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,

and therefore transact business within the State of Delaware related to Plaintiff's claims, and/or have engaged in systematic and continuous business contacts within the State of Delaware.

21. On information and belief, Defendants intend a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will continue to lead to foreseeable harm and injury to Hope in Delaware and this Judicial District.

22. Defendants have committed an act of infringement in this judicial district by filing ANDA No. 217214 with the intent to make, use, sell, offer for sale, and/or import the Accord ANDA Product in or into this judicial district, prior to the expiration of the patents-in-suit.

23. Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Accord ANDA Product, that will be purposefully directed at Delaware and elsewhere in the United States.

24. On information and belief, Defendants have systematic and continuous contacts with Delaware; have established distribution channels for drug products in Delaware; regularly and continuously conduct business in Delaware, including by selling drug products in Delaware, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in Delaware; and derive substantial revenue from the sale of drug products in Delaware.

25. On information and belief, if Accord's ANDA is approved, Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Accord ANDA Product within the United States, including in Delaware, consistent with Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Defendants regularly do business in Delaware, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for

distribution throughout the United States, including in Delaware. On information and belief, Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, the Accord ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of the patents-in-suit in the event that the Accord ANDA Product is approved before the patents-in-suit expire.

26. On information and belief, Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Defendants and/or for which Defendants are the named applicant(s) on approved ANDAs. On information and belief, various products for which Defendants are the named applicant(s) on approved ANDAs are available at hospital and/or retail pharmacies in Delaware.

27. On information and belief, Defendants have consented to (or not contested) personal jurisdiction in this Judicial District in one or more prior cases arising out of the filing of ANDAs, and/or have filed counterclaims in such cases. *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.

28. This Court has personal jurisdiction over Intas because, among other things, it: (1) has purposefully availed itself of the privilege of doing business in Delaware, including directly or indirectly through its subsidiary, Accord; and (2) maintains extensive and systematic contacts with the State of Delaware, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware, including through, directly or indirectly, Accord.

29. In the alternative, this Court has personal jurisdiction over Intas because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Hope's claims arise under federal law; (b) Intas is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Intas has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Intas satisfies due process.

30. On information and belief, Defendants work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

31. On information and belief, each of the Defendants participated, directly or indirectly, in the preparation and/or submission of Accord's ANDA. On information and belief, Defendants will work in privity and/or concert with each other and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Accord's ANDA Product, throughout the United States, including in Delaware and in this Judicial District, prior to the expiration of the patents-in-suit.

32. On information and belief, Intas intends to benefit directly if Accord's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Accord's ANDA.

33. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

34. On information and belief, Defendants have consented to (or not contested) venue in this Judicial District in one or more prior cases arising out of the filing of ANDAs, and/or have filed counterclaims in such cases. *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.

35. Venue is also proper in this Judicial District with respect to Intas because, upon information and belief, Intas is a foreign corporation that may be sued in any judicial district where it is subject to the personal jurisdiction of the Court.

THE PATENTS-IN-SUIT

36. The '973 patent, titled "Sodium Thiosulfate-Containing Pharmaceutical Compositions" was duly and legally issued on July 30, 2013 (attached as Exhibit A). Plaintiff Hope is the owner of all right, title, and interest in, and has all the rights to enforce, the '973 patent.

37. The '973 patent is listed in the Orange Book in conjunction with Hope's NDA Product.

38. The ’724 patent, titled “Sodium Thiosulfate-Containing Pharmaceutical Compositions” was duly and legally issued on May 24, 2016 (attached as Exhibit B). Plaintiff Hope is the owner of all right, title, and interest in, and has all the rights to enforce, the ’724 patent.

39. The ’724 patent is listed in the Orange Book in conjunction with Hope’s NDA Product.

40. The ’912 patent, titled “Sodium Thiosulfate-Containing Pharmaceutical Compositions” was duly and legally issued on March 7, 2017 (attached as Exhibit C). Plaintiff Hope is the owner of all right, title, and interest in, and has all the rights to enforce, the ’912 patent.

41. The ’912 patent is listed in the Orange Book in conjunction with Hope’s NDA Product.

42. The ’686 patent, titled “Sodium Thiosulfate-Containing Pharmaceutical Compositions” was duly and legally issued on November 19, 2019 (attached as Exhibit D). Plaintiff Hope is the owner of all right, title, and interest in, and has all the rights to enforce, the ’686 patent.

43. The ’686 patent is listed in the Orange Book in conjunction with Hope’s NDA Product.

COUNT I – INFRINGEMENT OF THE ’973 PATENT

44. Plaintiff incorporates each of the preceding paragraphs 1–43 as if fully set forth herein.

45. Defendants’ submission of Accord’s ANDA, with the accompanying Paragraph IV Certification and notice to Hope of same, to engage in the commercial manufacture, sale, offer for sale, or importation into the United States of Accord’s ANDA Product, prior to the expiration of the ’973 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A) by Defendants.

