IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ALCON INC., ALCON VISION, LLC, and ALCON LABORATORIES, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No._____
PADAGIS ISRAEL PHARMACEUTICALS LTD., PADAGIS US LLC, and PADAGIS LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Alcon Inc., Alcon Vision, LLC, and Alcon Laboratories, Inc. (collectively "Alcon") under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively "Padagis"). This action arises out of Padagis's submission of Abbreviated New Drug Application ("ANDA") No. 212137 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of SIMBRINZA® ("the Padagis ANDA Product") prior to the expiration of U.S. Patent Nos. 9,044,484 and 9,421,265 (collectively, the "Asserted Patents").

PARTIES

2. Plaintiff Alcon Inc. is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Rue Louis-d'Affry 6, 1701 Fribourg, Switzerland. Through its subsidiaries, Alcon Inc. is engaged in the business of creating, developing, and bringing to market life-changing vision and eye care products.

3. Plaintiff Alcon Vision, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 6201 South Freeway, Fort Worth, Texas, 76134. Alcon Vision, LLC is an indirect, wholly owned subsidiary of Alcon Inc. Alcon Vision, LLC sells SIMBRINZA® throughout the United States, including in Delaware.

4. Plaintiff Alcon Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 6201 South Freeway, Fort Worth, Texas, 76134. Alcon Laboratories, Inc. is a direct, wholly owned subsidiary of Alcon Inc.

5. Upon information and belief, Defendant Padagis Israel Pharmaceuticals Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 1 Rakefet Street, Shoham, Israel 6085001. Upon information and belief, Padagis Israel Pharmaceuticals Ltd. is a wholly owned subsidiary of Padagis LLC.

6. Upon information and belief, Defendant Padagis US LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 3940 Quebec Ave North, Minneapolis, MN, 55427. Upon information and belief, Padagis US LLC is a wholly owned subsidiary of Padagis LLC.

7. Upon information and belief, Defendant Padagis LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 1251 Lincoln Road, Allegan, Michigan, 49010.

8. Upon information and belief, Padagis LLC directs the operations, management, and activities of Padagis Israel Pharmaceuticals Ltd. and Padagis LLC in the United States.

9. Upon information and belief, Padagis engages in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs, such as zolmitriptan nasal spray, and brimonidine topical gel) throughout the United States, including in Delaware.

10. Upon information and belief, Padagis prepared and submitted ANDA No. 212137 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of SIMBRINZA® prior to the expiration of the Asserted Patents.

JURISDICTION AND VENUE

11. This case arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

13. This Court has personal jurisdiction over Padagis because Padagis, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by filing ANDA No. 212137, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c), including in Delaware. These acts have led and will continue to lead to foreseeable harm and injury to Alcon Inc., a foreign corporation, as well as to Alcon Vision, LLC and Alcon Laboratories, Inc., Delaware corporations, in Delaware. For example, on information and belief, following approval of ANDA No. 212137, Padagis will make, use, import, sell, and/or offer for sale the Padagis ANDA Product in the United States, including in Delaware, prior to the expiration of the Asserted Patents.

14. The Court also has personal jurisdiction over Padagis because, among other things, this action arises from Padagis's actions directed toward Delaware, and because, upon information and belief, Padagis has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware, including by marketing pharmaceutical products in Delaware.

15. Furthermore, this Court has personal jurisdiction over Padagis US LLC because, upon information and belief, Padagis US LLC is a corporation formed under the laws of the State of Delaware, and by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Padagis US LLC has therefore purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

16. This Court also has personal jurisdiction over Padagis LLC because, upon information and belief, Padagis LLC is a corporation formed under the laws of the State of Delaware, and by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Padagis LLC has therefore purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

17. This Court also has personal jurisdiction over Padagis Israel Pharmaceuticals Ltd. because Padagis Israel Pharmaceuticals Ltd. has previously availed itself of this forum by affirmatively filing counterclaims in other actions pending before this Court, including *Anacor Pharmaceuticals, Inc. et al v. Padagis Israel Pharmaceuticals, Ltd. f/k/a Perrigo Israel Pharmaceuticals, Ltd.*, No. 1-21-cv-01351-CFC (D. Del.).

18. On information and belief, Padagis Israel Pharmaceuticals Ltd.'s contacts with other states of the United States are no greater than its contacts with Delaware. Therefore, to the extent Padagis Israel Pharmaceuticals Ltd. denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with Delaware, this Court has personal jurisdiction over Padagis pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

19. Venue is proper in this Court as to Padagis US LLC under 28 U.S.C. § 1391(b) and 1400(b) because, upon information and belief, Padagis US LLC is incorporated under the state laws of Delaware and therefore resides in the District of Delaware.

20. Venue is proper in this Court as to Padagis LLC under 28 U.S.C. § 1391(b) and 1400(b) because, upon information and belief, Padagis LLC is incorporated under the state laws of Delaware and therefore resides in the District of Delaware.

