IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC. Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC., ZYDUS WORLDWIDE DMCC, ZYDUS HEALTHCARE (USA) LLC and ZYDUS LIFESCIENCES LIMITED (f/k/a 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 Zydus Lifesciences Limited f/k/a Cadila Healthcare Limited (d/b/a Zydus Cadila) ("Zydus Lifesciences") (collectively "Zydus" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 8,039,627 ("the '627 patent") and 8,357,697 ("the '697 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, 60 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 New Jersey 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.*, C.A. No. 1:21-cv-01118-MN (D. Del. filed July 30, 2021) ("the First Delaware Suit"), which on April 19, 2022 was consolidated in this Court in *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 1:21-cv-01042-MN (consolidated), and *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 2:21-cv-14447-KM-JSA (D.N.J. filed July 30, 2021) ("the First New Jersey Suit") (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 Valbenazine Capsules, 40 mg and 80 mg before the expiration of the First Suit Patents. The First Suits included counts of infringement of the First Suit Patents.

4. The First New Jersey Suit was dismissed in favor of continued prosecution of the First Delaware Suit after Zydus Pharmaceuticals, Zydus Worldwide and Cadila Healthcare

Limited answered that they would not contest subject matter jurisdiction, venue, or personal jurisdiction in Delaware for the alleged claims related to Zydus' ANDA No. 216137 (*see* Notice of Voluntary Dismissal ordered in the First New Jersey Suit on March 22, 2022; *see also* Answer in the First Delaware Suit at ¶¶ 12-13, 15-16, 27, 30-31, and 33 (filed February 8, 2022)).

5. Neurocrine also filed separate actions involving the same ANDA No. 216137 in this Court and the District of New Jersey 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 "Second Suit Patents") in *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 1:21-cv-01553-MN (D. Del. filed October 29, 2021) ("the Second Delaware Suit"), which on April 19, 2022 was consolidated in this Court in *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 1:21-cv-01042-MN (consolidated), and *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:21-cv-19466-KM-JSA (D.N.J. filed October 29, 2021) ("the Second New Jersey Suit") (collectively "the Second Suits").

6. The Second Suits were filed in response to a 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 Valbenazine Capsules, 40 mg and 80 mg before the expiration of the Second Suit Patents. The Second Suits included counts of infringement of the Second Suit Patents.

7. The Second New Jersey Suit was dismissed in favor of continued prosecution of the Second Delaware Suit after Zydus Pharmaceuticals, Zydus Worldwide and Zydus Lifesciences

f/k/a Cadila Healthcare Limited answered that they would not contest subject matter jurisdiction, venue, or personal jurisdiction in Delaware for the alleged claims related to Zydus' ANDA No. 216137 (*see* Notice of Voluntary Dismissal ordered in the Second New Jersey Suit on March 22, 2022; *see also* Answer in the Second Delaware Suit at ¶¶ 15-16, 18-19, 22, 30, 33-34, and 36 (filed March 18, 2022)).

8. Neurocrine further filed separate actions involving the same ANDA No. 216137 in this Court and the District of New Jersey for patent infringement of the '952 patent, the '058 patent, the '103 patent, the '104 patent, the '137 patent, the '148 patent, the '648 patent, the '902 patent, the '903 patent, the '771 patent, the '892 patent, the '141 patent, the '997 patent, the '941 patent, the '931 patent, the '939 patent and the '029 patent (collectively "Third Suit Patents"), in *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 1:22-cv-00439-MN (D. Del. filed April 1, 2022) ("the Third Delaware Suit"), which on November 18, 2022 was consolidated in this Court in *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 1:21-cv-01042-MN (consolidated), and *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 1:22-cv-01882-CPO-EAP (D.N.J. filed April 1, 2022) ("the Third New Jersey Suit") (collectively "the Third Suits").

9. The Third Suits were filed in response to a letter from Zydus dated February 18, 2022 ("Zydus' Third 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, 60 mg." Zydus' Third Notice Letter stated that Zydus had filed ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell and/or sell Valbenazine Capsules, 60 mg before the expiration of the Third Suit Patents. The Third Suit included counts of infringement of the Third Suit Patents.

10. The Third New Jersey Suit was dismissed in favor of continued prosecution of the Third Delaware Suit after Zydus Pharmaceuticals, Zydus Worldwide and Zydus Lifesciences f/k/a Cadila Healthcare Limited answered that they would not contest subject matter jurisdiction, venue, or personal jurisdiction in Delaware for the alleged claims related to Zydus' ANDA No. 216137 (*see* Notice of Voluntary Dismissal ordered in the Third New Jersey Suit on August 8, 2022; *see also* Answer in the Third Delaware Suit at ¶¶ 20-21, 23-24, 27, 35, 38-39, and 41 (filed August 1, 2022)).

