IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARCUTIS BIOTHERAPEUTICS, INC., Plaintiff, v. PADAGIS ISRAEL PHARMACEUTICALS LTD.; PADAGIS US LLC; and PADAGIS LLC, Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Arcutis Biotherapeutics, Inc. ("Arcutis" or "Plaintiff"), by and through its undersigned counsel, hereby files this Complaint for patent infringement against Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Defendants" or "Padagis"):

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, §§ 1, *et seq.*, including 35 U.S.C. § 271(e)(2); and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271 (a), (b), and (c); relating to patents that concern Arcutis's revolutionary steroid-free topical cream for the treatment of plaque psoriasis, ZORYVE® (roflumilast) cream, 0.3%.

2. This action arises out of Padagis's filing of Abbreviated New Drug Application ("ANDA") No. 219158 with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, prior to the expiration of U.S. Patent Nos. 9,884,050 (the "'050 Patent"), 9,907,788 (the "'788 Patent"),

10,940,142 (the "'142 Patent"), 11,129,818 (the "'818 Patent"), 11,793,796 (the "'796 Patent"), and 11,819,496 (the "'496 Patent") (collectively, the "Patents-in-Suit"), including any extensions and/or additional periods of exclusivity to which Arcutis is or will be entitled. Arcutis attaches hereto true and accurate copies of the Patents-in-Suit as Exhibits A–F.

THE PARTIES

3. Arcutis Biotherapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 3027 Townsgate Road, Suite 300, Westlake Village, CA, 91361. Arcutis is an innovator of dermatological drug products focused on meeting unmet needs in the treatment of immune-mediated skin diseases, including plaque psoriasis, atopic dermatitis, seborrheic dermatitis, and scalp psoriasis. Arcutis commercializes and distributes a novel non-steroidal topical cream for the treatment of plaque psoriasis under the registered trademark ZORYVE® in this District and throughout the United States. Arcutis is the original assignee of the Patents-in-Suit.

4. On information and belief, Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis Israel") is a company organized and existing under the laws of Israel with a principal place of business at 1 Burnstein Zvi, Yeruham, 8050315, Israel, and 1 Rakefet St., Shoham 608500, Israel.

5. On information and belief, Defendant Padagis US LLC ("Padagis US") 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.

6. On information and belief, Defendant Padagis LLC ("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.

7. On information and belief, Padagis, themselves and through their subsidiaries, affiliates, agents and partners, manufacture, distribute, and/or import generic copies of branded pharmaceutical products for sale and use throughout the United States, including in this District.

8. On information and belief, Padagis, themselves and with their subsidiaries, affiliates, agents, and partners, prepared and filed ANDA No. 219158 ("Padagis's ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Arcutis's ZORYVE® (roflumilast) cream, 0.3% ("Padagis's Proposed ANDA Product"), in the United States, including in this District, if the FDA approves Padagis's ANDA.

9. On information and belief, Padagis Israel Pharmaceuticals Ltd. and Padagis US LLC are wholly owned subsidiaries of Padagis LLC and are controlled by Padagis LLC.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100, *et seq*., including §§ 271(e)(2); 271(a), (b), and (c); and 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

Jurisdiction and Venue for Defendant Padagis Israel Ltd.

11. On information and belief, Padagis Israel prepared and filed Padagis's ANDA, seeking approval to manufacture, import, market, and/or sell a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, in this District, and thus committed an act of patent infringement in this District pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Arcutis in the State of Delaware and throughout the United States.

12. Upon information and belief, this Court has personal jurisdiction over Padagis Israel by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. Upon information and belief, Padagis Israel is in the business of, *inter alia*,

developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Padagis Israel directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States, including Delaware, and Delaware is a likely destination for Padagis's Proposed ANDA Product. Upon information and belief, Padagis Israel purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Padagis Israel has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Journey Medical Corp. v. Padagis Israel Pharms., Ltd.*, C.A. 1:21-cv-01152-CFC, D.I. 10 (D. Del. Oct. 1, 2021).

