IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No.
v.	)	
	)	
ANNORA PHARMA PRIVATE LIMITED,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity"), by and through its attorneys, brings this Complaint for patent infringement against Defendant Annora Pharma Private Limited ("Defendant"), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 10,799,453 ("the '453 patent"); 11,471,409 ("the '409 patent"); 11,484,498 ("the '498 patent"); 11,701,326 ("the '326 patent"); 11,918,685 ("the '685 patent"); 12,053,461 ("the '461 patent"); and 12,336,984 ("the '984 patent"), (collectively, the "Patents-in-Suit"), arising under the patent laws of the United States, Title 35, United States Code.

2. By letter dated July 30, 2025 ("Defendant's Notice Letter"), Defendant notified Azurity that it submitted Abbreviated New Drug Application ("ANDA") No. 220151 to the U.S. Food and Drug Administration ("FDA") under Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B)(iv)(I)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Azurity's KATERZIA® product (the "ANDA Product") before the expiration of the Patents-in-Suit.

3. This action arises out of the filing by Defendant of ANDA No. 220151 with FDA seeking approval to market a generic version of Azurity's amlodipine benzoate oral suspension that is the subject of New Drug Application ("NDA") No. 211340 ("Azurity's KATERZIA® product").

4. Azurity owns the Patents-in-Suit, which are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Azurity's KATERZIA® product.

5. Azurity seeks all available relief under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and other applicable laws for Defendant's infringement of the Patents-in-Suit.

THE PARTIES

6. Plaintiff Azurity Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, Massachusetts 01801, United States.

7. On information and belief, Defendant is a corporation organized and existing under the laws of India, having its principal place of business at Sy. No. 261, Plot Nos. 5, 7, 8, 9, 13 and 14, Annaram Village, Jinnaram Mandal, Medak Hyderabad, Telangana State – 502313, India.

8. On information and belief, Defendant is in the business of, among other things, manufacturing, marketing, distributing, importing for sale, and/or selling generic copies of branded pharmaceutical products throughout the United States, including this judicial district.

9. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 220151, Defendant will make, use,

offer to sell, and/or sell the ANDA Product throughout the United States, including in the State of Delaware, and/or import such generic products in the United States, including into the State of Delaware.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Defendant at least because Defendant has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Defendant intends to market, sell, and/or distribute generic pharmaceutical drug products within this State and to residents of this State, including the generic drug products that are the subject of ANDA No. 220151. The marketing, sale, and/or distribution of the generic drug products that are the subject of ANDA No. 220151 will lead to foreseeable harm and injury to Azurity in this State. This Court has personal jurisdiction over Defendant for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

12. This Court also has personal jurisdiction over Defendant by virtue of, *inter alia*, the fact that it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Azurity, which is a Delaware entity.

13. This Court further has personal jurisdiction over Defendant because, on information and belief, Defendant is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products, throughout the United States, including in Delaware. On information and belief, Defendant purposefully has conducted

and continues to conduct business in this judicial district, and this judicial district is a likely destination of Defendant's generic products, including the ANDA Product.

14. This Court has personal jurisdiction over Defendant because it has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in Delaware in previous suits without challenging personal jurisdiction. *E.g.*, *Harmony Biosciences, LLC et al. v. AET Pharma US, Inc. et al.*, C.A. No. 23-1340 (D. Del. Nov. 21, 2023) (declining to contest personal jurisdiction and asserting counterclaims for declaratory judgment of non-infringement and invalidity); *Merck Sharp & Dohme Corp. v. Annora Pharma Private Ltd. et al.*, C.A. No. 21-1006 (D. Del. July 9, 2021) (declining to contest personal jurisdiction and asserting counterclaims for declaratory judgment of non-infringement and invalidity).

15. Alternatively, this Court may exercise jurisdiction over Defendant pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Azurity's claims arise under federal law; (b) Defendant is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Defendant has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Defendant satisfies due process.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c). Defendant is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. §§ 1391(c).

17. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

18. The ’453 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on October 13, 2020. A true and correct copy of the ’453 Patent is attached to the Complaint as Exhibit A. Azurity is the assignee and owner of the ’453 patent.

19. Pursuant to 21 U.S.C. § 355, the ’453 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA® product is covered by at least one claim of the ’453 Patent.

20. The ’409 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on October 18, 2022. A true and correct copy of the ’409 Patent is attached to the Complaint as Exhibit B. Azurity is the assignee and owner of the ’409 patent.

21. Pursuant to 21 U.S.C. § 355, the ’409 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA ® product is covered by at least one claim of the ’409 Patent.

22. The ’498 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on November 1, 2022. A true and correct copy of the ’498 Patent is attached to the Complaint as Exhibit C. Azurity is the assignee and owner of the ’498 patent.

23. Pursuant to 21 U.S.C. § 355, the ’498 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA ® product is covered by at least one claim of the ’498 Patent.

24. The ’326 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on July 18, 2023. A true and correct copy of the ’326 Patent is attached to the Complaint as Exhibit D. Azurity is the assignee and owner of the ’326 patent.

25. Pursuant to 21 U.S.C. § 355, the ’326 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA ® product is covered by at least one claim of the ’326 Patent.

26. The ’685 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on March 5, 2024. A true and correct copy of the ’685 Patent is attached to the Complaint as Exhibit E. Azurity is the assignee and owner of the ’685 patent.

27. Pursuant to 21 U.S.C. § 355, the ’685 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA ® product is covered by at least one claim of the ’685 Patent.

28. The ’461 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on August 6, 2024. A true and correct copy of the ’461 Patent is attached to the Complaint as Exhibit F. Azurity is the assignee and owner of the ’461 patent.

29. Pursuant to 21 U.S.C. § 355, the ’461 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA ® product is covered by at least one claim of the ’461 Patent.

30. The ’984 Patent, entitled “Amlodipine Formulations,” was duly and legally issued on June 24, 2025. A true and correct copy of the ’984 Patent is attached to the Complaint as Exhibit G. Azurity is the assignee and owner of the ’984 patent.

31. Pursuant to 21 U.S.C. § 355, the ’984 Patent is listed in the Orange Book, in connection with Azurity’s KATERZIA® product. Azurity’s KATERZIA ® product is covered by at least one claim of the ’984 Patent.

INFRINGEMENT BY DEFENDANT

32. Defendant's Notice Letter states that it submitted ANDA No. 220151 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B)(iv)(I)) seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Product before expiration of the Patents-in-suit.

33. Upon information and belief, Defendant intends to engage in commercial manufacture, use, and sale of the ANDA Product promptly upon receiving FDA approval to do so.

34. Upon information and belief, Defendant is seeking approval to engage in the commercial manufacture, use, and sale of the ANDA Product before the expiration of the Patents-in-suit.

35. By filing ANDA No. 220151, Defendant has necessarily represented to FDA that the ANDA Product has the same active ingredients as Azurity's KATERZIA® product and is bioequivalent to Azurity's KATERZIA® product.

36. The Notice Letter contained an offer of confidential access ("Offer") to certain portions of ANDA No. 220151. Defendant requested that Azurity accept the Offer before receiving access to any portion of ANDA No. 220151. However, the Offer contained unreasonable restrictions that differ materially from standard terms of protective orders entered in this jurisdiction and that Defendant has agreed to in litigations with Azurity. *See* D. Del. L.R. 26.2 (prior to entry of a protective order, disclosure shall be limited to outside counsel who are "under an obligation to keep such documents confidential and to ***use them only for purposes of litigating the case***" (emphasis added)). Defendant's Offer far exceeds the "use" restriction contemplated by Local Rule 26.2.

