Cadila is incorporated in the Republic of India and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

The NDA

28. 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").

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

30. 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.

31. Valbenazine Capsules are marketed in the United States under the trademark INGREZZA®.

The Patents-in-Suit

32. The United States Patent and Trademark Office ("the PTO") issued the '941 patent on May 4, 2021, titled "Methods for the Administration of Certain VMAT2 Inhibitors." A true and correct copy of the '941 patent is attached as Exhibit A.

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

34. The ’941 patent currently expires on October 10, 2037.

35. The ’941 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 209241 for INGREZZA® Capsules.

36. The PTO issued the ’931 patent on June 8, 2021, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’931 patent is attached as Exhibit B.

37. Neurocrine owns the ’931 patent through assignment as recorded by the PTO at Reel 055564, Frame 0388.

38. The ’931 patent currently expires on August 14, 2039.

39. The ’931 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

40. The PTO issued the ’939 patent on June 8, 2021, titled “High Dosage Valbenazine Formulation and Compositions, Methods, and Kits Related Thereto.” A true and correct copy of the ’939 patent is attached as Exhibit C.

41. Neurocrine owns the ’939 patent through assignment as recorded by the PTO at Reel 054171, Frame 0426.

42. The ’939 patent currently expires on September 18, 2038.

43. The ’939 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

44. The PTO issued the ’029 patent on June 22, 2021, titled “Methods for the Administration of Certain VMAT2 Inhibitors.” A true and correct copy of the ’029 patent is attached as Exhibit D.

45. Neurocrine owns the '029 patent through assignment as recorded by the PTO at Reel 052974, Frame 0736.

46. The '029 patent currently expires on October 10, 2037.

47. The '029 patent is listed in the Orange Book in connection with NDA No. 209241 for INGREZZA® Capsules.

The ANDA

48. Upon information and belief, Zydus submitted ANDA No. 216137 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, import, offer to sell and/or sell in the United States Valbenazine Capsules, 40 mg and 80 mg (defined above as "Zydus' generic products"), which are generic versions of Neurocrine's INGREZZA® Capsules.

49. Zydus' Second Notice Letter states that ANDA No. 216137 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 and/or will not be infringed by the manufacture, use, import, offer to sell and/or sale of Zydus' generic products.

50. Plaintiff commenced this action within 45 days of receiving Zydus' Second Notice Letter.

COUNT I

(INFRINGEMENT OF THE '941 PATENT)

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

52. Upon information and belief, Zydus filed ANDA No. 216137 seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '941 patent.

53. Zydus' Second Notice Letter states that Zydus 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.

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

55. Upon information and belief, in its ANDA No. 216137, Zydus has represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

56. Zydus has actual knowledge of the '941 patent, as evidenced by Zydus' Second Notice Letter.

57. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '941 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell or sell Zydus' generic products before the expiration date of the '941 patent.

58. Upon information and belief, if ANDA No. 216137 is approved, Zydus intends to and will manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States.

59. Upon information and belief, if ANDA No. 216137 is approved, Zydus 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 Zydus' 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. 216137 shall be no earlier than the expiration of the '941 patent and any additional periods of exclusivity.

60. Upon information and belief, Zydus knows, should know and intends that physicians will prescribe and patients will take Zydus' generic products for which approval is sought in ANDA No. 216137, and therefore will infringe at least one claim of the '941 patent.

61. Upon information and belief, Zydus has knowledge of the '941 patent and, by its proposed package insert for Zydus' 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.

62. Upon information and belief, Zydus 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 Zydus' 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.

63. Upon information and belief, Zydus' actions relating to Zydus' ANDA No. 216137 complained of herein were done by and for the benefit of Zydus.

64. Plaintiff will be irreparably harmed by Zydus' infringing activities unless this Court enjoins those activities.

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

COUNT II

(INFRINGEMENT OF THE '931 PATENT)

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

67. Upon information and belief, Zydus filed ANDA No. 216137 seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '931 patent.

68. Zydus' Second Notice Letter states that Zydus 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 '931 patent are invalid, unenforceable and/or will not be infringed.

69. Upon information and belief, in its ANDA No. 216137, Zydus has represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

70. Zydus has actual knowledge of the '931 patent, as evidenced by Zydus' Second Notice Letter.

71. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '931 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell or sell Zydus' generic products before the expiration date of the '931 patent.

72. Upon information and belief, if ANDA No. 216137 is approved, Zydus intends to and will manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States.

73. Upon information and belief, if ANDA No. 216137 is approved, Zydus will infringe one or more claims of the '931 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Zydus' 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. 216137 shall be no earlier than the expiration of the '931 patent and any additional periods of exclusivity.

74. Upon information and belief, Zydus knows, should know and intends that physicians will prescribe and patients will take Zydus' generic products for which approval is sought in ANDA No. 216137, and therefore will infringe at least one claim of the '931 patent.

75. Upon information and belief, Zydus has knowledge of the '931 patent and, by its proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one claim of the '931 patent, either literally or under the doctrine of equivalents.

76. Upon information and belief, Zydus 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 Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '931 patent.

77. Upon information and belief, Zydus' actions relating to Zydus' ANDA No. 216137 complained of herein were done by and for the benefit of Zydus.

78. Plaintiff will be irreparably harmed by Zydus' infringing activities unless this Court enjoins those activities.

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

COUNT III

(INFRINGEMENT OF THE '939 PATENT)

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

81. Upon information and belief, Zydus filed ANDA No. 216137 seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '939 patent.

