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

OYSTER POINT PHARMA, INC., Plaintiff, v. APOTEX, INC., Defendant.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Oyster Point Pharma, Inc. ("Oyster Point"), by its undersigned attorneys, brings this Complaint against Defendant Apotex, Inc. ("Apotex"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. § 271(e)(2);

21 U.S.C. § 355(j) (the "Hatch-Waxman Act"); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, which arises from Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 217954 with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Oyster Point's TYRVAYA® (varenicline solution) prior to the expiration of U.S. Patent Nos. 9,504,644 ("the '644 patent"); 9,504,645 ("the '645 patent"); 9,532,944 ("the '944 patent"); 9,597,284 ("the '284 patent"); 10,456,396 ("the '396 patent"); and 11,224,598 ("the '598 patent"), collectively herein referred to as the "Patents-in-Suit." Plaintiff attaches hereto a true and accurate copy of each of the Patents-in-Suit as Exhibits A-F.

PARTIES

Plaintiff

2. Plaintiff Oyster Point is a corporation organized and existing under the laws of Delaware with its principal place of business at 202 Carnegie Center Drive, Princeton, NJ 08540.

3. Oyster Point is a biopharmaceutical company focused on the discovery, development, and commercialization of first-in-class therapies to treat ophthalmic diseases.

Defendant

4. On information and belief, Apotex, Inc. is a foreign corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. On information and belief, Apotex, itself and through its subsidiaries, affiliates, and agents, manufactures, uses, promotes, markets, sells, offers to sell, distributes, and/or imports generic versions of branded pharmaceutical products for marketing throughout the United States, including in this District.

JURISDICTION AND VENUE

6. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

7. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., including § 271(e)(2), 271(a), 271(b), and 271(c).

8. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). The Court also has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Oyster Point and Apotex of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-in-Suit.

9. This Court has personal jurisdiction over Apotex by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein.

10. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Apotex regularly and continuously transacts business within this District, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including New Jersey.

11. On information and belief, Apotex makes pharmaceutical products for sale in New Jersey, and currently markets, distributes, and sells either directly or through its subsidiaries, agents, and/or affiliates, pharmaceutical products throughout the United States, including in this District. On information and belief, Apotex derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

12. This Court also has personal jurisdiction because Apotex filed ANDA No. 217954 ("Apotex's ANDA"), seeking approval from the FDA to market and sell a generic version of Oyster Point's TYRVAYA® 0.03 mg per spray ("Apotex's ANDA Product") throughout the United States, including in New Jersey.

13. On information and belief, Apotex intends to commercially manufacture, use, and sell Apotex's ANDA Product upon receiving FDA approval. On information and belief, if and when the

FDA approves Apotex's ANDA, Apotex's ANDA Product would, among other things, be marketed, distributed and sold in New Jersey, and/or prescribed by physicians practicing within this District and/or dispensed by pharmacies located within this District, all of which would have a substantial effect on New Jersey. By filing its ANDA, Apotex has made clear that it intends to use its distribution channels to direct sales of Apotex's ANDA Product into New Jersey.

14. This Court has personal jurisdiction over Apotex because Apotex has previously been sued in this district and has not challenged personal jurisdiction, and Apotex has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Amgen Inc. v. Apotex Inc.*, No. 22-cv-03827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc.*, No. 22-cv-00322 (D.N.J.); *Takeda Pharms. Am., Inc., v. Apotex, Inc.*, No. 21-12998 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 19-05806 (D.N.J.); *Celgene Corp. v. Apotex Inc.*, No. 18-16395 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-03387 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. v. Apotex Inc.*, No. 17-05278 (D.N.J.); *AstraZeneca AB v. Apotex Corp.*, No. 15-08492 (D.N.J.); *Bausch & Lomb Inc. v. Apotex Inc.*, No. 15-03879 (D.N.J.); *Novartis Pharm. Corp. v. Apotex Inc.*, No. 15-03634 (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc.*, No. 15-02384 (D.N.J.); *Patheon Softgels Inc. v. Apotex Inc.*, No. 17-13819 (D.N.J.); *Dexcel Pharma Techs. Ltd. v. Apotex Corp.*, No. 17-02423 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. v. Apotex Inc.*, No. 18-11350 (D.N.J.). Upon information and belief, Apotex has also availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g.*, *Apotex Inc. v. Shire LLC*, No. 08-03598 (D.N.J.); *Apotex Inc. v. Pharm. Res., Inc.*, No. 06-01153 (D.N.J.).

15. Alternatively, this Court may exercise personal jurisdiction over Apotex pursuant to Federal Rule of Civil Procedure 4(k)(2) because Oyster Point's claims arise under federal law; Apotex is a foreign company not subject to general personal jurisdiction in the courts of any state; and Apotex has sufficient contacts with the United States as a whole, including but not limited to preparing and

submitting an ANDA to the FDA, and/or marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex satisfies due process.

16. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because Apotex is a foreign corporation organized and existing under the laws of Canada and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

PATENTS-IN-SUIT

17. On November 29, 2016, the U.S. Patent and Trademark Office duly and legally issued the '644 patent, titled "Methods of Increasing Tear Production." Attached as Exhibit A is true and correct copy of the '644 patent. The claims of the '644 patent are valid, enforceable, and not expired. Oyster Point is the owner and assignee of the '644 patent and has the right to enforce the '644 patent.

18. On November 29, 2016, the U.S. Patent and Trademark Office duly and legally issued the '645 patent, titled "Pharmaceutical Formulations for Treating Ocular Conditions." Attached as Exhibit B is true and correct copy of the '645 patent. The claims of the '645 patent are valid, enforceable, and not expired. Oyster Point is the owner and assignee of the '645 patent and has the right to enforce the '645 patent.

19. On January 3, 2017, the U.S. Patent and Trademark Office duly and legally issued the '944 patent, titled "Methods of Improving Ocular Discomfort." Attached as Exhibit C is a true and correct copy of the '944 patent. The claims of the '944 patent are valid, enforceable, and not expired. Oyster Point is the owner and assignee of the '944 patent and has the right to enforce the '944 patent.

20. On March 21, 2017, the U.S. Patent and Trademark Office duly and legally issued the '284 patent, titled "Dry Eye Treatments." Attached as Exhibit D is a true and correct copy of the '284

patent. The claims of the '284 patent are valid, enforceable, and not expired. Oyster Point is the owner and assignee of the '284 patent and has the right to enforce the '284 patent.

21. On October 29, 2019, the U.S. Patent and Trademark Office duly and legally issued the '396 patent, titled "Dry Eye Treatments." Attached as Exhibit E is a true and correct copy of the '396 patent. The claims of the '396 patent are valid, enforceable, and not expired. Oyster Point is the owner and assignee of the '396 patent and has the right to enforce the '396 patent.

22. On January 18, 2022, the U.S. Patent and Trademark Office duly and legally issued the '598 patent, titled "Methods of Increasing Lacrimal Proteins." Attached as Exhibit F is a true and correct copy of the '598 patent. The claims of the '598 patent are valid, enforceable, and not expired. Oyster Point is the owner and assignee of the '598 patent and has the right to enforce the '598 patent.

23. Each of the Patents-in-Suit is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book, for TYRVAYA®.

TYRVAYA®

24. Oyster Point holds approved New Drug Application ("NDA") No. 213978 for 0.03 mg per spray of varenicline solution for the treatment of the signs and symptoms of dry eye disease, as further described in the TYRVAYA® label, attached as Exhibit G.

25. Oyster Point markets the nasal spray approved under NDA No. 213978 in the United States under the registered trademark TYRVAYA®. FDA's Orange Book identifies the Patents-in-Suit for TYRVAYA®.

26. At least one claim of each of the Patents-in-Suit (all of which are listed in the Orange Book) covers TYRVAYA®, or approved methods of using TYRVAYA®.

APOTEX'S ACTS GIVING RISE TO THIS ACTION

27. On information and belief, Apotex prepared and filed Apotex's ANDA, seeking approval to manufacture, import, market, use, offer for sale, and/or sell Apotex's ANDA Product in the United States, including in this District, if the FDA approves Apotex's ANDA.

28. On information and belief, Apotex submitted to the FDA Apotex's ANDA under 21 U.S.C. § 355(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), to obtain FDA approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation in the United States of Apotex's ANDA Product before the expiration of the Patents-in-Suit.

29. Apotex has received FDA approval for other varenicline-based products in the United States and has publicly announced the "substantial effort" it has exerted toward marketing other varenicline-based products in the United States. *See* Apotex, *Apotex Receives FDA's Drug Shortage Assistance Award* (Apr. 19, 2023), https://www.apotex.com/us/about-us/press-center/2023/04/19/apotex-receives-fda-s-drug-shortage-assistance-award; *see also* Apotex, *APO-Varenicline Tablets*, https://www.apotex.com/products/us/detail.asp?m=69405.

30. On information and belief, the FDA has not yet approved Apotex's ANDA.

31. By a letter dated June 5, 2023 ("Apotex's Notice Letter"), Apotex notified Oyster Point that it had submitted Apotex's ANDA with certifications pursuant to Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to each of the Patents-in-Suit, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Product in or into the United States, including in this District, prior to the expiration of the Patents-in-Suit.

32. On information and belief, Apotex sent Apotex's Notice Letter to, *inter alia*, Oyster Point, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B).

33. In Apotex's Notice Letter, Apotex acknowledged that the Reference Listed Drug ("RLD") for Apotex's ANDA is TYRVAYA®, and stated that Apotex's ANDA Product contains varenicline as its active ingredient.

34. In Apotex's Notice Letter, Apotex also acknowledged that it represented to the FDA that its ANDA Product has the same active ingredient as TYRVAYA®; has the same dosage form and strength as TYRVAYA®; and is bioequivalent to TYRVAYA®.

35. On information and belief, Apotex is seeking approval to market its ANDA Product for the same approved indication as TYRVAYA®.