37. Defendant's Offer includes bars on FDA and patent prosecution work that have been previously rejected by courts in this district. Specifically, the Offer prohibits outside counsel who accesses the unspecified ANDA information from ever "engag[ing], formally or informally, in . . . any FDA counseling, litigation or other work before or involving the FDA" for all time and with respect to any subject matter. Such unreasonable bars on FDA work as conditions of access to confidential information are routinely rejected. *E.g.*, *Avion Pharms., LLC v. Granules Pharms., Inc.*, C.A. No. 20-898-LPS, 2021 WL 1785580, at *3 (D. Del. May 5, 2021) (explaining "[b]ecause there is little risk of 'inadvertent' disclosure of confidential materials to the FDA, requests for regulatory bars are routinely denied in this district"). The Offer also prohibits any outside counsel who accesses the unspecified ANDA information from ever "engag[ing], formally or informally, in any patent prosecution for Azurity" for all time and with respect to any subject matter. Such unreasonable bars on patent prosecution as conditions of access to confidential information are also routinely rejected. *E.g.*, *Avion Pharms.*, 2021 WL 1785580 at *3 (finding proposed prosecution bar was "overbroad" and ordering it be limited, among other aspects, to specific subject matter); *In re Deutsche Bank Tr. Co. Ams.*, 605 F.3d 1373, 1381 (Fed. Cir. 2010) ("We therefore hold that a party seeking imposition of a patent prosecution bar must show that the information designated to trigger the bar, ***the scope of activities prohibited by the bar***, ***the duration of the bar***, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competitive information.") (emphasis added).

38. Moreover, in a previous litigation between Azurity and Defendant involving a different ANDA product (the "2020 ANDA Product"), Defendant provided a nearly identical unreasonable offer of confidential access (the "2020 Offer") in its notice letter. During litigation,

however, Defendant agreed to a protective order with different terms that were reasonable conditions to access. *Silvergate Pharms, Inc. v. Annora Pharma Private LTD.*, C.A. No. 1:20-cv-00753 (LPS), D.I. 35, ¶ 4(b) (D. Del. Jun. 10, 2021) (agreeing in protective order that outside counsel "who are substantively involved in the drafting or prosecution of claims . . . relating to the Patents-in-Suit . . .; or the decision to file . . . any Citizen's Petitions with the FDA concerning any third-party enalapril maleate oral solution products, or any communications with the FDA related thereto, are excluded from access") [1].

39. As (1) the terms of Defendant's 2020 Offer and the present Offer are nearly identical, and (2) Defendant only allowed reasonable access to information in Defendant's 2020 ANDA after litigation commenced, any attempt to negotiate the terms of the present Offer prior to litigation would be futile and a waste of resources. *See, e.g.*, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 693 F. Supp. 2d 409, 416-17 (D. Del. 2010) (finding that patentee was not required to accept pre-suit Offer of Confidential Access to ANDA under terms it considered "unreasonable"); *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, C.A. No. 20-md-2930-RGA, 2022 WL 2304116, at *2 (D. Del. June 27, 2022) (in denying motion for fees, "credit[ing] [patentee's] argument that it believed attempting to negotiate reasonable terms for access to [the] ANDA within the 45-day window prior to filing suit would have been fruitless."); *see also Takeda Pharm. Co. Ltd. v. Zydus Pharm. (USA) Inc.*, Civil Action No. 18-1994 (FLW), 2021 U.S. Dist. LEXIS 138933 (D.N.J. July 26, 2021) (in dismissing "sham suit" allegation, explaining "Takeda, a brand-name manufacturer, need not review an ANDA in full (rather than the Paragraph IV Certification) during the 45-day notice period. It is difficult to

[1] Silvergate Pharmaceuticals, Inc. was a predecessor to Azurity.

infer bad faith from Takeda's failure to undertake an action which Hatch-Waxman does not require it to take.").

