IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HIKMA PHARMACEUTICALS USA INC., Plaintiff, v. PADAGIS ISRAEL PHARMACEUTICALS LIMITED, PADAGIS US LLC, and PADAGIS LLC, Defendants.	)	C.A. No. 23-654-GBW

ANSWER AND SEPARATE DEFENSES OF DEFENDANTS PADAGIS ISRAEL PHARMACETUICALS LTD, PADAGIS US LLC, AND PADAGIS LLC TO PLAINTIFF'S COMPLAINT AND COUNTERCLAIMS OF PADAGIS ISRAEL PHARMACEUTICALS LTD

Defendants Padagis Israel Pharmaceuticals Ltd ("Padagis Israel"), Padagis US LLC, and Padagis LLC (collectively, "Padagis" or "Defendants"), by and through the undersigned attorneys, hereby answer the Complaint of Plaintiff Hikma Pharmaceuticals USA Inc. ("Hikma" or "Plaintiff") as follows:

NATURE OF ACTION[1]

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Hikma's Complaint is for alleged patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, the

[1] Padagis has incorporated the headings that appear in the Complaint for convenience. Doing so thus does not indicate that Padagis agrees with the characterizations of the headings. Padagis maintains all rights to object to those characterizations.

Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but denies that Hikma is entitled to any relief. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Hikma's Complaint is for alleged patent infringement of U.S. Patent Nos. 10,722,510 ("the '510 patent"); 10,973,814 ("the '814 patent"); 11,135,155 ("the '155 patent"); 11,617,713 ("the '713 patent"); and 11,628,139 ("the '139 patent"), but denies that Hikma is entitled to any relief. Answering further, Padagis states that what purports to be a copy of the '510 patent is attached to Hikma's Complaint as Exhibit A; what purports to be a copy of the '814 patent is attached to Hikma's Complaint as Exhibit B; what purports to be a copy of the '155 patent is attached to Hikma's Complaint as Exhibit C; what purports to be a copy of the '713 patent is attached to Hikma's Complaint as Exhibit D; and what purports to be a copy of the '139 patent is attached to Hikma's Complaint as Exhibit E. Answering further, Padagis admits that Padagis Israel's Abbreviated New Drug Application ("ANDA") No. 216719 was submitted to the U.S. Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications") to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial

manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis further admits that the reference listed drug ("RLD") identified in Padagis Israel's ANDA No. 216719 is Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray. Padagis further admits that by letter dated May 2, 2023, written notification was given to, *inter alia*, Hikma, pursuant to 21 U.S.C. § 355(j)(2)(B), of the paragraph IV certifications contained in Padagis Israel's ANDA to the '510, '814, and '155 patents. Padagis further admits that by letter dated May 31, 2023, written notification was given to, *inter alia*, Hikma, pursuant to 21 U.S.C. § 355(j)(2)(B), of the paragraph IV certifications contained in Padagis Israel's ANDA to the '713 and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

PARTIES

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that, on information and belief, Plaintiff Hikma is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 200 Connell Drive, Suite 4100, Berkeley Heights, New Jersey 07922. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis Israel is an Israeli

corporation with a place of business at 1 Rakefet St., Shoham, Israel 6083705. Answering further, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis US LLC is a Delaware limited liability company with a place of business at 1251 Lincoln Road, Allegan, Michigan, 49010-9706. Answering further, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis LLC is a Delaware limited liability company with a place of business at 1251 Lincoln Road, Allegan, Michigan 49010. Answering further, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis US LLC and Padagis Israel are wholly-owned by Padagis LLC. Answering further, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Answering further, Padagis admits that Padagis Israel submitted ANDA No. 216719 pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Answering further, Padagis admits that Padagis Israel submitted ANDA No. 216719 pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations of this paragraph.