36. On information and belief, the proposed label for Apotex's ANDA Product ("Apotex's Proposed Label") will refer to the product as, *inter alia*, a treatment for the signs and symptoms of dry eye disease, and will indicate the strength of the ANDA Product as 0.03 mg/spray.

37. On information and belief, Apotex's Proposed Label will instruct patients, physicians and/or healthcare providers to administer Apotex's ANDA Product for, *inter alia*, the treatment of the signs and symptoms of dry eye disease.

38. On information and belief, Apotex's Proposed Label will contain data relating to the treatment of patients with dry eye disease, obtained from clinical studies involving, *inter alia*, TYRVAYA®.

39. On information and belief, Apotex, through its own actions and through the actions of its agents, affiliates, and subsidiaries, prepared and submitted Apotex's ANDA to the FDA, and intends to further seek approval for the product described in Apotex's ANDA.

40. On information and belief, if the FDA approves Apotex's ANDA, Apotex will make, use, distribute, promote, market, offer for sale, or sell Apotex's ANDA Product throughout the United States, or will import Apotex's ANDA Product into the United States. On information and belief, if the FDA approves Apotex's ANDA, Apotex, through its own actions and through the actions of its agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product in or into the United States.

41. On information and belief, Apotex, in concert with its agents, affiliates, and subsidiaries, filed Apotex's ANDA without adequate justification for asserting that the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of Apotex's ANDA Product.

42. On information and belief, Apotex has acted with full knowledge of the Patents-in-Suit and without a reasonable basis for believing that it would not be liable for direct infringement of these patents; active inducement of infringement by others of the Patents-in-Suit; and/or contribution to the infringement by others of the Patents-in-Suit.

43. Oyster Point received Apotex's Notice Letter on or about June 6, 2023.

44. Oyster Point brings this action before the expiration of forty-five days from the date Oyster Point received Apotex's Notice Letter. Accordingly, a thirty-month stay of FDA approval of Apotex's ANDA has been triggered pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: INFRINGEMENT OF THE '644 PATENT UNDER 35 U.S.C. § 271(e)(2)

45. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

46. On information and belief, Apotex's ANDA Product, and the use of Apotex's ANDA Product, are covered by one or more claims of the '644 patent.

47. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Apotex's ANDA Product prior to the expiration of the '644 patent.

48. Apotex's submission of Apotex's ANDA containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '644 patent is an act of

infringement of at least one of the claims of the '644 patent under 35 U.S.C. § 271(e)(2)(A).

49. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

50. As evidenced by Apotex's Notice Letter, which recites that Apotex's ANDA "contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Orange Book patents," which includes the '644 patent, Apotex knew of the '644 patent before filing Apotex's ANDA.

51. On information and belief, Apotex's infringement of the '644 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

52. Unless and until Apotex is enjoined from directly infringing the '644 patent, actively inducing infringement of the '644 patent, and contributing to the infringement of the '644 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '644 PATENT UNDER 35 U.S.C. § 271(b)-(c)

53. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

54. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

55. There is an actual case or controversy such that the Court may entertain Oyster Point's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

56. The use of Apotex's ANDA Product, including according to Apotex's Proposed Label, is covered by one or more claims of the '644 patent.

57. As evidenced at least by Apotex's Notice Letter, which confirms that Apotex's ANDA contains Paragraph IV certifications to the Orange Book patents, which includes the '644 patent, Apotex had actual knowledge, before filing Apotex's ANDA, of both the '644 patent and that Apotex's Proposed Label instructs infringement of the '644 patent.

58. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product and intends to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product in the United States.

59. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will immediately or imminently market or cause to be marketed Apotex's ANDA Product with Apotex's Proposed Label in the United States, including the offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, and therefore actively induce and/or contribute to infringement by others of one or more claims of the '644 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b) and/or (c), unless enjoined by the Court.

60. On information and belief, notwithstanding Apotex's knowledge of the claims of the '644 patent, Apotex has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling in or into the United States following FDA approval of Apotex's ANDA prior to the expiration of the '644 patent.

61. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's ANDA Product upon approval by the FDA.

62. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or

distribute Apotex's ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, patients, and/or other end users.

63. On information and belief, Apotex will knowingly and intentionally include with Apotex's ANDA Product Apotex's Proposed Label, which will include directions and instructions that instruct patients, physicians, and/or healthcare providers to use or administer Apotex's ANDA Product in accordance with the methods claimed in the '644 patent.

64. On information and belief, physicians, patients, and/or healthcare providers will administer Apotex's ANDA Product in the United States according to the directions and instructions in Apotex's Proposed Label, and such administration will constitute direct infringement of at least one claim of the '644 patent.

65. On information and belief, at least through Apotex's Proposed Label, Apotex will encourage physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users of Apotex's ANDA Product to directly infringe the '644 patent, and Apotex will know or should know that such conduct will occur.

66. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users with knowledge and specific intent that the conduct infringes the '644 patent.

67. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '644 patent.

68. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '644 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon FDA approval. Apotex's activities will be done with knowledge of the '644 patent and specific intent to infringe that patent.