11. Neurocrine further filed separate actions involving the same ANDA No. 216137 in this Court and the District of New Jersey for patent infringement of the U.S. Patent No. 11,311,532 (the '532 patent or "the Fourth Suit Patent), in *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 1:22-cv-01291-MN (D. Del. filed September 30, 2022) ("the Fourth Delaware Suit"), which on November 18, 2022 was consolidated in this Court in *Neurocrine Biosciences, Inc. v. Lupin Limited et al.*, No. 1:21-cv-01042-MN (consolidated), and *Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 3:22-cv-05830-CPO-EAP (D.N.J. filed September 30, 2022) ("the Fourth New Jersey Suit") (collectively "the Fourth Suits").

12. The Fourth Suits were filed in response to a letter from Zydus dated August 17, 2022 ("Zydus' Fourth 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, 60 mg, and 80 mg." Zydus' Fourth Notice Letter stated that Zydus had filed ANDA No. 216137, seeking approval to manufacture, use, import, offer to sell and/or sell Valbenazine Capsules, 40 mg, 60 mg, and 80 mg before the expiration of the Fourth Suit Patent. The Fourth Suit included counts of infringement of the Fourth Suit Patent.

13. The Fourth New Jersey Suit was dismissed in favor of continued prosecution of the Fourth Delaware Suit after Zydus Pharmaceuticals, Zydus Worldwide and Zydus Lifesciences f/k/a Cadila Healthcare Limited answered that they would not contest subject matter jurisdiction, venue, or personal jurisdiction in Delaware for the alleged claims related to Zydus' ANDA No. 216137 (*see* Notice of Voluntary Dismissal ordered in the Fourth New Jersey Suit on December 20, 2022; *see also* Answer in the Fourth Delaware Suit at ¶¶ 23-24, 26-28, 30, 38, 41-42 and 44 (filed December 6, 2022 in C.A. No. 1:21-cv-01042-MN (consolidated)).

14. This complaint is filed in response to a new, fifth letter from Zydus dated January 25, 2023 ("Zydus' Fifth 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, 60 mg, and 80 mg." Zydus' Fifth 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

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. Upon information and belief, Zydus Lifesciences 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.

21. Upon information and belief, Zydus Lifesciences Limited was formerly known as Cadila Healthcare Limited. *See Neurocrine Biosciences, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:21-cv-01553-MN, D.I. Nos. 17-20 (D. Del. filed March 18, 2022) (Answer and Corporate Disclosure Statements filed by Zydus Pharmaceuticals, Zydus Worldwide, and Cadila Healthcare Limited stating that Zydus Lifesciences Limited was formerly known as Cadila Healthcare Limited). When the First Suits and Second Suits were filed, First Suit and Second Suit Defendant Cadila Healthcare Limited was the company name associated with CIN L24230GJ1995PLC025878 and Registration Number 025878. As of the date of this filing, Zydus Lifesciences Limited is the company name associated with CIN L24230GJ1995PLC025878 and Registration Number 025878, and Zydus has identified this name change publicly. *See* https://www.zyduslife.com/zyduslife/ (accessed March 10, 2023) ("Cadila Healthcare Ltd., is renamed as Zydus Lifesciences Ltd.").

22. Upon information and belief, Zydus Pharmaceuticals is a subsidiary of Zydus Lifesciences.

23. Upon information and belief, Zydus Worldwide is a subsidiary of Zydus Lifesciences.

24. Upon information and belief, Zydus Healthcare is a subsidiary of Zydus Lifesciences.

25. Upon information and belief, Zydus Pharmaceuticals, Zydus Worldwide and Zydus Healthcare are generic pharmaceutical companies that, in coordination with each other and Zydus Lifesciences or at the direction of Zydus Lifesciences, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

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

27. Upon information and belief, venue and jurisdiction are proper for this proceeding.

28. Plaintiff believes this case belongs in Delaware but is concurrently filing a case in New Jersey out of an abundance of caution.

29. This Court has personal jurisdiction over Zydus Pharmaceuticals. Upon information and belief, Zydus Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. 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. Upon information and belief, Zydus Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zydus' generic products.

30. This Court has personal jurisdiction over Zydus Worldwide. Upon information and belief, Zydus Worldwide is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. 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. Upon information and belief, Zydus Worldwide purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zydus' generic products.

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

32. This Court has personal jurisdiction over Zydus Healthcare. Upon information and belief, Zydus Healthcare is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. 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. Upon information and belief, Zydus Healthcare purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zydus' generic products.

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

34. Upon information and belief, Zydus Pharmaceuticals is a United States agent for Zydus Lifesciences. Upon information and belief, Zydus Pharmaceuticals admits that "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Lifesciences[, which is] a global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States." https://zydususa.com/ (last accessed March 10, 2023).