JURISDICTION AND VENUE

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Hikma's Complaint is for alleged patent infringement under the patent laws of the United States, but denies that Hikma is entitled to any relief. Padagis admits that this Court has subject matter jurisdiction over Hikma's infringement claims against Padagis Israel. Padagis also states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Padagis denies any remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Hikma's infringement claims against Padagis US LLC and Padagis LLC.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Padagis denies any remaining allegations contained in this paragraph, including that Padagis has committed any alleged patent infringement and that Hikma is entitled to any relief.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Answering further, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph, including that Padagis has committed any alleged patent infringement and that Hikma is entitled to any relief.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Answering further, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph, including that Padagis has committed any alleged patent infringement and that Hikma is entitled to any relief.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Answering further, Padagis states that Padagis US LLC is a Delaware limited liability company. Padagis denies any remaining allegations contained in this paragraph, including that Padagis has committed any alleged patent infringement and that Hikma is entitled to any relief.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Answering further, Padagis states that Padagis LLC is a Delaware limited liability company. Padagis denies any remaining allegations contained in this paragraph, including that Padagis has committed any alleged patent infringement and that Hikma is entitled to any relief.

COMPLAINT:

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Answering further, Padagis admits that Padagis Israel was a named defendant in the complaints filed in Civil Action Nos. 1:21-cv-01351 and 1:22-cv-01422 in this Judicial District; and that Padagis Israel filed counterclaims in Civil Action Nos. 1:21-cv-01351 and 1:22-cv-01422 in this Judicial District. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest personal jurisdiction in the District of Delaware for purposes of this action only. Answering further, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Hikma's infringement claims against Padagis US LLC and Padagis LLC.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that Padagis does not contest venue for purposes of this action only. Answering further, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

THE FDA MARKETING APPROVAL PROCESS

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), sets forth a statutory framework that FDA follows for the approval of both brand-name and generic drugs. Padagis is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

COMPLAINT:

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that, under the FFDCA, as amended by Hatch-Waxman and the MMA, 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. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that an NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). Answering further, the decision to submit patent information to FDA rests with the NDA holder. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that upon approval of the NDA, FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii). Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis states that, under Hatch-Waxman, a generic

manufacturer may submit an ANDA to FDA, and the generic manufacturer must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j). Padagis denies any remaining allegations contained in this paragraph.

THE PATENTS-IN-SUIT

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that, according to the face of each respective patent, the U.S. Patent & Trademark Office ("USPTO") issued the '510, '814, '155, '713, and '139 patents on July 28, 2020; April 13, 2021; October 5, 2021; April 4, 2023; and April 18, 2023, respectively. Answering further, Padagis admits that, according to the face of each respective patent, each patent is entitled "LIQUID NALOXONE SPRAY" and lists as "Inventors" Kiran Amancha, Thrimoorthy Potta, Ningxin Yan, Venkat R. Goskonda, and either Shivani Chilampalli (the '510 patent) or Chandeshwari Chilampalli (the '814, '155, '713, and '139 patents). Padagis denies any remaining allegations contained in this paragraph, including that the '510, '814, '155, '713, and '139 patents were duly and legally issued, as well as any suggestion or implication that the patents' claims are valid or enforceable or that Padagis infringes any claims of the patents.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that, according to the online records of the USPTO, Hikma is the current assignee of the '510, '814, '155, '713, and '139 patents. Padagis denies any suggestion that the '510, '814, '155, '713, and '139 patents were duly and legally issued, as well as any suggestion or implication that the '510, '814, '155, '713, and '139 patents are valid or enforceable or that Padagis infringes any claims of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations of this paragraph.

THE KLOXXADO® PRODUCT

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that, according to FDA's online records, "HIKMA PHARMACEUTICALS USA INC" is the holder of NDA No. 212045 for Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray, and "Apr 29, 2021" is identified as the "Approval Date" for NDA No. 212045; and, according to the approved label for Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray, available from the online records of FDA: "KLOXXADO is an opioid antagonist 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." Padagis denies any remaining allegations of this paragraph.

COMPLAINT:

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®.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that each of the '510, '814, '155, '713, and '139 patents is currently listed in the Orange Book in conjunction with NDA No. 212045 for Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray. Padagis denies any remaining allegations of this paragraph.