13. On information and belief, Padagis Israel markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates, including Padagis US and Padagis LLC.

14. The Court also has personal jurisdiction over Padagis Israel because Padagis Israel has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drug—that will be purposefully directed at, upon information and belief, Delaware and elsewhere. Padagis Israel's ANDA filing constitutes a formal act that reliably indicates plans to engage in marketing of the proposed generic drug. Upon information and belief, Padagis Israel intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them. Upon information and belief, Padagis Israel will engage in marketing of its Proposed ANDA Product in Delaware upon approval of its ANDA.

15. Alternatively, this Court may exercise personal jurisdiction over Padagis Israel pursuant to Federal Rule of Civil Procedure 4(k)(2) because Padagis Israel has extensive contacts

with the United States, including but not limited to: (a) the fact that Arcutis's claims arise under federal law; (b) the fact that Padagis Israel is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Padagis Israel has sufficient contacts with the United States as a whole, including, without limitation, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Padagis Israel satisfies due process.

16. Venue is proper as to Padagis Israel in this District under 28 U.S.C. § 1391(c)(3) because Padagis Israel is a foreign corporation 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.

Jurisdiction and Venue for Padagis US LLC

17. Upon information and belief, this Court has personal jurisdiction over Padagis US by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. Upon information and belief, Padagis US is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Padagis US directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States, including Delaware, and Delaware is a likely destination for Padagis's Proposed ANDA Product. Upon information and belief, Padagis US purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Padagis US has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Hikma Pharms. USA Inc. v. Padagis Israel Pharms. Ltd.*, C.A. 1:23-cv-00654-GBW-SRF, D.I. 11 (Aug. 14, 2023).

18. This Court has personal jurisdiction over Padagis US in that it is incorporated in Delaware and by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Padagis US regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic copies of branded pharmaceutical products in the United States, including Delaware. On information and belief, Padagis US derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

19. On information and belief, Padagis US markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates, including Padagis LLC.

20. On information and belief, Padagis US is licensed to sell generic pharmaceutical products in Delaware, pursuant to 24 Del. C. § 2540.

21. On information and belief, Padagis US intends to commercially manufacture, use, and sell Padagis's Proposed ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Padagis's ANDA, Padagis's Proposed ANDA Product would, *inter alia*, be marketed, distributed, and sold in Delaware, and/or prescribed by practicing physicians and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

22. Venue is proper as to Padagis US in this District under 28 U.S.C. § 1400(b) because Padagis US is incorporated in and resides in Delaware.

Jurisdiction and Venue for Padagis LLC

23. Upon information and belief, this Court has personal jurisdiction over Padagis LLC by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged

herein. Upon information and belief, Padagis LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Padagis LLC directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States, including Delaware, and Delaware is a likely destination for Padagis's Proposed ANDA Product. Upon information and belief, Padagis LLC purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Padagis LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Hikma Pharms. USA Inc. v. Padagis Israel Pharms. Ltd.*, C.A. 1:23-cv-00654-GBW-SRF, D.I. 11 (D. Del. Aug. 14, 2023).

24. This Court has personal jurisdiction over Padagis LLC in that it is incorporated in Delaware and by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Padagis LLC regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic copies of branded pharmaceutical products in the United States, including Delaware. On information and belief, Padagis LLC derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

25. On information and belief, Padagis LLC intends to commercially manufacture, use, and sell Padagis's Proposed ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Padagis's ANDA, Padagis's Proposed ANDA Product would, *inter alia*, be marketed, distributed, and sold in Delaware, and/or prescribed by practicing

physicians and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

26. Venue is proper as to Padagis LLC in this District under 28 U.S.C. § 1400(b) because Padagis LLC is incorporated in and resides in Delaware.

BACKGROUND

Patents-in-Suit

U.S. Patent No. 9,884,050

27. U.S. Patent No. 9,884,050 (the "'050 Patent"), titled "Inhibition of Crystal Growth of Roflumilast," was duly and legally issued by the U.S. Patent and Trademark Office on February 6, 2018. A true and correct copy of the '050 Patent is attached hereto as Exhibit A.

