IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC and MEDA PHARMACEUTICALS INC., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD., PADAGIS US LLC, and PADAGIS LLC, Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Bayer HealthCare LLC ("Bayer") and Meda Pharmaceuticals Inc. ("Meda," and collectively with Bayer, "Plaintiffs") file this Complaint for patent infringement against Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Padagis's submission of an Abbreviated New Drug New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import azelastine hydrochloride nasal spray, 0.2055 mg/spray ("Padagis's ANDA Product"), prior to the expiration of U.S. Patent No. 8,071,073 ("the '073 patent"); U.S. Patent No. 8,518,919 ("the '919 patent"); and U.S. Patent No. 9,919,050 ("the '050 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Padagis notified Plaintiffs by letter dated August 31, 2023 ("Padagis's Notice Letter") that it had submitted to FDA ANDA No. 216801 ("Padagis's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use and/or sale of Padagis's ANDA Product prior to the expiration of the Patents-in-Suit. According to Padagis's Notice Letter, the "'established name' of the proposed drug product that is the subject of Padagis' ANDA is Azelastine Hydrochloride Nasal Spray, 205.5 mcg/spray."

PARTIES

3. Plaintiff Bayer HealthCare LLC is a limited liability company organized and existing under the laws of the States of Delaware, with its principal place of business at 100 Bayer Boulevard, Whippany, New Jersey. Bayer HealthCare LLC is the holder of New Drug Application ("NDA") No. 213872 for the sale of azelastine hydrochloride nasal solution (0.15%, 205.5 mcg/spray, OTC), which has been approved by FDA.

4. Plaintiff Meda Pharmaceuticals Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 1000 Mylan Boulevard, Canonsburg, PA 15317.

5. On information and belief, defendant Padagis Israel Pharmaceuticals Ltd. is a company organized and existing under the laws of Israel with a principal place of business at 1 Rakefet St., Shoham 608500, Israel. On information and belief, Padagis Israel Pharmaceuticals Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

6. On information and belief, defendant Padagis US LLC is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 1251 Lincoln Road, Allegan, Michigan, 49010. On information and belief, Padagis

US LLC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

7. On information and belief, defendant Padagis LLC is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 1251 Lincoln Road, Allegan, Michigan, 49010. On information and belief, Padagis LLC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. On information and belief, Padagis Israel Pharmaceuticals Ltd. and Padagis US LLC are wholly owned subsidiaries of Padagis LLC and are controlled and/or dominated by Padagis LLC.

9. On information and belief, Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC acted in concert to prepare and submit Padagis's ANDA to FDA.

JURISDICTION

10. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

11. This Court has personal jurisdiction over each of Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC.

12. Padagis LLC is subject to personal jurisdiction in Delaware because, among other things, Padagis LLC, itself and through its wholly-owned subsidiaries Padagis US LLC and Padagis Israel Pharmaceuticals Ltd., has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Padagis LLC is a company organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and

belief, Padagis LLC, itself and through its wholly-owned subsidiaries Padagis US LLC and Padagis Israel Pharmaceuticals Ltd., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Padagis LLC is subject to personal jurisdiction in Delaware because, on information and belief, it controls Padagis US LLC and Padagis Israel Pharmaceuticals Ltd. and therefore the activities of Padagis US LLC and Padagis Israel Pharmaceuticals Ltd. in this jurisdiction are attributed to Padagis LLC.

13. Padagis US LLC is subject to personal jurisdiction in Delaware because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Padagis US LLC is a company organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. Further, on information and belief, Padagis US LLC develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

14. Padagis Israel Pharmaceuticals Ltd. is subject to personal jurisdiction in Delaware because, among other things, it 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, Padagis Israel Pharmaceuticals Ltd. develops, manufactures, imports,

markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

15. On information and belief, Padagis knows and intends that following any approval of Padagis's ANDA, Padagis will manufacture and import into the United States Padagis's ANDA Product and directly or indirectly market, sell, and distribute Padagis's ANDA Product throughout the United States, including in Delaware. On information and belief, following any FDA approval of Padagis's ANDA, Padagis knows and intends that Padagis's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware. On information and belief, following any FDA approval of Padagis's ANDA, Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC will act in concert to distribute and sell Padagis's ANDA Product throughout the United States, including within Delaware.

16. On information and belief, Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Padagis's ANDA Product. On information and belief, Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC together participated in, assisted, and cooperated in the acts complained of herein.