PADAGIS'S ANDA SUBMISSION

COMPLAINT:

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").

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis further admits that by letter dated May 2, 2023, written notification was given to, *inter alia*, Hikma, pursuant to 21 U.S.C. § 355(j)(2)(B), of Padagis Israel's ANDA and the paragraph IV certifications to the '510, '814, and '155 patents contained therein. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis further admits that by letter dated May 2, 2023, written notification was given to, *inter alia*, Hikma, pursuant to 21 U.S.C. § 355(j)(2)(B), of Padagis

Israel's ANDA and the paragraph IV certifications to the '510, '814, and '155 patents contained therein. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis further admits that by letter dated May 31, 2023, written notification was given to, *inter alia*, Hikma, pursuant to 21 U.S.C. § 355(j)(2)(B), of Padagis Israel's ANDA and the paragraph IV certifications to the '713 and '139 patents contained therein. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or

importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph, including that the claims of the '510, '814, '155, '713, and '139 patents are valid or enforceable, that Padagis Israel's Naloxone Hydrochloride Nasal Spray, 8mg/spray, or its use, would infringe any valid and enforceable claims of the patents, or that Padagis infringes any claims of the patents.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that, as indicated by its letter dated May 2, 2023, Padagis Israel's ANDA contained the paragraph IV certifications to the '510, '814, and '155 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis further admits that by letters dated May 2, 2023, and May 31, 2023, written notification was given to, *inter alia*, Hikma, pursuant to 21 U.S.C.

§ 355(j)(2)(B), of the paragraph IV certifications contained in Padagis Israel's ANDA. Answering further, Padagis admits that according to the online records of this judicial District, Hikma filed the instant action on June 14, 2023. Padagis denies any remaining allegations contained in this paragraph.

COUNT 1: INFRINGEMENT OF THE '510 PATENT

COMPLAINT:

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

ANSWER: Padagis restates and incorporates each of its responses to the preceding paragraphs 1-34 as if fully set forth herein.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COUNT 2: INFRINGEMENT OF THE '814 PATENT

COMPLAINT:

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

ANSWER: Padagis restates and incorporates each of its responses to the preceding paragraphs 1-43 as if fully set forth herein.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COUNT 3: INFRINGEMENT OF THE '155 PATENT

COMPLAINT:

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

ANSWER: Padagis restates and incorporates each of its responses to the preceding paragraphs 1-52 as if fully set forth herein.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COUNT 4: INFRINGEMENT OF THE '713 PATENT

COMPLAINT:

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

ANSWER: Padagis restates and incorporates each of its responses to the preceding paragraphs 1-61 as if fully set forth herein.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COUNT 5: INFRINGEMENT OF THE '139 PATENT

COMPLAINT:

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

ANSWER: Padagis restates and incorporates each of its responses to the preceding paragraphs 1-70 as if fully set forth herein.

COMPLAINT:

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Padagis admits that Padagis Israel's ANDA No. 216719 was submitted to the FDA pursuant to 21 U.S.C. § 355(j); that Padagis Israel's ANDA contains paragraph IV certifications to the '510, '814, '155, '713, and '139 patents; and that Padagis Israel seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Naloxone Hydrochloride Nasal Spray, 8mg/spray, before the expiration of the '510, '814, '155, '713, and '139 patents. Padagis denies any remaining allegations contained in this paragraph.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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).

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

COMPLAINT:

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.

ANSWER: Denied.

* * *

RESPONSE TO PRAYER FOR RELIEF

Padagis denies that Hikma is entitled to any relief as set forth in Paragraphs (a)-(i) of the Complaint, or to any relief whatsoever, and further requests that Hikma's Complaint be dismissed

with prejudice and that Padagis be awarded its attorney fees and costs incurred in defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted (and, for purposes of clarity, those allegations not specifically admitted are denied), and without undertaking any of the burdens imposed by law on Hikma, Padagis asserts the following defenses to the Complaint:

First Defense

The manufacture, use, or sale of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '510 patent.