28. The claims of the '050 Patent are valid, enforceable, and not expired.

29. Arcutis is the original assignee of the '050 Patent.

U.S. Patent No. 9,907,788

30. U.S. Patent No. 9,907,788 (the "'788 Patent"), titled "Inhibition of Crystal Growth of Roflumilast," was duly and legally issued by the U.S. Patent and Trademark Office on March 6, 2018. A true and correct copy of the '788 Patent is attached hereto as Exhibit B.

31. The claims of the '788 Patent are valid, enforceable, and not expired.

32. Arcutis is the original assignee of the '788 Patent.

U.S. Patent No. 10,940,142

33. U.S. Patent No. 10,940,142 (the "'142 Patent"), titled "Inhibition of Crystal Growth of Roflumilast," was duly and legally issued by the U.S. Patent and Trademark Office on March 9, 2021. A true and correct copy of the '142 Patent is attached hereto as Exhibit C.

34. The claims of the '142 Patent are valid, enforceable, and not expired.

35. Arcutis is the original assignee of the ’142 Patent.

U.S. Patent No. 11,129,818

36. U.S. Patent No. 11,129,818 (the “’818 Patent”), titled “Topical Roflumilast Formulation Having Improved Delivery and Plasma Half Life,” was duly and legally issued by the U.S. Patent and Trademark Office on September 28, 2021. A true and correct copy of the ’818 Patent is attached hereto as Exhibit D.

37. The claims of the ’818 Patent are valid, enforceable, and not expired.

38. Arcutis is the original assignee of the ’818 Patent.

U.S. Patent No. 11,793,796

39. U.S. Patent No. 11,793,796 (the “’796 Patent”), titled “Inhibition of Crystal Growth of Roflumilast,” was duly and legally issued by the U.S. Patent and Trademark Office on October 24, 2023. A true and correct copy of the ’796 Patent is attached hereto as Exhibit E.

40. The claims of the ’796 Patent are valid, enforceable, and not expired.

41. Arcutis is the original assignee of the ’796 Patent.

U.S. Patent No. 11,819,496

42. U.S. Patent No. 11,819,496 (the “’496 Patent”), titled “Topical Roflumilast Formulation Having Improved Delivery and Plasma Half Life,” was duly and legally issued by the U.S. Patent and Trademark Office on November 21, 2023. A true and correct copy of the ’496 Patent is attached hereto as Exhibit F.

43. The claims of the ’496 Patent are valid, enforceable, and not expired.

44. Arcutis is the original assignee of the ’496 Patent.

Acts Giving Rise to This Action

45. Arcutis holds approved New Drug Application ("NDA") No. 215985 for 0.3% roflumilast cream for the treatment of plaque psoriasis, including intertriginous areas, in patients 6 years and older, as further described in the ZORYVE® label.

46. Arcutis markets the cream under NDA No. 215985 in the United States under the registered trademark ZORYVE®.

47. In conjunction with NDA No. 215985, Arcutis has listed with the FDA the following patents for ZORYVE® (roflumilast) cream, 0.3%: United States Patent Nos. 9,884,050; 9,907,788; 10,940,142; 11,129,818; 11,793,796; and 11,819,496. The FDA has published these patents in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book."

48. At least one claim of each of the Patents-in-Suit covers ZORYVE® (roflumilast) cream, 0.3%, and/or approved methods of using it.

49. On information and belief, Padagis prepared and submitted to the FDA ANDA No. 219158 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of Padagis's Proposed ANDA Product prior to the expiration of the Patents-in-Suit.

50. On information and belief, Padagis sent a letter dated February 13, 2024, to Arcutis (the "Paragraph IV Letter"), purporting to be a notice pursuant to 21 U.S.C. § 505(j)(2)(B). Padagis's Paragraph IV Letter purports to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit.