69. On information and belief, Apotex knows or should know that Apotex's ANDA Product and Apotex's Proposed Label will be especially made or adapted for use in infringing the '644 patent, that Apotex's ANDA Product and Apotex's Proposed Label is not a staple article or commodity of commerce, and that Apotex's ANDA Product and Apotex's Proposed Label are not suitable for substantial non-infringing use.

70. The commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product and Apotex's Proposed Label in or into the United States will contribute to the infringement of one or more claims of the '644 patent.

71. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of Apotex's ANDA Product and Apotex's Proposed Label will contribute to direct infringement of the '644 patent, and that use of Apotex's ANDA Product according to Apotex's Proposed Label by others constitutes direct infringement of the '644 patent.

72. Oyster Point is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product and Apotex's Proposed Label by Apotex prior to the expiration of the '644 patent will induce and/or contribute to direct infringement of the '644 patent.

73. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product and Apotex's Proposed Label is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

74. On information and belief, Apotex's infringement of the '644 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

75. Unless and until Apotex is enjoined from actively inducing infringement of the '644 patent and contributing to the infringement of the '644 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and, considering the balance of hardships between

Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT III: INFRINGEMENT OF THE '645 PATENT UNDER 35 U.S.C. § 271(e)(2)

76. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

77. On information and belief, Apotex's ANDA Product, and the use of Apotex's ANDA Product, are covered by one or more claims of the '645 patent.

78. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product prior to the expiration of the '645 patent.

79. Apotex's submission of Apotex's ANDA containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '645 patent is an act of infringement of at least one of the claims of the '645 patent under 35 U.S.C. § 271(e)(2)(A).

80. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

81. As evidenced by Apotex's Notice Letter, which recites that Apotex's ANDA "contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Orange Book patents," which includes the '645 patent, Apotex knew of the '645 patent before filing Apotex's ANDA.

82. On information and belief, Apotex's infringement of the '645 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

83. Unless and until Apotex is enjoined from directly infringing the '645 patent, actively inducing infringement of the '645 patent, and contributing to the infringement of the '645 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '645 PATENT UNDER 35 U.S.C. § 271(a)-(c)

84. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

85. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

86. There is an actual case or controversy such that the Court may entertain Oyster Point's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

87. Apotex's ANDA Product is covered by one or more claims of the '645 patent.

88. As evidenced at least by Apotex's Notice Letter, which confirms that Apotex's ANDA contains Paragraph IV certifications to the Orange Book patents, which includes the '645 patent, Apotex had actual knowledge, before filing Apotex's ANDA, of both the '645 patent and that Apotex's Proposed Label instructs infringement of the '645 patent.

89. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product and intends to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product in the United States.

90. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will immediately or imminently market or cause to be marketed Apotex's ANDA Product with Apotex's Proposed Label in the United States, including the making, using, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, and therefore directly infringe, actively

induce and/or contribute to infringement by others of one or more claims of the '645 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), 271(b), and/or (c), unless enjoined by the Court.

91. On information and belief, notwithstanding Apotex's knowledge of the claims of the '645 patent, Apotex has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling in or into the United States following FDA approval of Apotex's ANDA prior to the expiration of the '645 patent.

92. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's ANDA Product upon approval by the FDA.

93. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute Apotex's ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, patients, and/or other end users.

94. On information and belief, Apotex will knowingly and intentionally include with Apotex's ANDA Product Apotex's Proposed Label, which will include directions and instructions that instruct patients, physicians and/or healthcare providers to use or administer Apotex's ANDA Product.

95. On information and belief, physicians, patients, and/or healthcare providers will administer Apotex's ANDA Product in the United States according to the directions and instructions in Apotex's Proposed Label, and such administration will constitute direct infringement of at least one claim of the '645 patent.

96. On information and belief, at least through Apotex's Proposed Label, Apotex will encourage physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients,

and/or other end users of Apotex's ANDA Product to directly infringe the '645 patent, and Apotex will know or should know that such conduct will occur.

97. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users with knowledge and specific intent that the conduct infringes the '645 patent.

98. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '645 patent.

99. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '645 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon FDA approval. Apotex's activities will be done with knowledge of the '645 patent and specific intent to infringe that patent.

100. On information and belief, Apotex knows or should know that Apotex's ANDA Product and Apotex's Proposed Label will be especially made or adapted for use in infringing the '645 patent, that Apotex's ANDA Product and Apotex's Proposed Label is not a staple article or commodity of commerce, and that Apotex's ANDA Product and Apotex's Proposed Label are not suitable for substantial non-infringing use.

101. The commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product and Apotex's Proposed Label in or into the United States will contribute to the infringement of one or more claims of the '645 patent.

102. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of Apotex's ANDA Product and Apotex's Proposed Label will contribute to direct infringement of the '645 patent, and that use of Apotex's ANDA Product according to Apotex's Proposed Label by others constitutes direct infringement of the '645 patent.

103. Oyster Point is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product and Apotex's Proposed Label by Apotex prior to the expiration of the '645 patent will directly infringe, induce, and/or contribute to direct infringement of the '645 patent.

104. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product and Apotex's Proposed Label is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

105. On information and belief, Apotex's infringement of the '645 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

106. Unless and until Apotex is enjoined from directly infringing, actively inducing infringement of the '645 patent and contributing to the infringement of the '645 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and, considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT V: INFRINGEMENT OF THE '944 PATENT UNDER 35 U.S.C. § 271(e)(2)

107. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

108. On information and belief, Apotex's ANDA Product, and the use of Apotex's ANDA Product, are covered by one or more claims of the '944 patent.

109. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product prior to the expiration of the '944 patent.

110. Apotex's submission of Apotex's ANDA containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '944 patent is an act of

infringement of at least one of the claims of the '944 patent under 35 U.S.C. § 271(e)(2)(A).

111. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

112. As evidenced by Apotex's Notice Letter, which recites that Apotex's ANDA "contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Orange Book patents," which includes the '944 patent, Apotex knew of the '944 patent before filing Apotex's ANDA.

113. On information and belief, Apotex's infringement of the '944 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

114. Unless and until Apotex is enjoined from directly infringing the '944 patent, actively inducing infringement of the '944 patent, and contributing to the infringement of the '944 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '944 PATENT UNDER 35 U.S.C. § 271(b)-(c)

115. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

116. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

117. There is an actual case or controversy such that the Court may entertain Oyster Point's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

118. The use of Apotex's ANDA Product, including according to Apotex's Proposed Label, is covered by one or more claims of the '944 patent.

119. As evidenced at least by Apotex's Notice Letter, which confirms that Apotex's ANDA contains Paragraph IV certifications to the Orange Book patents, which includes the '944 patent, Apotex had actual knowledge, before filing Apotex's ANDA, of both the '944 patent and that Apotex's Proposed Label instructs infringement of the '944 patent.

120. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product and intends to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product in the United States.

121. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will immediately or imminently market or cause to be marketed Apotex's ANDA Product with Apotex's Proposed Label in the United States, including the offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, and therefore actively induce and/or contribute to infringement by others of one or more claims of the '944 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b) and/or (c), unless enjoined by the Court.

122. On information and belief, notwithstanding Apotex's knowledge of the claims of the '944 patent, Apotex has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling in or into the United States following FDA approval of Apotex's ANDA prior to the expiration of the '944 patent.

123. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's ANDA Product upon approval by the FDA.

124. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or

distribute Apotex's ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, patients, and/or other end users.

125. On information and belief, Apotex will knowingly and intentionally include with Apotex's ANDA Product Apotex's Proposed Label, which will include directions and instructions that instruct patients, physicians and/or healthcare providers to use or administer Apotex's ANDA Product in accordance with the methods claimed in the '944 patent.

126. On information and belief, physicians, patients, and/or healthcare providers will administer Apotex's ANDA Product in the United States according to the directions and instructions in Apotex's Proposed Label, and such administration will constitute direct infringement of at least one claim of the '944 patent.

127. On information and belief, at least through Apotex's Proposed Label, Apotex will encourage physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users of Apotex's ANDA Product to directly infringe the '944 patent, and Apotex will know or should know that such conduct will occur.

128. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users with knowledge and specific intent that the conduct infringes the '944 patent.

129. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '944 patent.

130. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '944 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon FDA approval. Apotex's activities will be done with knowledge of the '944 patent and specific intent to infringe that patent.

131. On information and belief, Apotex knows or should know that Apotex's ANDA Product and Apotex's Proposed Label will be especially made or adapted for use in infringing the '944 patent, that Apotex's ANDA Product and Apotex's Proposed Label is not a staple article or commodity of commerce, and that Apotex's ANDA Product and Apotex's Proposed Label are not suitable for substantial non-infringing use.

132. The commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product and Apotex's Proposed Label in or into the United States will contribute to the infringement of one or more claims of the '944 patent.

133. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of Apotex's ANDA Product and Apotex's Proposed Label will contribute to direct infringement of the '944 patent, and that use of Apotex's ANDA Product according to Apotex's Proposed Label by others constitutes direct infringement of the '944 patent.

134. Oyster Point is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product and Apotex's Proposed Label by Apotex prior to the expiration of the '944 patent will induce and/or contribute to direct infringement of the '944 patent.

135. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product and Apotex's Proposed Label is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

136. On information and belief, Apotex's infringement of the '944 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

137. Unless and until Apotex is enjoined from actively inducing infringement of the '944 patent and contributing to the infringement of the '944 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and, considering the balance of hardships between

Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT VII: INFRINGEMENT OF THE '284 PATENT UNDER 35 U.S.C. § 271(e)(2)

138. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

139. On information and belief, Apotex's ANDA Product, and the use of Apotex's ANDA Product, are covered by one or more claims of the '284 patent.

140. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product prior to the expiration of the '284 patent.

141. Apotex's submission of Apotex's ANDA containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '284 patent is an act of infringement of at least one of the claims of the '284 patent under 35 U.S.C. § 271(e)(2)(A).

142. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

143. As evidenced by Apotex's Notice Letter, which recites that Apotex's ANDA "contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Orange Book patents," which includes the '284 patent, Apotex knew of the '284 patent before filing Apotex's ANDA.

144. On information and belief, Apotex's infringement of the '284 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

145. Unless and until Apotex is enjoined from directly infringing the '284 patent, actively inducing infringement of the '284 patent, and contributing to the infringement of the '284 patent,

Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '284 PATENT UNDER 35 U.S.C. § 271(b)-(c)

146. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

147. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

148. There is an actual case or controversy such that the Court may entertain Oyster Point's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

149. The use of Apotex's ANDA Product, including according to Apotex's Proposed Label, is covered by one or more claims of the '284 patent.

150. As evidenced at least by Apotex's Notice Letter, which confirms that Apotex's ANDA contains Paragraph IV certifications to the Orange Book patents, which includes the '284 patent, Apotex had actual knowledge, before filing Apotex's ANDA, of both the '284 patent and that Apotex's Proposed Label instructs infringement of the '284 patent.

151. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product and intends to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product in the United States.

152. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will immediately or imminently market or cause to be marketed Apotex's ANDA Product with Apotex's Proposed Label in the United States, including the offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, and therefore actively induce and/or contribute to

infringement by others of one or more claims of the ’284 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b) and/or (c), unless enjoined by the Court.

153. On information and belief, notwithstanding Apotex’s knowledge of the claims of the ’284 patent, Apotex has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import Apotex’s ANDA Product with its product labeling in or into the United States following FDA approval of Apotex’s ANDA prior to the expiration of the ’284 patent.

154. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex’s ANDA Product upon approval by the FDA.

155. On information and belief, upon FDA approval of Apotex’s ANDA, Apotex will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute Apotex’s ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, patients, and/or other end users.

156. On information and belief, Apotex will knowingly and intentionally include with Apotex’s ANDA Product Apotex’s Proposed Label, which will include directions and instructions that instruct patients, physicians and/or healthcare providers to use or administer Apotex’s ANDA Product in accordance with the methods claimed in the ’284 patent.

157. On information and belief, physicians, patients, and/or healthcare providers will administer Apotex’s ANDA Product in the United States according to the directions and instructions in Apotex’s Proposed Label, and such administration will constitute direct infringement of at least one claim of the ’284 patent.

158. On information and belief, at least through Apotex’s Proposed Label, Apotex will encourage physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients,

and/or other end users of Apotex's ANDA Product to directly infringe the '284 patent, and Apotex will know or should know that such conduct will occur.

159. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users with knowledge and specific intent that the conduct infringes the '284 patent.

160. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '284 patent.

161. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '284 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon FDA approval. Apotex's activities will be done with knowledge of the '284 patent and specific intent to infringe that patent.

162. On information and belief, Apotex knows or should know that Apotex's ANDA Product and Apotex's Proposed Label will be especially made or adapted for use in infringing the '284 patent, that Apotex's ANDA Product and Apotex's Proposed Label is not a staple article or commodity of commerce, and that Apotex's ANDA Product and Apotex's Proposed Label are not suitable for substantial non-infringing use.

163. The commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product and Apotex's Proposed Label in or into the United States will contribute to the infringement of one or more claims of the '284 patent.

164. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of Apotex's ANDA Product and Apotex's Proposed Label will contribute to direct infringement of the '284 patent, and that use of Apotex's ANDA Product according to Apotex's Proposed Label by others constitutes direct infringement of the '284 patent.

165. Oyster Point is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product and Apotex's Proposed Label by Apotex prior to the expiration of the '284 patent will induce and/or contribute to direct infringement of the '284 patent.

166. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product and Apotex's Proposed Label is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

167. On information and belief, Apotex's infringement of the '284 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

168. Unless and until Apotex is enjoined from actively inducing infringement of the '284 patent and contributing to the infringement of the '284 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and, considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT IX: INFRINGEMENT OF THE '396 PATENT UNDER 35 U.S.C. § 271(e)(2)

169. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

170. On information and belief, Apotex's ANDA Product, and the use of Apotex's ANDA Product, are covered by one or more claims of the '396 patent.

171. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product prior to the expiration of the '396 patent.

172. Apotex's submission of Apotex's ANDA containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale,

and/or importation of Apotex's ANDA Product prior to the expiration of the '396 patent is an act of infringement of at least one of the claims of the '396 patent under 35 U.S.C. § 271(e)(2)(A).

173. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

174. As evidenced by Apotex's Notice Letter, which recites that Apotex's ANDA "contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Orange Book patents," which includes the '396 patent, Apotex knew of the '396 patent before filing Apotex's ANDA.

175. On information and belief, Apotex's infringement of the '396 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

176. Unless and until Apotex is enjoined from directly infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement of the '396 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT X: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '396 PATENT UNDER 35 U.S.C. § 271(b)-(c)

177. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

178. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

179. There is an actual case or controversy such that the Court may entertain Oyster Point's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

180. The use of Apotex's ANDA Product, including according to Apotex's Proposed Label, is covered by one or more claims of the '396 patent.