21. Venue is proper in this Court as to Padagis Israel Pharmaceuticals Ltd. under 28 U.S.C. § 1391(c)(3), because, upon information and belief, it is not a resident of the United States and may thus be sued in any judicial district.

BACKGROUND

22. U.S. Patent No. 9,044,484 ("the '484 Patent"), entitled "Aqueous Pharmaceutical Compositions Containing Borate-Polyol Complexes," was duly and legally issued on June 2, 2015. A true and correct copy of the '484 Patent is attached hereto as "Exhibit A." The '484 Patent will expire on October 30, 2030.

23. U.S. Patent No. 9,421,265 ("the '265 Patent"), entitled "Aqueous Pharmaceutical Compositions Containing Borate-Polyol Complexes," was duly and legally issued on August 23, 2016. A true and correct copy of the '265 Patent is attached hereto as "Exhibit B." The '265 Patent will expire on June 17, 2030.

24. The claims of the '484 and '265 Patents are valid, enforceable, and not expired. All rights and interests in the '484 and '265 Patents are owned by and assigned to Alcon Inc.

25. SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Alcon Vision, LLC sells SIMBRINZA® in the United States pursuant to New Drug Application No. 204251, which was approved by the FDA in 2013.

26. Alcon Laboratories, Inc. is the holder of New Drug Application ("NDA") No. 204251, by which the FDA granted approval for the marketing and sale of

brinzolamide/brimonidine tartrate ophthalmic suspension in the United States, under the trade name "SIMBRINZA®."

27. SIMBRINZA® is covered by, *inter alia*, at least claim 1 of the '484 Patent and at least claim 1 of the '265 Patent. The Asserted Patents have been listed in connection with SIMBRINZA® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "*Orange Book*."

28. By letter dated September 14, 2022, and received via Federal Express on September 16, 2022 (the "Notice Letter"), Padagis Israel Pharmaceuticals Ltd. notified Alcon that Padagis had submitted ANDA No. 212137 to the FDA for a generic version of SIMBRINZA®.

29. Further to the Offer of Confidential Access set forth in the Notice Letter, the parties negotiated terms pursuant to which Padagis Israel Pharmaceuticals Ltd. would produce ANDA No. 212137 to Alcon. Padagis Israel Pharmaceuticals Ltd. produced documents, purportedly from ANDA No. 212137, to Alcon's counsel on October 10, 2022.

30. By submitting ANDA No. 212137, Padagis has represented to the FDA that the Padagis ANDA Product has the same active ingredients, dosage form, and strength as SIMBRINZA®, and is bioequivalent to SIMBRINZA®.

31. In the Notice Letter, Padagis Israel Pharmaceuticals Ltd. stated that ANDA No. 212137 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '484 and '265 Patents, and alleged that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Padagis's ANDA Product.

32. Upon information and belief, Padagis had knowledge of the Asserted Patents when it submitted ANDA No. 212137 to the FDA.

33. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product immediately and imminently upon approval of ANDA No. 212137.

34. This action is being commenced before the expiration of forty-five days from the date of Alcon's receipt of the Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,044,484

35. The Alcon Parties incorporate each of the preceding paragraphs 1 – 34 as if fully set forth herein.

36. Claim 1 of the '484 patent requires a multi-dose ophthalmic composition, comprising: a therapeutically effective amount of brimonidine; a first polyol, the first polyol being selected from mannitol, sorbitol or a combination thereof wherein the concentration of the first polyol in the composition is at least 0.15 w/v % but is less than 0.5 w/v %; a second polyol, the second polyol being selected from propylene glycol, glycerine or a combination thereof wherein the concentration of the second polyol in the composition is at least 0.3 w/v % but less than 1.2 w/v % of the composition; borate in the composition at a concentration that is at least 0.1 w/v % but less than about 0.5 w/v %; BAC as an anti-microbial preservative, the concentration of BAC in the composition being greater than 0.0007 w/v % but less than 0.0035 w/v %; and water; wherein the composition has a pH that is at least 4 but less than 7.0.

37. On information and belief, and Padagis's representations, documents received pursuant to Padagis's Offer of Confidential Access accurately describe the Padagis ANDA product.

38. On information and belief, Padagis's representations and the documents received pursuant to Padagis's Offer of Confidential Access indicate that the Padagis ANDA Product meets

each and every limitation of at least claim 1 of the '484 patent either literally or under the doctrine of equivalents.

39. Padagis's submission of ANDA No. 212137 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product before the expiration of the '484 Patent constituted an act of infringement of at least claim 1 of the '484 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

40. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to expiration of the '484 Patent, and Padagis's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '484 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

41. Upon information and belief, upon FDA approval of ANDA No. 212137, Padagis intends to, and will, infringe at least claim 1 of the '484 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Padagis ANDA Product, unless enjoined by the Court.