51. Arcutis received Padagis's Paragraph IV Letter on February 14, 2024.

52. This action is being commenced before the expiration of 45 days from the date Arcutis received Padagis's Paragraph IV Letter, which triggers an automatic stay of FDA approval of Padagis's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

53. By filing Padagis's ANDA, Padagis has necessarily represented to the FDA that Padagis's Proposed ANDA Product has the same active ingredient as ZORYVE® (roflumilast) cream, 0.3%; has the same dosage form and strength as ZORYVE® (roflumilast) cream, 0.3%; and is bioequivalent to ZORYVE® (roflumilast) cream, 0.3%.

54. On information and belief, Padagis is seeking approval to market Padagis's Proposed ANDA Product for the same approved indication as ZORYVE® (roflumilast) cream, 0.3%.

55. On information and belief, Padagis's ANDA contains data from bioavailability or bioequivalence studies for Padagis's Proposed ANDA Product.

56. On information and belief, Padagis's proposed prescribing information for Padagis's Proposed ANDA Product (the "Proposed Padagis Label") will refer to the product as, *inter alia*, a roflumilast cream, 0.3%, for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

57. On information and belief, the Proposed Padagis Label will instruct and/or encourage physicians and healthcare providers to administer Padagis's Proposed ANDA Product for, *inter alia*, the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

58. On information and belief, if and when FDA approves Padagis's ANDA, Padagis will sell its approved generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, throughout the United States, including in Delaware.

59. Attached to Padagis's Paragraph IV Letter is a statement of the purported factual and legal bases for Padagis's position that the Patents-in-Suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Padagis's Proposed ANDA Product described in ANDA No. 219158.

60. In particular, Padagis's Paragraph IV Letter alleges that the claims of the Patents-in-Suit are not infringed and are invalid.

61. Padagis's Paragraph IV Letter included an Offer for Confidential Access to Application ("OCA") in which Padagis purported to offer to provide confidential access to certain information from Padagis's ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in 21 U.S.C. § 355(j)(5)(B)(iii) can be brought, subject to certain terms and conditions set forth in the OCA. Under 35 U.S.C. § 355(j)(5)(C)(i)(III), the "document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Padagis's OCA contained unreasonable restrictions, above and beyond those that would apply under a court-ordered protective order.

62. Since receiving Padagis's Paragraph IV Letter, Arcutis has been negotiating in good faith to reach a mutually-acceptable agreement under which Padagis would provide Padagis's ANDA to Arcutis. To date, Padagis has refused to offer Arcutis access to Padagis's ANDA under terms consistent with a protective order entered for the purpose of protecting trade secrets and other confidential business information. As a result, Arcutis has been unable to access Padagis's ANDA.

63. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including an automatic stay of FDA approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate, pursuant to 21 U.S.C. § 355(c)(3)(C).

64. Arcutis is not aware of any other means for obtaining information about Padagis's Proposed ANDA Product within the 45-day statutory period set forth in 21 U.S.C. § 355(c)(3)(C). In the absence of additional information, Arcutis resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and present to the Court evidence that Padagis's Proposed ANDA Product would infringe one or more claims of the Patents-in-Suit upon FDA approval.

65. Because Arcutis has been unable to obtain a copy of Padagis's ANDA, Arcutis alleges the causes herein based primarily on the representations contained in Padagis's Paragraph IV Letter and the other facts alleged herein.

COUNT I: INFRINGEMENT OF THE '050 PATENT UNDER 35 U.S.C. § 271(e)(2) BY PADAGIS'S ANDA

66. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

67. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of one or more claims of the '050 Patent by submitting ANDA No. 219158 to the FDA under Section 505(j) of the Food, Drug, and Cosmetic ("FD&C") Act to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product in the United States prior to the expiration of the '050 Patent.

68. Padagis has actual knowledge of the '050 Patent.

69. Padagis made and included in Padagis's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '050 Patent will not be infringed, is invalid, and/or is unenforceable.

70. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product prior to the expiration of the '050 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '050 Patent, including but not limited to claim 1.[1]

71. On information and belief, Padagis became aware of the '050 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of ZORYVE® (roflumilast) cream, 0.3%, by February 13, 2024, when Padagis sent its Paragraph IV Letter.

72. On information and belief, Padagis will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product. On information and belief, Padagis will engage in such activities upon the FDA's approval of Padagis's ANDA.

73. On information and belief, Padagis knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '050 Patent.

74. The commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product in violation of Arcutis's patent rights will cause harm to Arcutis for which damages are inadequate.

[1] Arcutis will identify all asserted claims of the '050 Patent in accordance with this Court's Local Rules and/or scheduling order.

75. Unless and until Padagis is enjoined from infringing the ’050 Patent, Arcutis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: INFRINGEMENT OF THE ’050 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) BY PADAGIS’S ANDA

76. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

77. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

78. There is an actual case or controversy such that the Court may entertain Arcutis’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.

79. Padagis has submitted Padagis’s ANDA for a generic version of Arcutis’s ZORYVE® (roflumilast) cream, 0.3%, product. According to Padagis’s Paragraph IV Letter, Padagis intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Padagis’s Proposed ANDA Product in the United States before the expiration of the ’050 Patent.

80. While the FDA has not yet approved Padagis’s ANDA, Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Padagis’s Proposed ANDA Product.

81. Padagis’s actions indicate that it does not intend to change its course of conduct.

82. On information and belief, upon FDA approval of Padagis’s ANDA, Padagis will infringe one or more claims of the ’050 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[2] by making, using, offering for sale, and/or selling Padagis’s

[2] Arcutis will identify all asserted claims of the ’050 Patent in accordance with this Court’s Local Rules and/or scheduling order.

Proposed ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '050 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

83. Padagis has actual knowledge of the '050 Patent.

84. On information and belief, Padagis became aware of the '050 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book.

COUNT III: INFRINGEMENT OF THE '788 PATENT UNDER 35 U.S.C. § 271(e)(2) BY PADAGIS'S ANDA

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

86. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of one or more claims of the '788 Patent by submitting ANDA No. 219158 to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product in the United States prior to the expiration of the '788 Patent.

87. Padagis has actual knowledge of the '788 Patent.

88. Padagis made and included in Padagis's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '788 Patent will not be infringed, is invalid, and/or is unenforceable.

89. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product prior to the expiration of the '788 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement, either literally or under the

doctrine of equivalents, of at least one of the claims of the '788 Patent, including but not limited to claim 1.[3]

90. On information and belief, Padagis became aware of the '788 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of ZORYVE® (roflumilast) cream, 0.3%, by February 13, 2024, when Padagis sent its Paragraph IV Letter.

91. On information and belief, Padagis will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product. On information and belief, Padagis will engage in such activities upon the FDA's approval of Padagis's ANDA.

92. On information and belief, Padagis knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '788 Patent.

93. The commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product in violation of Arcutis's patent rights will cause harm to Arcutis for which damages are inadequate.

94. Unless and until Padagis is enjoined from infringing the '788 Patent, Arcutis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: INFRINGEMENT OF THE '788 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) BY PADAGIS'S ANDA

95. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

96. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[3] Arcutis will identify all asserted claims of the '788 Patent in accordance with this Court's Local Rules and/or scheduling order.

97. There is an actual case or controversy such that the Court may entertain Arcutis'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.

98. Padagis has submitted Padagis's ANDA for a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, product. According to Padagis's Paragraph IV Letter, Padagis intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Padagis's Proposed ANDA Product in the United States before the expiration of the '788 Patent.

99. While the FDA has not yet approved Padagis's ANDA, Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Padagis's Proposed ANDA Product.

100. Padagis's actions indicate that it does not intend to change its course of conduct.

101. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '788 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[4] by making, using, offering for sale, and/or selling Padagis's Proposed ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '788 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

102. Padagis has actual knowledge of the '788 Patent.

[4] Arcutis will identify all asserted claims of the '788 Patent in accordance with this Court's Local Rules and/or scheduling order.