17. Padagis has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving

a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

18. On information and belief, Padagis, with knowledge of the Hatch-Waxman Act, directed Padagis's Notice Letter to Plaintiffs, entities incorporated in Delaware, and alleged in Padagis's Notice Letter that all of the Patents-in-Suit are invalid and/or not infringed. On information and belief, Padagis knowingly and deliberately challenged Plaintiffs' patent rights, and knew when it did so that it was triggering the forty-five day period for Plaintiffs to bring an action for patent infringement under the Hatch-Waxman Act.

19. Because Plaintiffs are incorporated in Delaware, Plaintiffs suffer injuries and consequences from Padagis's filing of Padagis's ANDA, challenging Plaintiffs' patent rights, in Delaware. On information and belief, Padagis knew that it was deliberately challenging the patent rights of Delaware entities and seeking to invalidate intellectual property held in Delaware. Padagis has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Padagis's Notice Letter to Plaintiffs, Delaware corporations, that it would be sued in Delaware for patent infringement.

20. In addition, this Court has personal jurisdiction over Padagis because Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Hikma Pharmaceuticals USA, Inc. v. Padagis Israel Pharmaceuticals Ltd. et al.*, Case No. 23-654-GBW, D.I. 11 (D. Del. Aug. 14, 2023); *Alcon Inc. et al. v. Padagis Israel Pharmaceuticals Ltd. et al.*, Case No. 22-1422-WCB, D.I. 20 (D. Del. Dec. 19, 2022); *Anacor Pharmaceuticals, Inc. et al. v.*

Padagis Israel Pharmaceuticals Ltd. et al., Case No. 21-1351-CFC, D.I. 11 (D. Del. Nov. 17, 2011); *VYNE Therapeutics Inc. v. Padagis Israel Pharmaceuticals Ltd.*, 21-cv-1152-CFC, D.I. 12 (D. Del. Oct. 1, 2021).

21. On information and belief, if Padagis's ANDA is approved, Padagis will directly or indirectly manufacture, market, sell, and/or distribute Padagis's ANDA Product within the United States, including in Delaware, consistent with Padagis's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Padagis regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Padagis's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Padagis's ANDA Product will be dispensed by pharmacies located within Delaware and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the Patents-in-Suit in the event that Padagis's ANDA Product is approved before the Patents-in-Suit expire.

22. On information and belief, Padagis derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Padagis and/or for which Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, or Padagis LLC is the named applicant on approved ANDAs. On information and belief, various products for which Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, or Padagis LLC is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

23. Venue is proper in this district as to Padagis US LLC and Padagis LLC pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Padagis US LLC and Padagis LLC are companies organized and existing under the laws of the State of Delaware and are subject to personal jurisdiction in this judicial district.

24. Venue is proper in this district as to Padagis Israel Pharmaceuticals Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Padagis Israel Pharmaceuticals Ltd. is a company organized and existing under the laws of Israel and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

25. Astepro® Allergy is an over-the-counter nasal spray containing azelastine hydrochloride (0.15%, 205.5 mcg/spray).

26. Astepro® Children's Allergy is an over-the-counter nasal spray containing azelastine hydrochloride (0.15%, 205.5 mcg/spray).

27. Plaintiffs are filing this Complaint within forty-five days of receipt of Padagis's Notice Letter.

COUNT I – INFRINGEMENT OF THE '073 PATENT

28. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

29. The '073 patent, entitled "Compositions Comprising Azelastine and Methods of Use Thereof" (attached as Exhibit A), was duly and legally issued on December 6, 2011.

30. Meda is the owner and assignee of the '073 patent.

31. Bayer holds an exclusive license to the '073 patent for the commercial exploitation and sale of Astepro® Allergy and Astepro® Children's Allergy.

32. In general, the claims of the '073 patent are directed to liquid pharmaceutical compositions comprising azelastine hydrochloride for treating allergic rhinitis or non-allergic vasomotor rhinitis.

33. The '073 patent has been listed in connection with NDA 213872 in the FDA's Orange Book.

34. In Padagis's Notice Letter, Padagis notified Plaintiffs of the submission of Padagis's ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Padagis's ANDA Product prior to the expiration of the '073 patent.

35. In Padagis's Notice Letter, Padagis also notified Plaintiffs that, as part of its ANDA, Padagis filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '073 patent. On information and belief, Padagis submitted its ANDA to FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '073 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product.