40. With respect to a different notice letter and ANDA product ("2024 ANDA Product"), Azurity previously attempted to negotiate an offer of confidential access with Defendant ("2024 Offer"). Defendant's proposed terms in the 2024 Offer were nearly identical to the terms of the Offer. As is reflected in the complaint filed in response to that notice letter, Defendant refused to reasonably negotiate the unduly restrictive terms of its 2024 Offer. *Azurity Pharms, Inc. v. Annora Pharma Private LTD.*, C.A. No. 3:24-08809-SDW, D.I. 1, ¶ 41 (D.N.J. Aug. 28, 2024) ("Azurity attempted to negotiate with Annora to obtain relevant information from ANDA No. 218168 under restrictions 'as would apply had a protective order been issued.' On August 16, 2024, counsel for Azurity proposed an amended Offer of Confidential Access seeking access to relevant sections of ANDA No. 218168. As of the filing of this Complaint, Annora has informed Azurity that Annora is represented by outside counsel, but neither Annora nor its counsel has provided any substantive response to Azurity's amended Offer of Confidential Access.").

41. As (1) the terms of Defendant's 2024 Offer and the present Offer are nearly identical and (2) Defendant previously failed to negotiate the terms of the 2024 Offer, any attempt to negotiate the terms of the present Offer prior to litigation would be futile.

42. To date, Defendant has not provided Azurity with access to any portion of ANDA No. 220151 or any information regarding the ANDA Product, beyond the sparse and incomplete information in Defendant's Notice Letter.

43. Defendant's Notice Letter provides no information about the content of Defendant's ANDA Product. Defendant's Notice Letter does not demonstrate that the ANDA Product will not infringe at least one of the claims of the Patents-in-Suit.

44. This action was commenced within forty-five days of Azurity's receipt of Defendant's Notice Letter.

CLAIMS FOR RELIEF

Count I —Infringement of the '453 Patent

45. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

46. Defendant's submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the '453 Patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the '453 Patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the '453 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

48. On information and belief, Defendant had actual and constructive knowledge of the '453 Patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the '453 Patent.

49. On information and belief, Defendant had specific intent to infringe the '453 Patent when it filed ANDA No. 220151.

50. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the '453 Patent.

51. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the '453 Patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

52. Azurity will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

Count II —Infringement of the '409 Patent

53. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

54. Defendant's submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the '409 Patent under 35 U.S.C. § 271(e)(2)(A).

55. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the '409 Patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the '409 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

56. On information and belief, Defendant had actual and constructive knowledge of the '409 Patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the '409 Patent.

57. On information and belief, Defendant had specific intent to infringe the '409 Patent when it filed ANDA No. 220151.

58. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the '409 Patent.

59. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the ’409 Patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

60. Azurity will be irreparably harmed by Defendant’s infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

Count III —Infringement of the ’498 Patent

61. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

62. Defendant’s submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the ’498 Patent under 35 U.S.C. § 271(e)(2)(A).

63. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the ’409 Patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the ’498 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

64. On information and belief, Defendant had actual and constructive knowledge of the ’498 Patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the ’498 Patent.

65. On information and belief, Defendant had specific intent to infringe the ’498 Patent when it filed ANDA No. 220151.

66. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the ’498 Patent.

67. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the '498 Patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

68. Azurity will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

Count IV —Infringement of the '326 Patent

69. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

70. Defendant's submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the '326 Patent under 35 U.S.C. § 271(e)(2)(A).

71. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the '326 patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the '326 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

72. On information and belief, Defendant had actual and constructive knowledge of the '326 patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the '326 Patent.

73. On information and belief, Defendant had specific intent to infringe the '326 patent when it filed ANDA No. 220151.

74. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the '326 Patent.

75. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the '326 Patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

76. Azurity will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

Count V —Infringement of the '685 Patent

77. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

78. Defendant's submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the '685 Patent under 35 U.S.C. § 271(e)(2)(A).

79. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the '685 Patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the '685 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

80. On information and belief, Defendant had actual and constructive knowledge of the '685 Patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the '685 Patent.

