**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| HIKMA PHARMACEUTICALS USA INC.,<br><br>*Plaintiff*,<br><br>v.<br><br>PADAGIS ISRAEL PHARMACEUTICALS LIMITED, PADAGIS US LLC, and PADAGIS LLC,<br><br>*Defendants.* | C.A. No. |

**COMPLAINT**

Plaintiff Hikma Pharmaceuticals USA Inc. ("Hikma" or "Plaintiff") for its Complaint against Defendants Padagis Israel Pharmaceuticals Limited ("Padagis Israel"), Padagis US LLC, and Padagis LLC (collectively, "Padagis") hereby alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. This action arises from Padagis Israel's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Hikma's Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray, before the expiration of U.S. Patent Nos. 10,722,510 (the "'510 patent," attached as Exhibit A), 10,973,814 (the "'814 patent," attached as Exhibit B), 11,135,155 (the "'155 patent," attached as Exhibit C), 11,617,713 (the "'713 patent," attached as Exhibit D), and 11,628,139 (the

"'139 patent," attached as Exhibit E), (collectively, the "patents-in-suit") throughout the United States, including in Delaware.

## PARTIES

3. Hikma Pharmaceuticals USA Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 200 Connell Drive, Suite 4100, Berkeley Heights, New Jersey 07922.

4. Upon information and belief, Defendant Padagis Israel Pharmaceuticals Limited is an Israeli corporation having a principal place of business at 1 Rakefet St., Shoham 608500, Israel.

5. Upon information and belief, Defendant Padagis US LLC is a Delaware limited liability company having a place of business at 3940 Quebec Ave. North, Minneapolis, Minnesota, 55427.

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

7. Upon information and belief, Defendants Padagis US LLC and Padagis Israel Pharmaceuticals Limited are wholly owned subsidiaries of Defendant Padagis LLC.

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

9. Upon information and belief, Padagis manufactures, imports, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

## JURISDICTION AND VENUE

10. Hikma seeks to enforce its federal patent rights under Title 35, United States Code. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

11. This Court has personal jurisdiction over Padagis because, among other reasons, it maintains an adequate presence in Delaware; it has substantial and continuous contacts with Delaware; and it has committed the acts of patent infringement alleged herein in Delaware.

12. Upon information and belief, Padagis is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States.

13. This Court has personal jurisdiction over Padagis by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and it intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury in Delaware to Hikma. For example, upon information and belief, Padagis is actively preparing to make the proposed generic copies of Kloxxado® (naloxone hydrochloride) that are the subject of Padagis's ANDA, and to use, sell, and offer for sale such generic copies in this state and this judicial district.

14. 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.

15. 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.

16. 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 filed in this forum, including *Anacor Pharmaceuticals, Inc. et al v. Padagis Israel Pharmaceuticals, Ltd. f/k/a Perrigo Israel Pharmaceuticals, Ltd.,* No. 1:21-cv-01351 (D. Del.) and *Alcon Inc. et al v. Padagis Israel Pharmaceuticals Ltd. et al*, No. 1:22-cv-01422 (D. Del).

17. Upon information and belief, Padagis Israel, Padagis US LLC, and Padagis LLC are agents of each other and/or operate in concert as integrated parts of the same business group.

18. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

## THE FDA MARKETING APPROVAL PROCESS

19. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules that FDA follows when considering the approval of applications for both brand-name and generic drugs.

20. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355. Alternatively, an applicant can use the 505(b)(2) "paper NDA" process for new drugs that are similar but not identical to existing ones. This process permits the applicant to rely on existing studies for a previously approved drug of the applicant's choosing while supplementing the application with new studies and data to support a safety and effectiveness determination. *Id*. § 355(b)(2).

21. An NDA or a paper NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

22. Upon approval of the NDA, FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

23. A pharmaceutical company may seek to market a generic version of the innovator's brand drug by submitting an ANDA under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

## THE PATENTS-IN-SUIT

24. The United States Patent & Trademark Office ("USPTO") duly and legally issued the '510, '814, '155, '713, and '139 patents, all titled "Liquid naloxone spray," on July 28, 2020; April 13, 2021; October 5, 2021; April 4, 2023; and April 18, 2023, respectively. The patents list Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda as inventors.

25. Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest in the '510, '814, '155, '713, and '139 patents, including the right to sue and to recover for past infringement.

## THE KLOXXADO® PRODUCT

26. Plaintiff sells Kloxxado® (naloxone hydrochloride) in the United States pursuant to Hikma Pharmaceuticals USA Inc.'s New Drug Application ("NDA") No. 212045 that has been approved by the FDA. Kloxxado® is a naloxone hydrochloride nasal spray, 8mg/spray, indicated

for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.