36. According to Padagis's Notice Letter, Padagis's ANDA Product is a nasal spray solution that contains azelastine hydrochloride. On information and belief, Padagis's ANDA Product meets the other limitations of at least claims 2 and 3 of the '073 patent.

37. On information and belief, Padagis's ANDA Product and the use of Padagis's ANDA Product in accordance with its proposed labeling are covered by at least claims 2 and 3 of the '073 patent.

38. In Padagis's Notice Letter, Padagis did not contest the infringement of claims 2, 3, 7-12, 14, 15, or 18–28 of the '073 patent on any basis other than the alleged invalidity of those claims.

39. Padagis's submission of Padagis's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product before the expiration of the '073 patent was an act of infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A).

40. On information and belief, Padagis will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of Padagis's ANDA.

41. On information and belief, the manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '073 patent, including at least claims 2 and 3 of the '073 patent.

42. On information and belief, the manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '073 patent, including at least claims 2 and 3 of the '073 patent.

43. On information and belief, Padagis plans and intends to, and will, actively induce infringement of the '073 patent when Padagis's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Padagis's activities will be done with knowledge of the '073 patent and specific intent to infringe that patent.

44. Notwithstanding Padagis's knowledge of the claims of the '073 patent, Padagis has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Padagis's

ANDA Product with its product labeling following FDA approval of Padagis's ANDA prior to the expiration of the '073 patent.

45. The foregoing actions by Padagis constitute and/or will constitute infringement of the '073 patent and active inducement of infringement by others of the '073 patent.

46. Plaintiffs will be substantially and irreparably damaged by infringement of the '073 patent.

47. Unless Padagis is enjoined from infringing the '073 patent and actively inducing infringement of the '073 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Padagis on the other regarding Padagis's infringement and active inducement of infringement of the '073 patent.

50. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or whose use is covered by the '073 patent, will infringe and induce the infringement by others of the '073 patent.

COUNT III – INFRINGEMENT OF THE '919 PATENT

51. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

52. The '919 patent, entitled, "Compositions Comprising Azelastine and Methods of use Thereof" (attached as Exhibit B), was duly and legally issued on August 27, 2013.

53. Meda is the owner and assignee of the '919 patent.

54. Bayer holds an exclusive license to the '919 patent for the commercial exploitation and sale of Astepro® Allergy and Astepro® Children's Allergy.

55. In general, the claims of the '919 patent are directed to methods for treating allergic rhinitis and non-allergic vasomotor rhinitis comprising administering a liquid pharmaceutical composition comprising azelastine hydrochloride.

56. The '919 patent has been listed in connection with NDA 213872 in FDA's Orange Book.

57. In Padagis's Notice Letter, Padagis notified Plaintiffs of the submission of Padagis's ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Padagis's ANDA Product prior to the expiration of the '919 patent.

58. In Padagis's Notice Letter, Padagis also notified Plaintiffs that, as part of its ANDA, Padagis filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '919 patent. On information and belief, Padagis submitted its ANDA to FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '919 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product.

59. According to Padagis's Notice Letter, Padagis's ANDA Product is a nasal spray solution that contains azelastine hydrochloride. On information and belief, the use of Padagis's ANDA Product in accordance with its proposed labeling is covered by at least claim 1 of the '919 patent.

60. In Padagis's Notice Letter, Padagis did not contest the infringement of any claim of the '919 patent on any basis other than the alleged invalidity of the claims.

61. Padagis's submission of Padagis's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product before the expiration of the '919 patent was an act of infringement of the '919 patent under 35 U.S.C. § 271(e)(2)(A).

62. On information and belief, Padagis will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product, including with its proposed labeling, immediately and imminently upon approval of Padagis's ANDA.

63. On information and belief, the manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '919 patent, including at least claim 1 of the '919 patent.

64. On information and belief, Padagis plans and intends to, and will, actively induce infringement of the '919 patent when Padagis's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Padagis's activities will be done with knowledge of the '919 patent and specific intent to infringe that patent.

65. On information and belief, Padagis knows that Padagis's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '919 patent, that Padagis's ANDA Product is not a staple article or commodity of commerce, and that Padagis's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Padagis plans and intends to, and will, contribute to infringement of the '919 patent immediately and imminently upon approval of Padagis's ANDA.

66. Notwithstanding Padagis's knowledge of the claims of the '919 patent, Padagis has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Padagis's ANDA Product with its proposed labeling following FDA approval of Padagis's ANDA prior to the expiration of the '919 patent.

