IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEUROCRINE BIOSCIENCES, INC. Plaintiff, v. TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS DEVELOPMENT, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD. Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

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

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 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 Teva's filing of an Abbreviated New Drug Application ("ANDA") No. 215984 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell and/or sell Valbenazine Capsules, 40 mg and 80 mg ("Teva's generic products") before the expiration of the patents-in-suit.

2. Neurocrine filed two separate actions involving the same ANDA No. 215984 in this Court for patent infringement. The first suit alleged 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. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01043-MN (D. Del. filed July 16, 2021) ("the First Suit"). The second suit alleged infringement of U.S. Patent No. 10,993,941 ("the '941 patent" or "Second Suit Patent") in *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01148-MN (D. Del. filed August 6, 2021) ("the Second Suit").

3. The First Suit was filed in response to a letter from Teva dated June 3, 2021 ("Teva's First Notice Letter"), purporting to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the First Suit Patents]." The First Suit included counts of infringement of the First Suit Patents. Teva's First Notice Letter defined Teva as Teva Development.

4. The Second Suit was filed in response to a second letter from Teva dated June 24, 2021 ("Teva's Second Notice Letter"), purporting to include a "Notice of ANDA No. 215984 Valbenazine Capsules, 40 mg and 80 mg; With Paragraph IV Certification Concerning [the Second Suit Patent]." The Second Suit included a count of infringement of the Second Suit Patent. Teva's Second Notice Letter defined Teva as Teva Development.

5. This complaint is filed in response to a new, third letter from Teva dated December 9, 2021 ("Teva's Third Notice Letter"), purporting to include a "Notice of ANDA No. 215984

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

THE PARTIES

6. 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.

7. 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.

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

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

10. In its January 5, 2022 answers in the First Suit and the Second Suit, Teva stated that "Teva Development was incorporated on October 23, 2020 and became Teva Inc. through a name change on June 23, 2021." Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Complaint at 4, *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01148-MN (D. Del. 2021), D.I. 13; Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc.'s Answer, Affirmative

Defenses, and Counterclaims to Complaint at 4, *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc. et al.*, No. 1:21-cv-01043-MN (D. Del. 2021), D.I. 12. In Teva's Third Notice Letter, however, Teva once again identifies Teva Development as the entity providing notice and further states that FDA has assigned "Teva's ANDA," where "Teva" is defined as "Teva Development," to be ANDA No. 215984.

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

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

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

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

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

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

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

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

JURISDICTION AND VENUE

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

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

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

22. This Court has personal jurisdiction over Teva USA. Upon information and belief, Teva USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva USA directly,

or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva's generic products.

23. Upon information and belief, Teva USA states that it "is the leading generic drug company in the United States." https://www.tevausa.com/about-teva/ (accessed January 19, 2022).

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

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

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

27. Upon information and belief, Teva admits that "1 of every 9 prescriptions in the US" is filled with a Teva product. https://www.tevapharm.com/teva-worldwide/ (accessed January 19, 2022). Upon information and belief, Teva has at least 30 locations across the U.S. and its territories. https://businessfacilities.com/2018/07/teva-pharmaceuticals-moving-u-s-

headquarters-parsippany-troy-hills-new-jersey/ (accessed January 19, 2022). Upon information and belief, Teva admits it has at least 100 pending first-to-file ANDAs in the U.S. and at least 270 product registrations pending FDA approval. https://www.tevapharm.com/globalassets/scs-files---global/teva-infographic-files/teva_infographic_english_may2020.pdf (accessed January 19, 2022).

28. Upon information and belief, Teva is engaged in the submission and approval of ANDAs for the U.S. market, admitting Teva has "over 100 pending first-to-files in the U.S." *See, e.g.*, https://www.tevausa.com/news-and-media/press-releases/teva-wins-generic-uceris-patent-trial/ (accessed January 19, 2022).

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

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

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

32. For these reasons and for other reasons that will be presented to the Court if

jurisdiction is challenged, the Court has personal jurisdiction over Teva.

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

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

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

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

FACTUAL BACKGROUND

The NDA

37. 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").

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

39. 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.

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

The Patents-in-Suit

41. The United States Patent and Trademark Office ("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 A.

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

43. The '931 patent currently expires on August 14, 2039.

44. The '931 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 209241 for INGREZZA® Capsules.

45. 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 B.

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

47. The '939 patent currently expires on September 18, 2038.

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

49. 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 C.

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

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

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

The ANDA

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

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

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

COUNT I

(INFRINGEMENT OF THE '931 PATENT)

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

57. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '931 patent.

58. Teva's Third Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '931 patent are invalid, unenforceable and/or will not be infringed.

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

60. Teva has actual knowledge of the ’931 patent, as evidenced by Teva’s Third Notice Letter.

61. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the ’931 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva’s generic products before the expiration date of the ’931 patent.

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

63. Upon information and belief, if ANDA No. 215984 is approved, Teva 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 Teva’s generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the ’931 patent and any additional periods of exclusivity.

64. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva’s generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the ’931 patent.

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

66. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '931 patent.

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

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

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

COUNT II

(INFRINGEMENT OF THE '939 PATENT)

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

71. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '939 patent.

72. Teva's Third Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '939 patent are invalid, unenforceable and/or will not be infringed.

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

74. Teva has actual knowledge of the '939 patent, as evidenced by Teva's Third Notice Letter.

75. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '939 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '939 patent.

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

77. Upon information and belief, if ANDA No. 215984 is approved, Teva 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 Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '939 patent and any additional periods of exclusivity.

78. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '939 patent.

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

80. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '939 patent.

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

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

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

COUNT III

(INFRINGEMENT OF THE '029 PATENT)

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

85. Upon information and belief, Teva filed ANDA No. 215984 seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '029 patent.

86. Teva's Third Notice Letter states that Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '029 patent are invalid, unenforceable and/or will not be infringed.

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

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

89. Teva has actual knowledge of the '029 patent, as evidenced by Teva's Third Notice Letter.

90. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '029 patent by submitting, or causing to be submitted, to the FDA ANDA No. 215984, seeking approval to manufacture, use, import, offer to sell or sell Teva's generic products before the expiration date of the '029 patent.

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

92. Upon information and belief, if ANDA No. 215984 is approved, Teva 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 Teva's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 215984 shall be no earlier than the expiration of the '029 patent and any additional periods of exclusivity.

93. Upon information and belief, Teva knows, should know and intends that physicians will prescribe and patients will take Teva's generic products for which approval is sought in ANDA No. 215984, and therefore will infringe at least one claim of the '029 patent.

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

95. Upon information and belief, Teva is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '029 patent.

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

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

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '931 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '931 patent;

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

'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);

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

D. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '931 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '931 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '939 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '939 patent;

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

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

I. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '939 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

J. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '939 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

K. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '029 patent through Teva's submission of ANDA No. 215984 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Teva's generic products in the United States before the expiration of the '029 patent;

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

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

N. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from manufacturing, using, offering for sale or selling Teva's generic products within the United States, or importing Teva's generic products into the United States, until the expiration of the '029 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

O. The entry of a preliminary and/or permanent injunction, enjoining Teva and all persons acting in concert with Teva from seeking, obtaining or maintaining approval of the ANDA until the expiration of the '029 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

P. 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);

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

R. 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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