Second Defense

The manufacture, use, or sale of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '814 patent.

Third Defense

The manufacture, use, or sale of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '155 patent.

Fourth Defense

The manufacture, use, or sale of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '713 patent.

Fifth Defense

The manufacture, use, or sale of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '139 patent.

Sixth Defense

The claims of the '510 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

Seventh Defense

The claims of the '814 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

Eighth Defense

The claims of the '155 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

Ninth Defense

The claims of the '713 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

Tenth Defense

The claims of the '139 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

Eleventh Defense

The Complaint fails to state a claim upon which relief can be granted.

Twelfth Defense

This Court lacks subject matter jurisdiction over Hikma's infringement claims against Padagis US LLC.

Thirteenth Defense

This Court lacks subject matter jurisdiction over Hikma's infringement claims against Padagis LLC.

Fourteenth Defense

Any additional defenses or counterclaims that discovery may reveal, as Hikma has not begun producing discovery to Padagis (indeed, Hikma has not yet even identified the asserted patent claims), and Padagis has not yet had the opportunity to pursue any relevant third-party discovery.

PADAGIS ISRAEL PHARMACEUTICALS LTD'S COUNTERCLAIMS

Padagis Israel Pharmaceuticals Ltd ("Padagis Israel"), for its Counterclaims against Hikma Pharmaceuticals USA Inc. ("Hikma" or "Plaintiff"), alleges as follows:

The Parties

1. Padagis Israel is an Israeli corporation with a place of business at 1 Rakefet St., Shoham, Israel 6083705.

2. On information and belief, and according to its Complaint, Plaintiff Hikma is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 200 Connell Drive, Suite 4100, Berkeley Heights, New Jersey 07922. (Complaint at ¶ 3).

Jurisdiction and Venue

3. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

4. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has personal jurisdiction over Hikma because it has purposefully availed itself of the rights and privileges of this forum by suing Padagis Israel in this District, and, on information and belief, because Hikma conducts substantial business in, and has regular systematic contact with, this District.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

Background

A. FDA Approval Of New Brand-Name Drugs.

7. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth a statutory framework that the U.S. Food and Drug Administration ("FDA") follows for the approval of both brand-name and generic drugs.

8. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

9. An NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was

submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). The decision to submit patent information to FDA rests solely with the NDA holder.

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

B. Generic Competition – Abbreviated New Drug Applications.

11. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

12. To receive approval of its ANDA, an applicant generally must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

13. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant generally must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

14. When seeking FDA approval to market prior to patent expiration, an ANDA applicant generally submits a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

15. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

16. If the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), FDA typically cannot approve the ANDA for 30 months, unless the District Court enters an order that shortens that period. *See* 21 U.S.C. § 355(j)(5)(B)(iii). For this reason alone, patentees and NDA holders have a significant financial incentive to bring an infringement suit against an ANDA applicant regardless of the merit – or lack thereof – of that infringement suit.

C. Naloxone Hydrochloride Nasal Spray, 8mg/Spray, And The Patents-In-Suit.

17. On or about July 28, 2020, according to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), U.S. Patent No. 10,722,510 ("the '510 patent"), entitled "Liquid Naloxone Spray," issued. The '510 patent is assigned on its face to Hikma Pharmaceuticals USA Inc. The named inventors on the face of the '510 patent are Kiran Amancha, Shivani Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda. What purports to be a true and correct copy of the '510 patent is attached to Hikma's Complaint as Exhibit A.

18. Plaintiff asserts that "Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest" in the '510 patent, "including the right to sue and to recover for past infringement" of that patent. (Complaint at ¶¶ 2, 25).

19. On or about April 13, 2021, according to the electronic records of USPTO, U.S. Patent No. 10,973,814 ("the '814 patent"), entitled "Liquid Naloxone Spray," issued. The '814 patent is assigned on its face to Hikma Pharmaceuticals USA Inc. The named inventors on the face of the '814 patent are Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta,

Ningxin Yan, and Venkat R. Goskonda. What purports to be a true and correct copy of the '814 patent is attached to Hikma's Complaint as Exhibit B.