181. As evidenced at least by Apotex's Notice Letter, which confirms that Apotex's ANDA contains Paragraph IV certifications to the Orange Book patents, which includes the '396 patent, Apotex had actual knowledge, before filing Apotex's ANDA, of both the '396 patent and that Apotex's Proposed Label instructs infringement of the '396 patent.

182. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product and intends to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product in the United States.

183. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will immediately or imminently market or cause to be marketed Apotex's ANDA Product with Apotex's Proposed Label in the United States, including the offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, and therefore actively induce and/or contribute to infringement by others of one or more claims of the '396 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b) and/or (c), unless enjoined by the Court.

184. On information and belief, notwithstanding Apotex's knowledge of the claims of the '396 patent, Apotex has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling in or into the United States following FDA approval of Apotex's ANDA prior to the expiration of the '396 patent.

185. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's ANDA Product upon approval by the FDA.

186. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or

distribute Apotex's ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, patients, and/or other end users.

187. On information and belief, Apotex will knowingly and intentionally include with Apotex's ANDA Product Apotex's Proposed Label, which will include directions and instructions that instruct patients, physicians and/or healthcare providers to use or administer Apotex's ANDA Product in accordance with the methods claimed in the '396 patent.

188. On information and belief, physicians, patients, and/or healthcare providers will administer Apotex's ANDA Product in the United States according to the directions and instructions in Apotex's Proposed Label, and such administration will constitute direct infringement of at least one claim of the '396 patent.

189. On information and belief, at least through Apotex's Proposed Label, Apotex will encourage physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users of Apotex's ANDA Product to directly infringe the '396 patent, and Apotex will know or should know that such conduct will occur.

190. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users with knowledge and specific intent that the conduct infringes the '396 patent.

191. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '396 patent.

192. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '396 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon FDA approval. Apotex's activities will be done with knowledge of the '396 patent and specific intent to infringe that patent.

193. On information and belief, Apotex knows or should know that Apotex's ANDA Product and Apotex's Proposed Label will be especially made or adapted for use in infringing the '396 patent, that Apotex's ANDA Product and Apotex's Proposed Label is not a staple article or commodity of commerce, and that Apotex's ANDA Product and Apotex's Proposed Label are not suitable for substantial non-infringing use.

194. The commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product and Apotex's Proposed Label in or into the United States will contribute to the infringement of one or more claims of the '396 patent.

195. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of Apotex's ANDA Product and Apotex's Proposed Label will contribute to direct infringement of the '396 patent, and that use of Apotex's ANDA Product according to Apotex's Proposed Label by others constitutes direct infringement of the '396 patent.

196. Oyster Point is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product and Apotex's Proposed Label by Apotex prior to the expiration of the '396 patent will induce and/or contribute to direct infringement of the '396 patent.

197. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product and Apotex's Proposed Label is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

198. On information and belief, Apotex's infringement of the '396 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

199. Unless and until Apotex is enjoined from actively inducing infringement of the '396 patent and contributing to the infringement of the '396 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and, considering the balance of hardships between

Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT XI: INFRINGEMENT OF THE '598 PATENT UNDER 35 U.S.C. § 271(e)(2)

200. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

201. On information and belief, Apotex's ANDA Product, and the use of Apotex's ANDA Product, are covered by one or more claims of the '598 patent.

202. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product prior to the expiration of the '598 patent.

203. Apotex's submission of Apotex's ANDA containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product prior to the expiration of the '598 patent is an act of infringement of at least one of the claims of the '598 patent under 35 U.S.C. § 271(e)(2)(A).

204. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

205. As evidenced by Apotex's Notice Letter, which recites that Apotex's ANDA "contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the Orange Book patents," which includes the '598 patent, Apotex knew of the '598 patent before filing Apotex's ANDA.

206. On information and belief, Apotex's infringement of the '598 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

207. Unless and until Apotex is enjoined from directly infringing the '598 patent, actively inducing infringement of the '598 patent, and contributing to the infringement of the '598 patent,

Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT XII: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '598 PATENT UNDER 35 U.S.C. § 271(b)-(c)

208. Oyster Point incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

209. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

210. There is an actual case or controversy such that the Court may entertain Oyster Point's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

211. The use of Apotex's ANDA Product, including according to Apotex's Proposed Label, is covered by one or more claims of the '598 patent.

212. As evidenced at least by Apotex's Notice Letter, which confirms that Apotex's ANDA contains Paragraph IV certifications to the Orange Book patents, which includes the '598 patent, Apotex had actual knowledge, before filing Apotex's ANDA, of both the '598 patent and that Apotex's Proposed Label instructs infringement of the '598 patent.

213. On information and belief, Apotex submitted or caused submission of Apotex's ANDA to obtain FDA approval of Apotex's ANDA Product and intends to manufacture, use, offer for sale, sell, and/or import Apotex's ANDA Product in the United States.

214. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will immediately or imminently market or cause to be marketed Apotex's ANDA Product with Apotex's Proposed Label in the United States, including the offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product, and therefore actively induce and/or contribute to

infringement by others of one or more claims of the ’598 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b) and/or (c), unless enjoined by the Court.