35. Upon information and belief, Zydus Healthcare is a United States agent for Zydus Lifesciences. Upon information and belief, Zydus Healthcare "procures products from third parties and sells goods and services to Zydus Cadila [i.e., Zydus Lifesciences]." https://www.zyduslife.com/public/pdf/financial/subsidaries(2018-2019)/Zydus%20Healthcare%20(USA)%20LLC_Dec'18.pdf (accessed March 10, 2023). Upon information and belief, Zydus Healthcare "also provides services to . . . Zydus Worldwide." *Id*. Upon information and belief, Zydus Lifesciences avails itself of the services of Zydus Healthcare "for getting its various products registered in USA for the purpose of marketing its generic products in USA. [Zydus Lifesciences] is mandatorily required to get approval of US Food & Drug Authority (FDA) for each and every product to be marketed in USA and for that purpose it has to carry out various administrative and legal formalities through its associate enterprise [Zydus Healthcare] in USA." Income Tax Appellate Tribunal - Ahmedabad Order, dated June 6, 2018, https://indiankanoon.org/doc/36216909/ (accessed March 10, 2023).

36. Upon information and belief, Zydus Pharmaceuticals, Zydus Worldwide, Zydus Healthcare and Zydus Lifesciences 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.

37. Upon information and belief, Zydus Pharmaceuticals "is ranked the fifth largest unbranded generic corporation in the US based on dispensed prescriptions," "remains diligent in ensuring a quality and affordable supply of our products in the US," and "look[s] for new ways to bring value to the US market" as it "focus[es] on expanding [its] portfolio of complex generics, including modified release solid orals, transdermals, injectables, and oral suspensions." https://zydususa.com/overview/ (accessed March 10, 2023). Upon information and belief, Zydus Pharmaceuticals admits that "Zydus's generic products can be found across the country in most pharmacies, both in store as well as mail order." https://zydususa.com/faq/ (accessed March 10, 2023).

38. Upon information and belief, Zydus Pharmaceuticals admits that it "manufactures its products in state-of-the-art facilities in . . . the US." https://zydususa.com/our-facilities/ (accessed March 10, 2023).

39. Upon information and belief, Zydus Pharmaceuticals is engaged in the submission and approval of ANDAs for the U.S. market, admitting "Zydus Pharmaceuticals has filed over 129 drug master files (DMFs), received final USFDA approval on 302 [ANDAs] and has over 110 ANDAs pending approval with the USFDA." https://zydususa.com/overview/ (accessed March 10, 2023). Upon information and belief, Zydus "also has approximately 300 additional products in various stages of development." *Id.*

40. Upon information and belief, Zydus Lifesciences "has manufacturing sites and research facilities . . . in the US" and "has a strong presence in the regulated markets of the US." https://www.zyduslife.com/index (accessed March 10, 2023). Upon information and belief, Zydus

Lifesciences describes itself "[a]s one of the key players amongst the pharmaceutical manufacturing companies." *Id.*

41. Zydus' ANDA filing regarding the patent-in-suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Zydus' intent to market and sell Zydus' generic products in this judicial district.

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

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

44. 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.

45. 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.

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

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

FACTUAL BACKGROUND

The NDA

48. 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").

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

50. 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.

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

The Patents-in-Suit

52. 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.

53. Neurocrine owns the '627 patent through assignment.

54. 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 Certificate Extending Patent Term Under 35 U.S.C. 156, which is attached as Exhibit B. In Exhibit B, the PTO certified

that the term of the '627 patent is extended by 552 days. Accordingly, the '627 patent will expire on April 11, 2031.

55. 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.

56. 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.

57. Neurocrine owns the '697 patent through assignment.

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

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

The ANDA

60. 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, 60 mg and 80 mg (defined above as "Zydus' generic products"), which are generic versions of Neurocrine's INGREZZA® Capsules.

61. Zydus' Fifth 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.

62. Plaintiff commenced this action within 45 days of receiving Zydus' Fifth Notice Letter.

COUNT I

(INFRINGEMENT OF THE '627 PATENT)

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

64. 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 '627 patent.

65. The Fifth 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 '627 patent are invalid, unenforceable and/or will not be infringed.

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

67. 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.

68. Zydus has actual knowledge of the '627 patent, as evidenced by at least Zydus' Fifth Notice Letter.

69. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '627 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 '627 patent.

70. 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.

71. Upon information and belief, if ANDA No. 216137 is approved, Zydus 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 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 '627 patent.

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

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

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

COUNT II

(INFRINGEMENT OF THE '697 PATENT)

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

76. 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 '697 patent.

77. The Fifth 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 '697 patent are invalid, unenforceable and/or will not be infringed.

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

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

80. Zydus has actual knowledge of the '697 patent, as evidenced by at least Zydus' Fifth Notice Letter.

81. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed at least one claim of the '697 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 '697 patent.

82. 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.

83. Upon information and belief, if ANDA No. 216137 is approved, Zydus 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 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 '697 patent.

84. 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 '697 patent.

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

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

86. 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 '697 patent.

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

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

89. 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 '627 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 '627 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 '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 Zydus' 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 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 '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 Zydus and all persons acting in concert with Zydus 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 Zydus has infringed at least one claim of the '697 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 '697 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 '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 Zydus' 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 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 '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 Zydus and all persons acting in concert with Zydus 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 issuance of a declaration that this is an exceptional case and an award to Plaintiff of its costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

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

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

ASHBY & GEDDES

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