IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOPE MEDICAL ENTERPRISES, INC., d/b/a Hope Pharmaceuticals, Plaintiff, v. ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Hope Medical Enterprises, Inc., d/b/a Hope Pharmaceuticals ("Hope" or "Plaintiff"), by its attorneys, brings this complaint against Defendants Intas Pharmaceuticals Ltd. ("Intas") and Accord Healthcare, Inc. ("Accord" or, collectively with Intas, "Defendants"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, that arises out of Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a purported generic version of Hope's Sodium Thiosulfate Injection, 250 mg/mL, prior to the expiration of U.S. Patent Nos. 8,496,973 ("the '973 patent"); 9,345,724 ("the '724 patent"); 9,585,912 ("the '912 patent"); and 10,479,686 ("the '686 patent") (collectively, "the patents-in-suit").

PARTIES

2. Plaintiff Hope is a corporation organized and existing under the laws of the State of Arizona, having a principal place of business at 16416 N. 92nd Street #125, Scottsdale, AZ 85260.

3. On information and belief, Defendant Intas is a corporation organized and existing under the laws of India, having a principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India. On information and belief, Intas is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

4. On information and belief, Defendant Accord is a wholly owned subsidiary of Intas, and is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road #210B, Durham, NC 27703. On information and belief, Accord is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

HOPE'S SODIUM THIOSULFATE DRUG PRODUCT

5. Hope is the holder of New Drug Application ("NDA") No. 203923, under which the FDA approved the commercial marketing of Hope's Sodium Thiosulfate Injection, 250 mg/mL ("Hope's NDA Product" or "the NDA Product") on February 14, 2012, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), for sequential use with sodium nitrite for the treatment of acute cyanide poisoning that is judged to be serious or life-threatening. Hope commenced commercial sales of its Sodium Thiosulfate Injection for this indication in 2012 and it is marketed in the United States for sequential use with sodium nitrite

and sold either as a standalone injection or as part of Hope's Nithiodote® kits (in combination with a sodium nitrite injection).

6. Hope's NDA Product is covered by one or more claims of the patents-in-suit. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit have been listed in connection with NDA No. 203923 in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

ACCORD'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

7. By a letter dated June 13, 2022 ("Accord Notice Letter"), Accord notified Plaintiff that Defendants had submitted to the FDA ANDA No. 217214 ("Accord's ANDA") describing a purported generic version of a sodium thiosulfate injection USP, 12.5 grams/50 mL (250 mg/mL) single-dose vial ("Accord ANDA Product"). Defendants seek FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Accord ANDA Product in or into the United States, including Delaware, prior to the expiration of the patents-in-suit.

8. On information and belief, Defendants know and intend that upon approval of Accord's ANDA, Defendants will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Accord ANDA Product throughout the United States, including in Delaware.

9. On information and belief, Defendants have submitted or caused the submission of Accord's ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Accord ANDA Product, as a purported generic version of Hope's NDA Product, prior to the expiration of the patents-in-suit.

10. The Accord Notice Letter acknowledged that the Reference Listed Drug for Accord's ANDA is Hope's NDA Product.

11. By filing the ANDA, Defendants have represented to the FDA that Accord's ANDA Product is bioequivalent to Hope's NDA Product.

12. The Accord Notice Letter also notified Plaintiff that, as part of Accord's ANDA, Defendants had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), with respect to the '973, '724, and '912 patents.

13. On information and belief, Defendants submitted Accord's ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the '973, '724, and '912 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product.

14. On information and belief, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Accord's ANDA, and intend to further prosecute Accord's ANDA. On information and belief, if the FDA approves Accord's ANDA, Defendants will manufacture, distribute, promote, market, use, offer for sale, or sell the Accord ANDA Product within the United States, or will import the Accord ANDA Product into the United States. On information and belief, if the FDA approves Accord's ANDA, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, distribution, promotion, marketing, use, offer for sale, sale, or importation of the Accord ANDA Product in or into the United States.

15. Plaintiff brings this action within forty-five days of receipt of the Accord Notice Letter. Accordingly, Plaintiff is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

JURISDICTION AND VENUE

16. Plaintiff incorporates each of the preceding paragraphs 1–15 as if fully set forth herein.

17. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, including 35 U.S.C. § 271(e)(2). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

18. Venue is proper in this Court because, among other things, Accord, through its counsel, has consented to jurisdiction and venue in Delaware for purposes of this action, prior to the filing of this Complaint.

19. Moreover, Defendants have litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware and/or have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of ANDAs. *See, e.g.*, *Purdue Pharma LP et al. v. Accord Healthcare Inc. et al.*, C.A. No. 22-913 (D. Del.), D.I. 1 ¶¶ 17–18; *Eagle Pharms. Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 22-704 (D. Del.), D.I. 11 ¶¶ 13–28; *Otsuka Pharm. Co. et al. v. Accord Healthcare, Inc.*, C.A. No. 19-1987-LPS (D. Del.), D.I. 9 ¶¶ 8, 9, 13; *Novartis Pharms. Corp. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-1043-LPS (D. Del.), D.I. 46 ¶¶ 11–13, 216–221; *Biogen Int'l GmbH et al. v. Accord Healthcare Inc.*, C.A. No. 17-872-LPS (D. Del.), D.I. 8 ¶¶ 1 [*sic*], 3 [*sic*]; *Purdue Pharma LP et al. v. Accord Healthcare Inc. et al.*, C.A. No. 20-1362-RGA (D. Del.), D.I. 14 ¶¶ 18–25.

20. Defendants are subject to personal jurisdiction in Delaware because, among other things, Defendants have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being sued in this Court. On information and belief, Defendants develop, manufacture, import, market, distribute, use, offer to sell, and/or sell generic drugs throughout the United States, including in the State of Delaware,

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