20. Plaintiff asserts that "Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest" in the '814 patent, "including the right to sue and to recover for past infringement" of that patent. (Complaint at ¶¶ 2, 25).

21. On or about October 5, 2021, according to the electronic records of USPTO, U.S. Patent No. 11,135,155 ("the '155 patent"), entitled "Liquid Naloxone Spray," issued. The '155 patent is assigned on its face to Hikma Pharmaceuticals USA Inc. The named inventors on the face of the '155 patent are Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda. What purports to be a true and correct copy of the '155 patent is attached to Hikma's Complaint as Exhibit C.

22. Plaintiff asserts that "Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest" in the '155 patent, "including the right to sue and to recover for past infringement" of that patent. (Complaint at ¶¶ 2, 25).

23. On or about April 4, 2023, according to the electronic records of USPTO, U.S. Patent No. 11,617,713 ("the '713 patent"), entitled "Liquid Naloxone Spray," issued. The '713 patent is assigned on its face to Hikma Pharmaceuticals USA Inc. The named inventors on the face of the '713 patent are Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda. What purports to be a true and correct copy of the '713 patent is attached to Hikma's Complaint as Exhibit D.

24. Plaintiff asserts that "Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest" in the '713 patent, "including the right to sue and to recover for past infringement" of that patent. (Complaint at ¶¶ 2, 25).

25. On or about April 18, 2023, according to the electronic records of USPTO, U.S. Patent No. 11,628,139 ("the '139 patent"), entitled "Liquid Naloxone Spray," issued. The '139 patent is assigned on its face to Hikma Pharmaceuticals USA Inc. The named inventors on the face of the '139 patent are Kiran Amancha, Chandeshwari Chilampalli, Thrimoorthy Potta, Ningxin Yan, and Venkat R. Goskonda. What purports to be a true and correct copy of the '139 patent is attached to Hikma's Complaint as Exhibit E.

26. Plaintiff asserts that "Hikma Pharmaceuticals USA Inc. lawfully owns all right, title, and interest" in the '139 patent, "including the right to sue and to recover for past infringement" of that patent. (Complaint at ¶¶ 2, 25).

27. According to the online records of FDA, "HIKMA PHARMACEUTICALS USA INC" is identified as the holder of NDA No. 212045 for Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray, and "Apr 29, 2021" is identified as the "Approval Date" for NDA No. 212045.

28. On information and belief, Hikma, or someone on Hikma's behalf, submitted the '510 patent to FDA for listing in the Orange Book in connection with NDA No. 212045.

29. On information and belief, Hikma, or someone on Hikma's behalf, submitted the '814 patent to FDA for listing in the Orange Book in connection with NDA No. 212045.

30. On information and belief, Hikma, or someone on Hikma's behalf, submitted the '155 patent to FDA for listing in the Orange Book in connection with NDA No. 212045.

31. On information and belief, Hikma, or someone on Hikma's behalf, submitted the '713 patent to FDA for listing in the Orange Book in connection with NDA No. 212045.

32. On information and belief, Hikma, or someone on Hikma's behalf, submitted the '139 patent to FDA for listing in the Orange Book in connection with NDA No. 212045.

33. By virtue of the submission of the '510 patent to FDA, FDA listed the '510 patent in the Orange Book in connection with the approved NDA No. 212045.

34. By virtue of the submission of the '814 patent to FDA, FDA listed the '814 patent in the Orange Book in connection with the approved NDA No. 212045.

35. By virtue of the submission of the '155 patent to FDA, FDA listed the '155 patent in the Orange Book in connection with the approved NDA No. 212045.

36. By virtue of the submission of the '713 patent to FDA, FDA listed the '713 patent in the Orange Book in connection with the approved NDA No. 212045.

37. By virtue of the submission of the '139 patent to FDA, FDA listed the '139 patent in the Orange Book in connection with the approved NDA No. 212045.