103. On information and belief, Padagis became aware of the '788 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book.

COUNT V: INFRINGEMENT OF THE '142 PATENT UNDER 35 U.S.C. § 271(e)(2) BY PADAGIS'S ANDA

104. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

105. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of one or more claims of the '142 Patent by submitting ANDA No. 219158 to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product in the United States prior to the expiration of the '142 Patent.

106. Padagis has actual knowledge of the '142 Patent.

107. Padagis made and included in Padagis's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '142 Patent will not be infringed, is invalid, and/or is unenforceable.

108. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product prior to the expiration of the '142 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '142 Patent, including but not limited to claim 1.[5]

109. On information and belief, Padagis became aware of the '142 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange

[5] Arcutis will identify all asserted claims of the '142 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book as covering the approved product and uses of ZORYVE® (roflumilast) cream, 0.3%, by February 13, 2024, when Padagis sent its Paragraph IV Letter.

110. On information and belief, Padagis will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product. On information and belief, Padagis will engage in such activities upon the FDA's approval of Padagis's ANDA.

111. On information and belief, Padagis knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '142 Patent.

112. The commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product in violation of Arcutis's patent rights will cause harm to Arcutis for which damages are inadequate.

113. Unless and until Padagis is enjoined from infringing the '142 Patent, Arcutis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI: INFRINGEMENT OF THE '142 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) BY PADAGIS'S ANDA

114. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

115. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. There is an actual case or controversy such that the Court may entertain Arcutis'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.

117. Padagis has submitted Padagis's ANDA for a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, product. According to Padagis's Paragraph IV Letter, Padagis intends to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of Padagis's Proposed ANDA Product in the United States before the expiration of the '142 Patent.

118. While the FDA has not yet approved Padagis's ANDA, Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Padagis's Proposed ANDA Product.

119. Padagis's actions indicate that it does not intend to change its course of conduct.

120. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '142 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[6] by making, using, offering for sale, and/or selling Padagis's Proposed ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '142 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

121. Padagis has actual knowledge of the '142 Patent.

122. On information and belief, Padagis became aware of the '142 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book.

COUNT VII: INFRINGEMENT OF THE '818 PATENT UNDER 35 U.S.C. § 271(e)(2) BY PADAGIS'S ANDA

123. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

124. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of one or more claims of the '818 Patent by submitting ANDA No. 219158 to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, use,

[6] Arcutis will identify all asserted claims of the '142 Patent in accordance with this Court's Local Rules and/or scheduling order.

offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product in the United States prior to the expiration of the '818 Patent.

125. Padagis has actual knowledge of the '818 Patent.

126. Padagis made and included in Padagis's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '818 Patent will not be infringed, is invalid, and/or is unenforceable.

127. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product prior to the expiration of the '818 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '818 Patent, including but not limited to claim 1.[7]

128. On information and belief, Padagis became aware of the '818 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of ZORYVE® (roflumilast) cream, 0.3%, by February 13, 2024, when Padagis sent its Paragraph IV Letter.

129. On information and belief, Padagis will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product. On information and belief, Padagis will engage in such activities upon the FDA's approval of Padagis's ANDA.

130. On information and belief, Padagis knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '818 Patent.

[7] Arcutis will identify all asserted claims of the '818 Patent in accordance with this Court's Local Rules and/or scheduling order.

131. The commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product in violation of Arcutis's patent rights will cause harm to Arcutis for which damages are inadequate.

132. Unless and until Padagis is enjoined from infringing the '818 Patent, Arcutis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII: INFRINGEMENT OF THE '818 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) BY PADAGIS'S ANDA

133. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

134. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

135. There is an actual case or controversy such that the Court may entertain Arcutis'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.

136. Padagis has submitted Padagis's ANDA for a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, product. According to Padagis's Paragraph IV Letter, Padagis intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Padagis's Proposed ANDA Product in the United States before the expiration of the '818 Patent.

137. While the FDA has not yet approved Padagis's ANDA, Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Padagis's Proposed ANDA Product.