82. Zydus' Second Notice Letter states that Zydus 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 '939 patent are invalid, unenforceable and/or will not be infringed.

83. Upon information and belief, in its ANDA No. 216137, Zydus has represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

84. Zydus has actual knowledge of the '939 patent, as evidenced by Zydus' Second Notice Letter.

85. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '939 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell or sell Zydus' generic products before the expiration date of the '939 patent.

86. Upon information and belief, if ANDA No. 216137 is approved, Zydus intends to and will manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States.

87. Upon information and belief, if ANDA No. 216137 is approved, Zydus will infringe one or more claims of the '939 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Zydus' 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. 216137 shall be no earlier than the expiration of the '939 patent and any additional periods of exclusivity.

88. Upon information and belief, Zydus knows, should know and intends that physicians will prescribe and patients will take Zydus' generic products for which approval is sought in ANDA No. 216137, and therefore will infringe at least one claim of the '939 patent.

89. Upon information and belief, Zydus has knowledge of the '939 patent and, by its proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one claim of the '939 patent, either literally or under the doctrine of equivalents.

90. Upon information and belief, Zydus 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 Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '939 patent.

91. Upon information and belief, Zydus' actions relating to Zydus' ANDA No. 216137 complained of herein were done by and for the benefit of Zydus.

92. Plaintiff will be irreparably harmed by Zydus' infringing activities unless this Court enjoins those activities.

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

COUNT IV

(INFRINGEMENT OF THE '029 PATENT)

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

95. Upon information and belief, Zydus filed ANDA No. 216137 seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '029 patent.

96. Zydus' Second Notice Letter states that Zydus 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 '029 patent are invalid, unenforceable and/or will not be infringed.

97. Upon information and belief, Zydus admits infringement of at least one claim of the '029 patent because Zydus' Second Notice Letter did not provide any non-infringement allegation with respect to at least one claim of the '029 patent.

98. Upon information and belief, in its ANDA No. 216137, Zydus has represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to Neurocrine's INGREZZA® Capsules.

99. Zydus has actual knowledge of the '029 patent, as evidenced by Zydus' Second Notice Letter.

100. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '029 patent by submitting, or causing to be submitted, to the FDA ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell or sell Zydus' generic products before the expiration date of the '029 patent.

101. Upon information and belief, if ANDA No. 216137 is approved, Zydus intends to and will manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States.

102. Upon information and belief, if ANDA No. 216137 is approved, Zydus will infringe one or more claims of the '029 patent under § 271(a), either literally or under the doctrine of

equivalents, by making, using, offering to sell, selling and/or importing Zydus' 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. 216137 shall be no earlier than the expiration of the '029 patent and any additional periods of exclusivity.

103. Upon information and belief, Zydus knows, should know and intends that physicians will prescribe and patients will take Zydus' generic products for which approval is sought in ANDA No. 216137, and therefore will infringe at least one claim of the '029 patent.

104. Upon information and belief, Zydus has knowledge of the '029 patent and, by its proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one claim of the '029 patent, either literally or under the doctrine of equivalents.

105. Upon information and belief, Zydus 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 Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '029 patent.

106. Upon information and belief, Zydus' actions relating to Zydus' ANDA No. 216137 complained of herein were done by and for the benefit of Zydus.

107. Plaintiff will be irreparably harmed by Zydus' infringing activities unless this Court enjoins those activities.

108. 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 Zydus has infringed at least one claim of the '941 patent through Zydus' submission of ANDA No. 216137 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '941 patent;

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

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

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

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

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Zydus has infringed at least one claim of the '931 patent through Zydus' submission of ANDA No. 216137 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '931 patent;

G. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Zydus' making, using, offering to sell, selling or importing of Zydus' generic products before the expiration of the '931 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '931 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 Zydus' generic products shall be no earlier than the expiration date of the '931 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 Zydus and all persons acting in concert with Zydus from manufacturing, using, offering for sale or selling Zydus' generic products within the United States, or importing Zydus' generic products into the United States, until the expiration of the '931 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 Zydus and all persons acting in concert with Zydus from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '931 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 Zydus has infringed at least one claim of the '939 patent through Zydus' submission of ANDA No. 216137 to the FDA

seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '939 patent;

L. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Zydus' making, using, offering to sell, selling or importing of Zydus' generic products before the expiration of the '939 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '939 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 Zydus' generic products shall be no earlier than the expiration date of the '939 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 Zydus and all persons acting in concert with Zydus from manufacturing, using, offering for sale or selling Zydus' generic products within the United States, or importing Zydus' generic products into the United States, until the expiration of the '939 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 Zydus and all persons acting in concert with Zydus from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '939 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 Zydus has infringed at least one claim of the '029 patent through Zydus' submission of ANDA No. 216137 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Zydus' generic products in the United States before the expiration of the '029 patent;

Q. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Zydus' making, using, offering to sell, selling or importing of Zydus' generic products before the expiration of the '029 patent will infringe, actively induce infringement and/or contribute to the infringement of at least one claim of the '029 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 Zydus' generic products shall be no earlier than the expiration date of the '029 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 Zydus and all persons acting in concert with Zydus from manufacturing, using, offering for sale or selling Zydus' generic products within the United States, or importing Zydus' generic products into the United States, until the expiration of the '029 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 Zydus and all persons acting in concert with Zydus from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '029 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

U. 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);

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

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

Respectfully submitted,

/s/ Guillermo Artiles

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