38. On or about June 14, 2023, Hikma purports to have brought suit against Padagis Israel, asserting infringement of "one or more claims" of the '510, '814, '155, '713, and '139 patents, but not otherwise identifying the asserted claims of the '510, '814, '155, '713, and '139 patents.

D. Padagis Israel's Naloxone Hydrochloride Nasal Spray, 8mg/Spray, ANDA.

39. Padagis Israel filed an ANDA with FDA seeking approval for Naloxone Hydrochloride Nasal Spray, 8mg/spray ("Padagis Israel's ANDA").

40. FDA assigned Padagis Israel's ANDA No. 216719.

41. Padagis Israel's ANDA identifies Kloxxado® (naloxone hydrochloride), Nasal Spray, 8mg/spray, as the reference listed drug ("RLD").

42. Because Padagis Israel's ANDA seeks FDA approval to market its generic Naloxone Hydrochloride Nasal Spray, 8mg/spray, before expiration of the Orange Book-listed

'510, '814, '155, '713, and '139 patents, Padagis Israel's ANDA includes paragraph IV certifications to the '510, '814, '155, '713, and '139 patents.

43. By letter dated May 2, 2023, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Padagis Israel provided, *inter alia*, Hikma with notice that Padagis Israel submitted an ANDA containing a paragraph IV certification to the '510, '814, and '155 patents ("Padagis Israel's May 2, 2023 Notice Letter").

44. Padagis Israel's May 2, 2023 Notice Letter included a detailed statement setting forth factual and legal bases as to why each claim of the '510, '814, and '155 patents is invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719, and, *inter alia*, expressly reserved the right to raise additional defenses in the event that suit was filed on the '510, '814, and/or '155 patents.

45. Hikma received a copy of Padagis Israel's May 2, 2023 Notice Letter.

46. By letter dated May 31, 2023, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Padagis Israel provided, *inter alia*, Hikma with notice that Padagis Israel's ANDA had been amended to contain a paragraph IV certification to the '713 and '139 patents ("Padagis Israel's May 31, 2023 Notice Letter").

47. Padagis Israel's May 31, 2023 Notice Letter included a detailed statement setting forth factual and legal bases as to why each claim of the '713 and '139 patents is invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719, and, *inter alia*, expressly reserved the right to raise additional defenses in the event that suit was filed on the '713 and/or '139 patents.

48. Hikma received a copy of Padagis Israel's May 31, 2023 Notice Letter.

49. The claims of the '510 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719.

50. The claims of the '814 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719.

51. The claims of the '155 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719.

52. The claims of the '713 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719.

53. The claims of the '139 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Padagis Israel's ANDA No. 216719.

COUNT I
(Declaration of Non-Infringement of the '510 Patent)

54. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-53.

55. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would infringe any valid and enforceable claim of the '510 patent.

56. The manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '510 patent, either literally or under the doctrine of equivalents, directly or indirectly.

57. Padagis Israel is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '510 patent.

COUNT II
(Declaration of Invalidity of the '510 Patent)

58. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-57.

59. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the invalidity of the '510 patent.

60. The claims of the '510 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged claimed invention of the '510 patent was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

b. The alleged claimed invention of the '510 patent was described in a patent issued under 35 U.S.C. § 151, or in an application for patent published or deemed published under 35 U.S.C. § 122(b), in which the patent or application, as the case may be, names

another inventor and was effectively filed before the effective filing date of the claimed invention.

c. Any differences between the alleged claimed invention of the '510 patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

d. The alleged claimed invention of the '510 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '510 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '510 patent and would have had a reasonable expectation of success in doing so.

e. The '510 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the same.

f. The claims of the '510 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

g. The subject matter claimed in the '510 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '510 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Padagis Israel's May 2, 2023 Notice Letter and/or Padagis Israel's May 31, 2023 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,416,886; U.S. Patent No. 4,626,539; U.S. Patent No. 4,782,047; U.S. Patent No. 5,866,154; U.S. Patent No. 5,897,858; U.S. Patent No. 6,677,346 B1; U.S. Patent No. 7,214,381 B2; U.S. Patent No. 8,216,604 B2; U.S. Patent No. 8,399,508 B2; U.S. Patent No. 9,211,253 B2.