46. There is a justiciable controversy between the parties hereto as to the infringement of the '973 patent.

47. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will infringe one or more claims of the '973 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States.

48. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will induce infringement of one or more claims of the '973 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, upon FDA approval of Accord's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '973 patent and knowledge that their acts are encouraging infringement.

49. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will contributorily infringe one or more claims of the '973 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Accord's ANDA Product is especially adapted for a use that infringes one or more claims of the '973 patent and that there is no substantial non-infringing use for Accord's ANDA Product.

50. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '973 patent is not enjoined.

51. Plaintiff does not have an adequate remedy at law.

COUNT II – INFRINGEMENT OF THE '724 PATENT

52. Plaintiff incorporates each of the preceding paragraphs 1–51 as if fully set forth herein.

53. Defendants' submission of Accord's ANDA, with the accompanying Paragraph IV Certification and notice to Hope of same, to engage in the commercial manufacture, sale, offer for sale, or importation into the United States of Accord's ANDA Product, prior to the expiration of the '724 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A) by Defendants.

54. There is a justiciable controversy between the parties hereto as to the infringement of the '724 patent.

55. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States.

56. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will induce infringement of one or more claims of the '724 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, upon FDA approval of Accord's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '724 patent and knowledge that their acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will contributorily infringe one or more claims of the '724 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Accord's ANDA Product is especially adapted for a use that infringes one or more claims of the '724 patent and that there is no substantial non-infringing use for Accord's ANDA Product.

58. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '724 patent is not enjoined.

59. Plaintiff does not have an adequate remedy at law.

COUNT III – INFRINGEMENT OF THE '912 PATENT

60. Plaintiff incorporates each of the preceding paragraphs 1–59 as if fully set forth herein.

61. Defendants' submission of Accord's ANDA, with the accompanying Paragraph IV Certification and notice to Hope of same, to engage in the commercial manufacture, sale, offer for sale, or importation into the United States of Accord's ANDA Product, prior to the expiration of the '912 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A) by Defendants.

62. There is a justiciable controversy between the parties hereto as to the infringement of the '912 patent.

63. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will infringe one or more claims of the '912 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States.

64. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will induce infringement of one or more claims of the '912 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, upon FDA approval of Accord's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '912 patent and knowledge that their acts are encouraging infringement.

65. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will contributorily infringe one or more claims of the '912 patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Accord's ANDA Product is especially adapted for a use that infringes one or more claims of the '912 patent and that there is no substantial non-infringing use for Accord's ANDA Product.

66. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '912 patent is not enjoined.

67. Plaintiff does not have an adequate remedy at law.

COUNT IV – INFRINGEMENT OF THE '686 PATENT

68. Plaintiff incorporates each of the preceding paragraphs 1–67 as if fully set forth herein.

69. Defendants' submission of Accord's ANDA to engage in the commercial manufacture, sale, offer for sale, or importation into the United States of Accord's ANDA Product, prior to the expiration of the '686 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A) by Defendants.

70. There is a justiciable controversy between the parties hereto as to the infringement of the '686 patent.

71. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will infringe one or more claims of the '686 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States.

72. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will induce infringement of one or more claims of the '686 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, upon FDA approval of Accord's ANDA, Defendants will

intentionally encourage acts of direct infringement with knowledge of the '686 patent and knowledge that their acts are encouraging infringement.

73. Unless enjoined by this Court, upon FDA approval of Accord's ANDA, Defendants will contributorily infringe one or more claims of the '686 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Accord's ANDA Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Accord's ANDA Product is especially adapted for a use that infringes one or more claims of the '686 patent and that there is no substantial non-infringing use for Accord's ANDA Product.

74. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '686 patent is not enjoined.

75. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Hope respectfully requests the following relief:

(a) A Judgment that Defendants have infringed the patents-in-suit by submitting ANDA No. 217214 with the accompanying Paragraph IV Certification and notice to Hope of same;

(b) A Judgment that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Accord's ANDA Product would infringe one or more claims of the patents-in-suit;

(c) An Order that the effective date of FDA approval of ANDA No. 217214 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Hope is or becomes entitled;

(d) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Accord's ANDA Product until after the

expiration of the patents-in-suit, or any later expiration of exclusivity to which Hope is or becomes entitled;

(e) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Hope is or becomes entitled;

(f) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Accord's ANDA Product would directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(g) To the extent that Defendants, their officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, have committed any acts of infringement of the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Hope damages for such acts;

(h) If Defendants, their officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Accord's ANDA Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Hope resulting from such infringement, together with interest;

(i) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(j) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Hope its attorneys' fees incurred in this action;

(k) A Judgment awarding Hope its costs and expenses incurred in this action; and

(l) Such further and other relief as this Court may deem just and proper.

ASHBY & GEDDES

/s/ John G. Day

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