27. In accordance with 21 U.S.C. § 355(b)(1), the '510, '814, '155, '713, and '139 patents are listed in the Orange Book in connection with NDA No. 212045 as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Kloxxado®.

**PADAGIS'S ANDA SUBMISSION**

28. By letter dated May 2, 2023 ("Notice Letter"), Padagis Israel notified Plaintiff that it had submitted to FDA its ANDA No. 216719 ("ANDA") for Padagis's naloxone hydrochloride nasal spray, 8mg/spray, a drug product that is a generic version of Kloxxado® (naloxone hydrochloride) ("Padagis's ANDA Product").

29. Upon information and belief, the purpose of submitting the ANDA to FDA was to obtain marketing approval from FDA to engage in the commercial manufacture, use, and/or sale of Padagis's ANDA Product prior to the expiration of the '510, '814, '155, '713, and '139 patents.

30. In the Notice Letter, Padagis Israel notified Plaintiff that, as part of its ANDA, Padagis Israel included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that, in its opinion and to the best of its knowledge, the '510, '814, and '155 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of Padagis's ANDA Product.

31. By letter dated May 31, 2023 ("Amended Notice Letter"), Padagis Israel notified Plaintiff that, as part of its ANDA, Padagis Israel included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that, in its opinion and to the best of its knowledge, the '713 and '139 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and/or sale of the proposed ANDA Product.

32. The use of Padagis's ANDA Product is covered by one or more claims of the '510, '814, '155, '713, and '139 patents.

33. Padagis had knowledge of the '510, '814, and '155 patents when it submitted its ANDA.

34. This action was commenced before the expiration of forty-five days from the date Plaintiff received the Notice Letter, which Plaintiff received on or about May 3, 2023.

**COUNT 1: INFRINGEMENT OF THE '510 PATENT**

35. Paragraphs 1 to 34 are incorporated as if fully set forth herein.

36. Padagis's ANDA Product, and/or the use thereof, is covered by one or more claims of the '510 patent.

37. The submission of ANDA No. 216719 with a Paragraph IV certification regarding the '510 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Padagis's ANDA Product before the expiration of the '510 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '510 patent under 35 U.S.C. § 271(e)(2).

38. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product before the expiration of the '510 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '510 patent under 35 U.S.C. § 271.

39. Unless enjoined by this Court, Padagis intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of the ANDA.

40. Unless enjoined by this Court, Padagis intends to, and will, actively induce infringement of the '510 patent when the ANDA is approved, and intends to, and will, do so, immediately and imminently upon approval.

41. The foregoing actions by Padagis before the expiration of the '510 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), or (c).

42. Unless Padagis is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and/or contributing to the infringement of the '510 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

43. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for ANDA No. 216719 to be a date that is not earlier than the date on which the '510 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

**COUNT 2: INFRINGEMENT OF THE '814 PATENT**

44. Paragraphs 1 to 43 are incorporated as if fully set forth herein.

45. Padagis's ANDA Product, and/or the use thereof, is covered by one or more claims of the '814 patent.

46. The submission of ANDA No. 216719 with a Paragraph IV certification regarding the '814 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Padagis's ANDA Product before the expiration of the '814 patent constitutes

infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '814 patent under 35 U.S.C. § 271(e)(2).

47. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product before the expiration of the '814 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '814 patent under 35 U.S.C. § 271.

48. Unless enjoined by this Court, Padagis intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of the ANDA.

49. Unless enjoined by this Court, Padagis intends to, and will, actively induce infringement of the '814 patent when the ANDA is approved, and intends to, and will, do so, immediately and imminently upon approval.

50. The foregoing actions by Padagis before the expiration of the '814 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

51. Unless Padagis is enjoined from infringing the '814 patent, actively inducing infringement of the '814 patent, and/or contributing to the infringement of the '814 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

52. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for ANDA No. 216719 to be a

date which is not earlier than the date on which the '814 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

**COUNT 3: INFRINGEMENT OF THE '155 PATENT**

53. Paragraphs 1 to 52 are incorporated as if fully set forth herein.

54. Padagis's ANDA Product, and/or the use thereof, is covered by one or more claims of the '155 patent.

55. The submission of ANDA No. 216719 with a Paragraph IV certification regarding the '155 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Padagis's ANDA Product before the expiration of the '155 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '155 patent under 35 U.S.C. § 271(e)(2).

56. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product before the expiration of the '155 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '155 patent under 35 U.S.C. § 271.

57. Unless enjoined by this Court, Padagis intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of the ANDA.

58. Unless enjoined by this Court, Padagis intends to, and will, actively induce infringement of the '155 patent when the ANDA is approved, and intends to, and will, do so, immediately and imminently upon approval.