61. Padagis Israel is entitled to a declaration that the claims of the '510 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT III
(Declaration of Non-Infringement of the '814 Patent)

62. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-61.

63. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or

importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would infringe any valid and enforceable claim of the '814 patent.

64. The manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '814 patent, either literally or under the doctrine of equivalents, directly or indirectly.

65. Padagis Israel is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '814 patent.

COUNT IV
(Declaration of Invalidity of the '814 Patent)

66. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-65.

67. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the invalidity of the '814 patent.

68. The claims of the '814 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged claimed invention of the '814 patent was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

b. The alleged claimed invention of the '814 patent was described in a patent issued under 35 U.S.C. § 151, or in an application for patent published or deemed published

under 35 U.S.C. § 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

c. Any differences between the alleged claimed invention of the '814 patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

d. The alleged claimed invention of the '814 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '814 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '814 patent and would have had a reasonable expectation of success in doing so.

e. The '814 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the same.

f. The claims of the '814 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

g. The subject matter claimed in the '814 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '814 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Padagis Israel's May 2, 2023 Notice Letter and/or Padagis Israel's May 31, 2023 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,416,886; U.S. Patent No. 4,626,539; U.S. Patent No. 4,782,047; U.S. Patent No. 5,866,154; U.S. Patent No. 5,897,858; U.S. Patent No. 6,677,346 B1; U.S. Patent No. 7,214,381 B2; U.S. Patent No. 8,216,604 B2; U.S. Patent No. 8,399,508 B2; U.S. Patent No. 9,211,253 B2.

69. Padagis Israel is entitled to a declaration that the claims of the '814 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT V
(Declaration of Non-Infringement of the '155 Patent)

70. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-69.

71. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or

importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would infringe any valid and enforceable claim of the '155 patent.

72. The manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '155 patent, either literally or under the doctrine of equivalents, directly or indirectly.

73. Padagis Israel is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '155 patent.

COUNT VI
(Declaration of Invalidity of the '155 Patent)

74. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-73.

75. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the invalidity of the '155 patent.

76. The claims of the '155 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged claimed invention of the '155 patent was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

b. The alleged claimed invention of the '155 patent was described in a patent issued under 35 U.S.C. § 151, or in an application for patent published or deemed published

under 35 U.S.C. § 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

c. Any differences between the alleged claimed invention of the '155 patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

d. The alleged claimed invention of the '155 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '155 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '155 patent and would have had a reasonable expectation of success in doing so.

e. The '155 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the same.

f. The claims of the '155 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

g. The subject matter claimed in the '155 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '155 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Padagis Israel's May 2, 2023 Notice Letter and/or Padagis Israel's May 31, 2023 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,416,886; U.S. Patent No. 4,626,539; U.S. Patent No. 4,782,047; U.S. Patent No. 5,866,154; U.S. Patent No. 5,897,858; U.S. Patent No. 6,677,346 B1; U.S. Patent No. 7,214,381 B2; U.S. Patent No. 8,216,604 B2; U.S. Patent No. 8,399,508 B2; U.S. Patent No. 9,211,253 B2.

77. Padagis Israel is entitled to a declaration that the claims of the '155 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT VII
(Declaration of Non-Infringement of the '713 Patent)

78. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-77.

79. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or

importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would infringe any valid and enforceable claim of the '713 patent.

80. The manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '713 patent, either literally or under the doctrine of equivalents, directly or indirectly.

81. Padagis Israel is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '713 patent.

COUNT VIII
(Declaration of Invalidity of the '713 Patent)

82. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-81.

83. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the invalidity of the '713 patent.