67. The foregoing actions by Padagis constitute and/or will constitute infringement of the '919 patent; active inducement of infringement of the '919 patent; and contribution to the infringement by others of the '919 patent.

68. Plaintiffs will be substantially and irreparably damaged by infringement of the '919 patent.

69. Unless Padagis is enjoined from infringing the '919 patent, actively inducing infringement of the '919 patent, and contributing to the infringement by others of the '919 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '919 PATENT

70. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

71. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '919 patent.

72. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product whose use is covered by the '919 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '919 patent.

COUNT V – INFRINGEMENT OF THE '050 PATENT

73. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

74. The '050 patent, entitled "Compositions Comprising Azelastine" (attached as Exhibit C), was duly and legally issued on March 20, 2018.

75. Meda is the owner and assignee of the '050 patent.

76. Bayer holds an exclusive license to the '050 patent for the commercial exploitation and sale of Astepro® Allergy and Astepro® Children's Allergy.

77. In general, the claims of the '050 patent are directed to liquid intranasal compositions comprising azelastine hydrochloride.

78. Astepro® Allergy is covered by the '050 patent, including at least claim 1 of the '050 patent, and the '050 patent has been listed in connection with NDA 213872 in the FDA's Orange Book.

79. In Padagis's Notice Letter, Padagis notified Plaintiffs of the submission of Padagis's ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Padagis's ANDA Product prior to the expiration of the '050 patent.

80. In Padagis's Notice Letter, Padagis also notified Plaintiffs that, as part of its ANDA, Padagis filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '050 patent. On information and belief, Padagis submitted its ANDA to FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '050 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product.

81. According to Padagis's Notice Letter, Padagis's ANDA Product is a nasal spray solution that contains azelastine hydrochloride. On information and belief, Padagis's ANDA Product meets the other limitations of at least claim 1 of the '050 patent.

82. On information and belief, Padagis's ANDA Product and the use of Padagis's ANDA Product in accordance with its proposed labeling are covered by at least claim 1 of the '050 patent.

83. Padagis's submission of Padagis's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product before the expiration of the '050 patent was an act of infringement of the '050 patent under 35 U.S.C. § 271(e)(2)(A).

84. On information and belief, Padagis will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of Padagis's ANDA.

85. On information and belief, the manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '050 patent, including at least claim 1 of the '050 patent.

86. In Padagis's Notice Letter, Padagis did not contest the infringement of any claim of the '050 patent on any basis other than the alleged invalidity of the claims.

87. Padagis's submission of Padagis's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product before the expiration of the '050 patent was an act of infringement of the '050 patent under 35 U.S.C. § 271(e)(2)(A).

88. On information and belief, Padagis will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of its ANDA.

89. On information and belief, the manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '050 patent, including at least claim 1 of the '050 patent.

90. On information and belief, the manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '050 patent, including at least claim 1 of the '050 patent.

91. On information and belief, Padagis plans and intends to, and will, actively induce infringement of the '050 patent when Padagis's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Padagis's activities will be done with knowledge of the '050 patent and specific intent to infringe that patent.

92. Notwithstanding Padagis's knowledge of the claims of the '050 patent, Padagis has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Padagis's ANDA Product with its proposed labeling following FDA approval of Padagis's ANDA prior to the expiration of the '050 patent.

93. The foregoing actions by Padagis constitute and/or will constitute infringement of the '050 patent and active inducement of infringement of the '050 patent.

94. Plaintiffs will be substantially and irreparably damaged by infringement of the '050 patent.

95. Unless Padagis is enjoined from infringing the ’050 patent and actively inducing infringement of the ’050 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’050 PATENT

96. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

97. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Padagis on the other regarding Padagis’s infringement and active inducement of infringement of the ’050 patent.

98. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis’s ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or whose use is covered by the ’050 patent, will infringe and induce the infringement of the ’050 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a) A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Padagis’s submission to FDA of Padagis’s ANDA;

b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Padagis’s ANDA Product, or any other drug product that infringes or the use of which infringes one or more of the Patents-in-Suit, be not earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

c) A preliminary and permanent injunction enjoining Padagis, and all persons acting

in concert with Padagis, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Padagis's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the Patents-in-Suit, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product, or any other drug product which is covered by or whose use is covered by one-or-more of the Patents-in-Suit, prior to the latest of the expiration dates of the Patents-in-Suit, will infringe, induce the infringement of, and/or contribute to the infringement by others of, the Patents-in-Suit;

e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

f) Costs and expenses in this action; and

g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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