42. Upon information and belief, Padagis intends to, and will, actively induce infringement of the '484 patent under 35 U.S.C. § 271(b) when ANDA No. 212137 is approved by marketing the Padagis ANDA Product along with instructions directing users to infringe the '484 patent, unless enjoined by the Court.

43. Upon information and belief, Padagis intends to, and will, contribute to infringement of the '484 patent under 35 U.S.C. § 271(c) when ANDA No. 212137 is approved, unless enjoined by the Court, because Padagis knows that the Padagis ANDA Product is especially made or adapted for use in infringing the '484 patent, and that the Padagis ANDA Product is not suitable for substantial noninfringing use.

44. Padagis's infringement is imminent because, among other things, Padagis has notified Alcon of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product before the expiration of the '484 Patent.

45. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '484 Patent.

46. Pursuant to 28 U.S.C. § 2201, Alcon is entitled to a declaratory judgment that Padagis's making, using, offering to sell, selling, and/or importing the Padagis ANDA Product, inducement thereof or contribution thereto, will infringe the '484 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Upon information and belief, Padagis acted, and, upon FDA approval of ANDA No. 212137, will act, without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the '484 Patent. This is an exceptional case.

48. Unless Padagis is enjoined from directly or indirectly infringing the '484 Patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 9,421,265

49. Alcon incorporates each of the preceding paragraphs 1 – 48 as if fully set forth herein.

50. Claim 1 of the '265 patent requires a multi-dose ophthalmic composition, comprising: a first polyol, the first polyol being selected from mannitol, sorbitol or a combination thereof; a second polyol, the second polyol being selected from propylene glycol, glycerine or a combination thereof; an effective amount of borate, the effective amount being less than about 0.5 w/v % of the overall composition; BAC as an anti-microbial preservative, the concentration of BAC in the composition being greater than 0.00001 w/v % but less than 0.0035 w/v %; a

therapeutic agent; and water; wherein the composition is a suspension with the therapeutic agent and carboxyvinyl polymer as a suspending agent.

51. On information and belief, and Padagis's representations, documents received pursuant to Padagis's Offer of Confidential Access accurately describe the Padagis ANDA product.

52. On information and belief, Padagis's representations and the documents received pursuant to Padagis's Offer of Confidential Access indicate that the Padagis ANDA Product meets each and every limitation of at least claim 1 of the '265 patent either literally or under the doctrine of equivalents.

53. Padagis's submission of ANDA No. 212137 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product before the expiration of the '265 Patent constituted an act of infringement of at least claim 1 of the '265 Patent, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

54. Padagis's commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product prior to expiration of the '265 Patent, and Padagis's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '265 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

55. Upon information and belief, upon FDA approval of ANDA No. 212137, Padagis intends to, and will, infringe at least claim 1 of the '265 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Padagis ANDA Product, unless enjoined by the Court.

56. Upon information and belief, Padagis intends to, and will, actively induce infringement of the '265 patent under 35 U.S.C. § 271(b) when ANDA No. 212137 is approved by marketing the Padagis ANDA Product along with instructions directing users to infringe the '265 patent, unless enjoined by the Court.

57. Upon information and belief, Padagis intends to, and will, contribute to infringement of the '265 patent under 35 U.S.C. § 271(c) when ANDA No. 212137 is approved, unless enjoined by the Court, because Padagis knows that the Padagis ANDA Product is especially made or adapted for use in infringing the '265 patent, and that the Padagis ANDA Product is not suitable for substantial noninfringing use.

58. Padagis's infringement is imminent because, among other things, Padagis has notified Alcon of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product before the expiration of the '265 Patent.

59. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '265 Patent.

60. Pursuant to 28 U.S.C. § 2201, Alcon is entitled to a declaratory judgment that Padagis's making, using, offering to sell, selling, and/or importing the Padagis ANDA Product, inducement thereof or contribution thereto, will infringe the '265 Patent pursuant, either literally or under the doctrine of equivalents, to 35 U.S.C. §§ 271(a), (b), and/or (c).

61. Upon information and belief, Padagis acted, and upon FDA approval of ANDA No. 212137, will act, without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the '265 Patent. This is an exceptional case.

62. Unless Padagis is enjoined from directly or indirectly infringing the '265 Patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Alcon asks that this Court grant the following relief:

63. A judgment that the claims of the Asserted Patents are infringed by Padagis's submission of ANDA No. 212137 under 35 U.S.C. § 271(e)(2)(A);

64. A declaratory judgment that Padagis's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Padagis ANDA Product prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

65. A judgment that the Asserted Patents are not invalid or unenforceable;

66. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Padagis's ANDA No. 212137 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Alcon is or becomes entitled;

67. An Order permanently enjoining Padagis, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Padagis, from making, using, offering to sell, selling, or importing the Padagis ANDA Product until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Alcon is or becomes entitled;

68. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Alcon if Padagis engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Padagis ANDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Alcon is or becomes entitled;

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

70. Such further and other relief as this Court deems proper and just.

/s/ John W. Shaw

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