81. On information and belief, Defendant had specific intent to infringe the '685 Patent when it filed ANDA No. 220151.

82. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the '685 Patent.

83. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the '685 Patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

84. Azurity will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

Count VI —Infringement of the '461 Patent

85. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

86. Defendant's submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the '461 Patent under 35 U.S.C. § 271(e)(2)(A).

87. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the '461 Patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the '461 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

88. On information and belief, Defendant had actual and constructive knowledge of the '461 Patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the '461 Patent.

89. On information and belief, Defendant had specific intent to infringe the '461 patent when it filed ANDA No. 220151.

90. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the '461 Patent.

91. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the '461 Patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

92. Azurity will be irreparably harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

Count VII —Infringement of the '984 Patent

93. Azurity incorporates each of the preceding paragraphs as if fully set forth herein.

94. Defendant's submission of ANDA No. 220151 to FDA, including its Section 505(j)(2)(A)(vii)(IV) certification, constituted an act of infringement of the '984 Patent under 35 U.S.C. § 271(e)(2)(A).

95. Upon information and belief, the commercial manufacture, use, offer for sale, sale, or import of the ANDA Product—if approved by FDA, prior to the expiration of the '984 Patent, and for use in accordance with its proposed labeling—would constitute acts of infringement of the '984 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

96. On information and belief, Defendant had actual and constructive knowledge of the '984 patent prior to submitting ANDA No. 220151 and was aware that submission of the ANDA to FDA constituted an act of infringement of the '984 Patent.

97. On information and belief, Defendant had specific intent to infringe the '984 Patent when it filed ANDA No. 220151.

98. There are no substantial non-infringing uses for the ANDA Product other than as the pharmaceutical claimed in the '984 Patent.

99. Azurity is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of approval of ANDA No. 220151 be a date that is not earlier than the expiration of the ’984 patent, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled.

100. Azurity will be irreparably harmed by Defendant’s infringing activities unless those activities are enjoined by this Court. Azurity does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Azurity prays for judgment that:

A. Defendant has infringed one or more claims of the ’453 Patent either literally or under the doctrine of equivalents;

B. Defendant has infringed one or more claims of the ’409 Patent either literally or under the doctrine of equivalents;

C. Defendant has infringed one or more claims of the ’498 Patent either literally or under the doctrine of equivalents;

D. Defendant has infringed one or more claims of the ’326 Patent either literally or under the doctrine of equivalents;

E. Defendant has infringed one or more claims of the ’685 Patent either literally or under the doctrine of equivalents;

F. Defendant has infringed one or more claims of the ’461 Patent either literally or under the doctrine of equivalents;

G. Defendant has infringed one or more claims of the ’984 Patent either literally or under the doctrine of equivalents;

H. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of ANDA No. 220151 will not be earlier than the expiration date of the Patents-in-Suit, or any later expiration of any extensions or exclusivities to which Azurity is or becomes entitled;

I. Pursuant to 35 U.S.C. § 271(e)(4)(B), Defendant, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the ANDA Product and any other product that infringes or induces or contributes to the infringement of one or more of the Patents-in-Suit, prior to the expiration of the Patents-in-Suit, including any extensions or exclusivities to which Azurity is or becomes entitled;

J. Pursuant to 35 U.S.C. § 271(e)(4)(C), Azurity be awarded monetary relief to the extent Defendant commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the Patents-in-Suit within the United States prior to the expiration of the Patents-in-Suit, including any later expiration of extensions or exclusivities to which Azurity is or becomes entitled, and that any such monetary relief be awarded to Azurity with prejudgment interest;

K. The ’453 patent, the ’409 patent, the ’498 patent, the ’326 patent, the ’685 patent, the ’461 patent, and the ’984 patent are valid and enforceable;

L. This is an exceptional case under 35 U.S.C. § 285, and that Azurity be awarded reasonable attorneys’ fees and costs; and

M. Azurity be awarded such other and further relief as this Court deems just and proper.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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