138. Padagis's actions indicate that it does not intend to change its course of conduct.

139. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '818 Patent, including without limitation claim 1, either literally

or under the doctrine of equivalents,[8] by making, using, offering for sale, and/or selling Padagis's Proposed ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '818 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

140. Padagis has actual knowledge of the '818 Patent.

141. On information and belief, Padagis became aware of the '818 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book.

COUNT IX: INFRINGEMENT OF THE '796 PATENT UNDER 35 U.S.C. § 271(e)(2) BY PADAGIS'S ANDA

142. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

143. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of one or more claims of the '796 Patent by submitting ANDA No. 219158 to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product in the United States prior to the expiration of the '796 Patent.

144. Padagis has actual knowledge of the '796 Patent.

145. Padagis made and included in Padagis's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '796 Patent will not be infringed, is invalid, and/or is unenforceable.

146. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product prior to the expiration of the '796 Patent, and its inducement

[8] Arcutis will identify all asserted claims of the '818 Patent in accordance with this Court's Local Rules and/or scheduling order.

of and/or contribution to such conduct, would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '796 Patent, including but not limited to claim 1.[9]

147. On information and belief, Padagis became aware of the '796 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book as covering the approved product and uses of ZORYVE® (roflumilast) cream, 0.3%, by February 13, 2024, when Padagis sent its Paragraph IV Letter.

148. On information and belief, Padagis will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product. On information and belief, Padagis will engage in such activities upon the FDA's approval of Padagis's ANDA.

149. On information and belief, Padagis knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '796 Patent.

150. The commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product in violation of Arcutis's patent rights will cause harm to Arcutis for which damages are inadequate.

151. Unless and until Padagis is enjoined from infringing the '796 Patent, Arcutis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT X: INFRINGEMENT OF THE '796 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) BY PADAGIS'S ANDA

152. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

[9] Arcutis will identify all asserted claims of the '796 Patent in accordance with this Court's Local Rules and/or scheduling order.

153. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

154. There is an actual case or controversy such that the Court may entertain Arcutis'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.

155. Padagis has submitted Padagis's ANDA for a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, product. According to Padagis's Paragraph IV Letter, Padagis intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Padagis's Proposed ANDA Product in the United States before the expiration of the '796 Patent.

156. While the FDA has not yet approved Padagis's ANDA, Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Padagis's Proposed ANDA Product.

157. Padagis's actions indicate that it does not intend to change its course of conduct.

158. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '796 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[10] by making, using, offering for sale, and/or selling Padagis's Proposed ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '796 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

159. Padagis has actual knowledge of the '796 Patent.

[10] Arcutis will identify all asserted claims of the '796 Patent in accordance with this Court's Local Rules and/or scheduling order.

160. On information and belief, Padagis became aware of the '796 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book.

COUNT XI: INFRINGEMENT OF THE '496 PATENT UNDER 35 U.S.C. § 271(e)(2) BY PADAGIS'S ANDA

161. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

162. Pursuant to 35 U.S.C. § 271(e)(2)(A), Padagis has committed an act of infringement of one or more claims of the '496 Patent by submitting ANDA No. 219158 to the FDA under Section 505(j) of the FD&C Act to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product in the United States prior to the expiration of the '496 Patent.

163. Padagis has actual knowledge of the '496 Patent.

164. Padagis made and included in Padagis's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '496 Patent will not be infringed, is invalid, and/or is unenforceable.

165. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's Proposed ANDA Product prior to the expiration of the '496 Patent, and its inducement of and/or contribution to such conduct, would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '496 Patent, including but not limited to claim 1.[11]

166. On information and belief, Padagis became aware of the '496 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange

[11] Arcutis will identify all asserted claims of the '496 Patent in accordance with this Court's Local Rules and/or scheduling order.

Book as covering the approved product and uses of ZORYVE® (roflumilast) cream, 0.3%, by February 13, 2024, when Padagis sent its Paragraph IV Letter.