215. On information and belief, notwithstanding Apotex’s knowledge of the claims of the ’598 patent, Apotex has continued to assert its intent to manufacture, use, offer for sale, sell, distribute, and/or import Apotex’s ANDA Product with its product labeling in or into the United States following FDA approval of Apotex’s ANDA prior to the expiration of the ’598 patent.

216. On information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex’s ANDA Product upon approval by the FDA.

217. On information and belief, upon FDA approval of Apotex’s ANDA, Apotex will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute Apotex’s ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, patients, and/or other end users.

218. On information and belief, Apotex will knowingly and intentionally include with Apotex’s ANDA Product Apotex’s Proposed Label, which will include directions and instructions that instruct patients, physicians and/or healthcare providers to use or administer Apotex’s ANDA Product in accordance with the methods claimed in the ’598 patent.

219. On information and belief, physicians, patients, and/or healthcare providers will administer Apotex’s ANDA Product in the United States according to the directions and instructions in Apotex’s Proposed Label, and such administration will constitute direct infringement of at least one claim of the ’598 patent.

220. On information and belief, at least through Apotex’s Proposed Label, Apotex will encourage physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients,

and/or other end users of Apotex's ANDA Product to directly infringe the '598 patent, and Apotex will know or should know that such conduct will occur.

221. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians, healthcare professionals, resellers, pharmacies, hospitals, clinics, patients, and/or other end users with knowledge and specific intent that the conduct infringes the '598 patent.

222. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '598 patent.

223. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '598 patent when Apotex's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon FDA approval. Apotex's activities will be done with knowledge of the '598 patent and specific intent to infringe that patent.

224. On information and belief, Apotex knows or should know that Apotex's ANDA Product and Apotex's Proposed Label will be especially made or adapted for use in infringing the '598 patent, that Apotex's ANDA Product and Apotex's Proposed Label is not a staple article or commodity of commerce, and that Apotex's ANDA Product and Apotex's Proposed Label are not suitable for substantial non-infringing use.

225. The commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product and Apotex's Proposed Label in or into the United States will contribute to the infringement of one or more claims of the '598 patent.

226. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of Apotex's ANDA Product and Apotex's Proposed Label will contribute to direct infringement of the '598 patent, and that use of Apotex's ANDA Product according to Apotex's Proposed Label by others constitutes direct infringement of the '598 patent.

227. Oyster Point is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product and Apotex's Proposed Label by Apotex prior to the expiration of the '598 patent will induce and/or contribute to direct infringement of the '598 patent.

228. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ANDA Product and Apotex's Proposed Label is in violation of Oyster Point's patent rights and will cause harm to Oyster Point for which damages are inadequate.

229. On information and belief, Apotex's infringement of the '598 patent was, is, and would be willful. Apotex's conduct renders this case "exceptional" under 35 U.S.C. § 285.

230. Unless and until Apotex is enjoined from actively inducing infringement of the '598 patent and contributing to the infringement of the '598 patent, Oyster Point will suffer irreparable injury. Oyster Point has no adequate remedy at law and, considering the balance of hardships between Oyster Point and Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

PRAYER FOR RELIEF

WHEREFORE, Oyster Point prays that this Court grant the following relief:

A. A judgment that Apotex has infringed the '644 patent, the '645 patent, the '944 patent, the '284 patent, the '396 patent, and the '598 patent by submitting Apotex's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the making, using, offering to sell, selling within the United States, and/or importation into the United States of Apotex's ANDA Product will constitute infringement of the '644 patent, the '645 patent, the '944 patent, the '284 patent, the '396 patent, and/or the '598 patent;

B. A judgment entered declaring that the Patents-in-Suit have not been proven invalid or unenforceable;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Apotex's ANDA shall be a date which is not earlier than the latest expiration date of any of the Patents-in-Suit as extended by any applicable periods of exclusivity to which Oyster Point is or will be entitled;

D. An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Apotex, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the United States, and/or importing into the United States any of Apotex's ANDA Product until after the latest expiration date of any of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Oyster Point is or will be entitled;

E. An order pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that Apotex's commercial manufacture, use, offer for sell, sale, and/or importation of Apotex's ANDA Product in or into the United States prior to the expiration of the Patents-in-Suit (including such actions by its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Apotex or acting on Apotex's behalf) will constitute infringement of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

F. Damages or other monetary relief under 35 U.S.C. § 271(a), (b), (c) and (e)(4)(c), and/or 35 U.S.C. § 284, including costs, fees, pre- and post-judgment interest, to Oyster Point if Apotex engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of any of Apotex's ANDA Product prior to the latest expiration date of any of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Oyster Point is or will be entitled;

G. An order that this case is exceptional under 35 U.S.C. § 285, and that Oyster Point be awarded reasonable attorneys' fees and costs; and

H. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: July 19, 2023

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 19, 2023

Respectfully Submitted:

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiff seeks, *inter alia*, declaratory relief.

Dated: July 19, 2023

s/ Gregory D. Miller
Gregory D. Miller