IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

HIKMA PHARMACEUTICALS USA INC., *Plaintiff*, v. PADAGIS ISRAEL PHARMACEUTICALS LIMITED, PADAGIS US LLC, and PADAGIS LLC, *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 Michigan.

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 Michigan; it has substantial and continuous contacts with Michigan; and it has committed the acts of patent infringement alleged herein in Michigan.

12. Upon information and belief, Padagis is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Michigan 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 Michigan. These acts have led and will lead to foreseeable harm and injury in Michigan 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 has a place of business at 1251 Lincoln Road, Allegan, Michigan 49010, and by virtue of, *inter alia*, its systematic and continuous contacts with the State of Michigan. Padagis US LLC has therefore purposely availed itself of the benefits and protections of Michigan's laws. Upon information and belief, Padagis US is also appointed the registered agent in Michigan for receipt of service by process on behalf of Padagis Israel.

15. This Court also has personal jurisdiction over Padagis LLC because, upon information and belief, Padagis LLC has a place of business at 1251 Lincoln Road, Allegan, Michigan 49010, and by virtue of, *inter alia*, its systematic and continuous contacts with the State of Michigan. Padagis LLC has therefore purposely availed itself of the benefits and protections of Michigan's laws.

16. Upon information and belief, Padagis Israel has consented to the jurisdiction of the United States District Court for the Western District of Michigan for the purposes of any infringement action commenced based on the of a Paragraph IV certification for ANDA No. 216719.

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.

WINSTON & STRAWN LLP

Dated: June 16, 2023

/s/ Scott Ahmad

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JS 44 (Rev. 09/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

HIKMA PHARMACEUTICALS USA INC.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Scott Ahmad, Winston & Strawn LLP
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DEFENDANTS

PADAGIS ISRAEL PHARMACEUTICALS LIMITED, PADAGIS US LLC and PADAGIS LLC

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
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- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
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- ❒ 151 Medicare Act
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- ☒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit (15 USC 1681 or 1692)
- ❒ 485 Telephone Consumer Protection Act
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. §§ 1331, 1338, 2201 and 2202; 35 U.S.C. §§ 100, 271(a)-(c), (e)

Brief description of cause:
Action for patent infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(a)-(c), (e)

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ❒ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
June 15, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Kurt Mathis

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.