167. On information and belief, Padagis will engage in the commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product. On information and belief, Padagis will engage in such activities upon the FDA's approval of Padagis's ANDA.

168. On information and belief, Padagis knows or should know that its commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product will infringe and/or actively induce and/or contribute to the actual infringement of the '496 Patent.

169. The commercial manufacture, importation, use, sale, and/or offer for sale of Padagis's Proposed ANDA Product in violation of Arcutis's patent rights will cause harm to Arcutis for which damages are inadequate.

170. Unless and until Padagis is enjoined from infringing the '496 Patent, Arcutis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XII: INFRINGEMENT OF THE '496 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) BY PADAGIS'S ANDA

171. Arcutis incorporates each of the preceding paragraphs as if fully set forth herein.

172. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

173. There is an actual case or controversy such that the Court may entertain Arcutis'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.

174. Padagis has submitted Padagis's ANDA for a generic version of Arcutis's ZORYVE® (roflumilast) cream, 0.3%, product. According to Padagis's Paragraph IV Letter, Padagis intends to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of Padagis's Proposed ANDA Product in the United States before the expiration of the '496 Patent.

175. While the FDA has not yet approved Padagis's ANDA, Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Padagis's Proposed ANDA Product.

176. Padagis's actions indicate that it does not intend to change its course of conduct.

177. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '496 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents,[12] by making, using, offering for sale, and/or selling Padagis's Proposed ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and/or contributing to infringement of the '496 Patent by others, under 35 U.S.C. §§ 271(a)-(c), unless enjoined by the Court.

178. Padagis has actual knowledge of the '496 Patent.

179. On information and belief, Padagis became aware of the '496 Patent no later than the date on which it was issued by the Patent and Trademark Office and/or was listed in the Orange Book.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Arcutis hereby demands a trial by jury of all issues that are or may become triable.

PRAYER FOR RELIEF

WHEREFORE, Arcutis respectfully prays for the following relief:

[12] Arcutis will identify all asserted claims of the '496 Patent in accordance with this Court's Local Rules and/or scheduling order.

A. A judgment be issued declaring that (1) Defendants have infringed one or more claims of the '050 Patent, the '788 Patent, the '142 Patent, the '818 Patent, the '796 Patent, and/or the '496 Patent under 35 U.S.C. §§ 271, *et seq.*, by submitting ANDA No. 219158 under Section 505(j) of the FD&C Act seeking approval for the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Padagis's Proposed ANDA Product prior to expiration of the Patents-in-Suit, and (2) that Defendants' commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Padagis's Proposed ANDA Product will constitute infringement of one or more claims of the '050 Patent, the '788 Patent, the '142 Patent, the '818 Patent, the '796 Patent, and/or the '496 Patent;

B. A judgment be issued declaring that the '050 Patent, the '788 Patent, the '142 Patent, the '818 Patent, the '796 Patent, and/or the '496 Patent are not invalid or unenforceable;

C. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Defendants' ANDA No. 219158 shall be a date which is not earlier than the expiration date of the Patents-in-Suit, as extended by any applicable periods of exclusivity;

D. An order be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the Patents-in-Suit prior to expiration of the Patents-in-Suit, inclusive of any extensions;

E. An order be issued under 35 U.S.C. § 283 permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the Patents-in-Suit prior to expiration of the Patents-in-Suit, inclusive of any extensions;

F. An order be issued pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis's Proposed 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 Padagis or acting on Padagis'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;

G. 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 Plaintiff if Padagis engages in commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Padagis's Proposed ANDA Product prior to the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiff is or will be entitled;

H. This case be declared an exceptional case under 35 U.S.C. § 285, and that Arcutis be awarded reasonable attorneys' fees and costs;

I. The Court award costs and expenses in this action;

J. An accounting be performed of Padagis's infringing activities not presented at trial and an award by the Court of additional damages for any such infringing sales; and

K. This Court award such other and further relief as it may deem just and proper.

Dated: March 27, 2024

FISH & RICHARDSON P.C.

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