59. The foregoing actions by Padagis before the expiration of the '155 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the

infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

60. Unless Padagis is enjoined from infringing the '155 patent, actively inducing infringement of the '155 patent, and/or contributing to the infringement of the '155 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

61. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for ANDA No. 216719 to be a date which is not earlier than the date on which the '155 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

**COUNT 4: INFRINGEMENT OF THE '713 PATENT**

62. Paragraphs 1 to 61 are incorporated as if fully set forth herein.

63. Padagis's ANDA Product, and/or the use thereof, is covered by one or more claims of the '713 patent.

64. The submission of ANDA No. 216719 with a Paragraph IV certification regarding the '713 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Padagis's ANDA Product before the expiration of the '713 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '713 patent under 35 U.S.C. § 271(e)(2).

65. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product before the expiration of the '713 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '713 patent under 35 U.S.C. § 271.

66. Unless enjoined by this Court, Padagis intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of the ANDA.

67. Unless enjoined by this Court, Padagis intends to, and will, actively induce infringement of the '713 patent when the ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

68. The foregoing actions by Padagis before the expiration of the '713 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

69. Unless Padagis is enjoined from infringing the '713 patent, actively inducing infringement of the '713 patent, and/or contributing to the infringement of the '713 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

70. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for ANDA No. 216719 to be a date which is not earlier than the date on which the '713 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

**COUNT 5: INFRINGEMENT OF THE '139 PATENT**

71. Paragraphs 1 to 70 are incorporated as if fully set forth herein.

72. Padagis's ANDA Product, and/or the use thereof, is covered by one or more claims of the '139 patent.

73. The submission of ANDA No. 216719 with a Paragraph IV certification regarding the '139 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Padagis's ANDA Product before the expiration of the '139 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more of the claims of the '139 patent under 35 U.S.C. § 271(e)(2).

74. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product before the expiration of the '139 patent would infringe, either literally or under the doctrine of equivalents, one or more claims of the '139 patent under 35 U.S.C. § 271.

75. Unless enjoined by this Court, Padagis intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Padagis's ANDA Product immediately and imminently upon approval of the ANDA.

76. Unless enjoined by this Court, Padagis intends to, and will, actively induce infringement of the '139 patent when the ANDA is approved, and intends to, and will, do so, immediately and imminently upon approval.

77. The foregoing actions by Padagis before the expiration of the '139 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b) or (c).

78. Unless Padagis is enjoined from infringing the '139 patent, actively inducing infringement of the '139 patent, and/or contributing to the infringement of the '139 patent, Hikma will suffer irreparable injury for which Hikma has no adequate remedy at law. Pursuant to 35

U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

79. Hikma is entitled to relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for ANDA No. 216719 to be a date which is not earlier than the date on which the '139 patent expires or any later expiration of exclusivity to which Hikma is or becomes entitled.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff requests the following relief:

a. Judgment in favor of Plaintiff and against Defendants;

b. Judgment that the '510, '814, '155, '713, and '139 patents are valid and enforceable;

c. Judgment that Padagis has infringed, literally and/or by the doctrine of equivalents, one or more claims of the '510, '814, '155, '713, and '139 patents by submitting ANDA No. 216719, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Padagis's ANDA Product in the United States will constitute infringement, contributory infringement, or actively induced infringement of the '510, '814, '155, '713, and '139 patents;

d. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 216719 relating to Padagis's ANDA Product shall be not earlier than the date of expiration of the '510, '814, '155, '713, and '139 patents, or any later date of exclusivity to which Hikma is or becomes entitled;

e. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, and Fed. R. Civ. P. 65, restraining and enjoining Padagis and its officers, partners, agents, attorneys, servants, employees, parents, subsidiaries, divisions,

affiliate corporations, other related business entities, and all other persons acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation within the United States of Padagis's ANDA Product, and any product that is similar to or only colorably different from that product, and from infringing, contributorily infringing, or inducing others to infringe the '510, '814, '155, '713, and '139 patents, before the expiration of the '510, '814, '155, '713, and '139 patents or any later date of exclusivity to which Hikma is or becomes entitled;

f. Damages or other monetary relief, including pre-judgment and post-judgment interest, to the extent that Padagis engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation within the United States of Padagis's ANDA Product, or any product that infringes the '510, '814, '155, '713, and '139 patents, or contributes to or actively induces infringement of the '510, '814, '155, '713, and '139 patents, before the expiration of the '510, '814, '155, '713, and '139 patents or any later date of exclusivity to which Hikma is or becomes entitled;

g. A declaration that this is an exceptional case and an award of reasonable attorney's fees and expenses to Plaintiff pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

h. Plaintiff's reasonable costs and expenses incurred in bringing and prosecuting this action; and

i. Such other and further relief as the Court deems just and appropriate.

HEYMAN ENERIO
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