84. The claims of the '713 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged claimed invention of the '713 patent was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

b. The alleged claimed invention of the '713 patent was described in a patent issued under 35 U.S.C. § 151, or in an application for patent published or deemed published

under 35 U.S.C. § 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

c. Any differences between the alleged claimed invention of the '713 patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

d. The alleged claimed invention of the '713 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '713 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '713 patent and would have had a reasonable expectation of success in doing so.

e. The '713 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the same.

f. The claims of the '713 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

g. The subject matter claimed in the '713 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '713 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Padagis Israel's May 2, 2023 Notice Letter and/or Padagis Israel's May 31, 2023 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,416,886; U.S. Patent No. 4,626,539; U.S. Patent No. 4,782,047; U.S. Patent No. 5,866,154; U.S. Patent No. 5,897,858; U.S. Patent No. 6,677,346 B1; U.S. Patent No. 7,214,381 B2; U.S. Patent No. 8,216,604 B2; U.S. Patent No. 8,399,508 B2; U.S. Patent No. 9,211,253 B2.

85. Padagis Israel is entitled to a declaration that the claims of the '713 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT IX
(Declaration of Non-Infringement of the '139 Patent)

86. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-85.

87. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or

importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would infringe any valid and enforceable claim of the '139 patent.

88. The manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '139 patent, either literally or under the doctrine of equivalents, directly or indirectly.

89. Padagis Israel is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA would not infringe any valid and enforceable claim of the '139 patent.

COUNT X
(Declaration of Invalidity of the '139 Patent)

90. Padagis Israel realleges and incorporates by reference the allegations of Paragraphs 1-89.

91. A present, genuine, and justiciable controversy exists between Hikma and Padagis Israel regarding, *inter alia*, the invalidity of the '139 patent.

92. The claims of the '139 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged claimed invention of the '139 patent was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

b. The alleged claimed invention of the '139 patent was described in a patent issued under 35 U.S.C. § 151, or in an application for patent published or deemed published

under 35 U.S.C. § 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

c. Any differences between the alleged claimed invention of the '139 patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

d. The alleged claimed invention of the '139 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '139 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '139 patent and would have had a reasonable expectation of success in doing so.

e. The '139 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the same.

f. The claims of the '139 patent are invalid because they do not inform those skilled in the art about the scope of the alleged invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

g. The subject matter claimed in the '139 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed invention pertains. Non-limiting examples of prior art rendering each of the claims of the '139 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Padagis Israel's May 2, 2023 Notice Letter and/or Padagis Israel's May 31, 2023 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,416,886; U.S. Patent No. 4,626,539; U.S. Patent No. 4,782,047; U.S. Patent No. 5,866,154; U.S. Patent No. 5,897,858; U.S. Patent No. 6,677,346 B1; U.S. Patent No. 7,214,381 B2; U.S. Patent No. 8,216,604 B2; U.S. Patent No. 8,399,508 B2; U.S. Patent No. 9,211,253 B2.

93. Padagis Israel is entitled to a declaration that the claims of the '139 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

REQUEST FOR RELIEF

WHEREFORE, Padagis Israel respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff/Counterclaim-Defendant Hikma as follows:

(a) Declaring that the manufacture, sale, offer for sale, use or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 does not and will not infringe (either literally or under

the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '510 patent;

(b) Declaring that the claims of the '510 patent are invalid;

(c) Declaring that the manufacture, sale, offer for sale, use or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '814 patent;

(d) Declaring that the claims of the '814 patent are invalid;

(e) Declaring that the manufacture, sale, offer for sale, use or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '155 patent;

(f) Declaring that the claims of the '155 patent are invalid;

(g) Declaring that the manufacture, sale, offer for sale, use or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '713 patent;

(h) Declaring that the claims of the '713 patent are invalid;

(i) Declaring that the manufacture, sale, offer for sale, use or importation of the Naloxone Hydrochloride Nasal Spray, 8mg/spray, product described in Padagis Israel's ANDA No. 216719 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '139 patent;

(j) Declaring that the claims of the '139 patent are invalid;

(k) Ordering that Hikma's Complaint be dismissed with prejudice and judgment entered in favor of Padagis Israel;

(l) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Padagis Israel attorneys' fees, costs, and expenses in this action; and

(m) Awarding Padagis Israel any further and additional relief as the Court deems just and proper.

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