

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL)
CORPORATION,)
)
)
Plaintiff,) C.A. No.
)
v.)
)
)
ALKEM LABORATORIES LTD.;)
THE PHARMA NETWORK, LLC; and)
ASCEND LABORATORIES, LLC,)
)
Defendants.)
)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation (“Medicis”) for its Complaint against Defendants Alkem Laboratories Ltd. (“Alkem”), The Pharma Network, LLC (“TPN”), and Ascend Laboratories, LLC (“Ascend”) (collectively “Defendants”) alleges as follows:

I. THE PARTIES

1. Medicis is a Delaware corporation with its principal place of business at 7720 North Dobson Road, Scottsdale, AZ 85256. Medicis is a leading independent specialty pharmaceutical company in the United States focusing on the treatment of dermatological conditions. Medicis’s products have earned wide acceptance by both physicians and patients, including Medicis’s SOLODYN® extended release tablets for acne treatment.

2. On information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, with a principal place of business at Devashish, Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai 400013, India. On information and belief, Alkem is in the business of manufacturing generic pharmaceutical drugs that it distributes and

sells in the State of Delaware and throughout the United States, by and with Defendants TPN and Ascend.

3. On information and belief, Defendant TPN is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 180 Summit Avenue, Suite 200, Montvale, NJ 07645, and is a subsidiary of Alkem. TPN, through its wholly owned subsidiary, Ascend, is in the business of marketing, distributing, and selling, in the State of Delaware and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Alkem.

4. On information and belief, TPN is also the United States agent for Alkem for purposes including, but not limited to, submitting regulatory submissions to and corresponding with the United States Food and Drug Administration (“FDA”).

5. On information and belief, Defendant Ascend is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 180 Summit Avenue, Suite 200, Montvale, NJ 07645, and is a wholly owned subsidiary of TPN. Ascend is in the business of marketing, distributing, and selling, in the State of Delaware and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Alkem.

6. On information and belief, Defendants collaborate to manufacture, import, market, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the State of Delaware and in the United States.

7. On information and belief, TPN is so controlled and/or dominated by Alkem that, in effect, TPN does not have a separate corporate existence.

8. On information and belief, Ascend is so controlled and/or dominated by Alkem that, in effect, Ascend does not have a separate corporate existence.

II. NATURE OF THE ACTION

9. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, et seq.) based upon Defendants' infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of Medicis's U.S. Patent No. 5,908,838 as set forth in the duly issued Ex Parte Reexamination Certificate on June 1, 2010 ("the '838 patent"), and/or infringement of one or more claims of Medicis's U.S. Patent No. 7,790,705 ("the '705 patent"), and/or infringement of and one or more claims of Medicis's U.S. Patent No. 8,268,804 ("the '804 patent").

10. On information and belief, Alkem, by and with TPN and Ascend, filed Abbreviated New Drug Application No. 204453 (the "Alkem ANDA") under 21 U.S.C. § 355(j) to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets in their 45 milligram ("mg"), 65 mg, 90 mg, 115 mg, and 135 mg strengths for the treatment of acne.

11. Defendants have infringed one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their filing of the Alkem ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") seeking FDA approval of the Alkem ANDA prior to expiration of the '838 patent.

12. Defendants have infringed one or more claims of the '705 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their filing of the Alkem ANDA with a Paragraph IV certification seeking FDA approval of the Alkem ANDA prior to expiration of the '705 patent.

13. Defendants have infringed one or more claims of the '804 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their filing of the Alkem ANDA with a Paragraph IV certification seeking FDA approval of the Alkem ANDA prior to expiration of the '804 patent.

III. JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over Medicis's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, inter alia, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Medicis, a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below.

16. This Court has personal jurisdiction over Alkem by virtue of, inter alia, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

17. This Court has personal jurisdiction over TPN by virtue of, inter alia, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

18. This Court has personal jurisdiction over Ascend by virtue of, inter alia, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

19. On information and belief, through its relationship with TPN and Ascend, Alkem does substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware.

20. On information and belief, the claims in this action partially arise out of acts committed by Defendants in Delaware. Defendants collaborate to develop, manufacture, seek approval for, and sell FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and in the United States. On information and belief, Defendants collaborate to develop, manufacture, seek approval for, and sell the disputed generic pharmaceutical drug, which will cause tortious injury to Medicis, a Delaware corporation. Moreover, on information and belief, Defendants, following any FDA approval of the Alkem ANDA, will sell the generic product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States, using Ascend as the marketer, distributor, and seller.

21. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

IV. PATENTS-IN-SUIT

22. The allegations of ¶¶ 1-21 are incorporated herein by reference.

23. Medicis is the owner of all rights, title and interest in the '838 patent, entitled "Method for the Treatment of Acne." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '838 patent on June 1, 1999, to Eugene H. Gans, which was assigned to Medicis. A true and correct copy of the '838 patent, as reexamined, is attached to this Complaint as Exhibit A.

24. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in their 45 mg, 90 mg, and 135 mg strengths under 21 U.S.C. § 355(b), for the treatment of acne. On July 23, 2009, the FDA approved Medicis's supplement to new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in its 65 mg and 115 mg strengths under 21 U.S.C. § 355(b), for the

treatment of acne. On August 27, 2010, the FDA approved Medicis's supplement to new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in its 55 mg, 80 mg, and 105 mg strengths under 21 U.S.C. § 355(b), for the treatment of acne.

25. The use of SOLODYN® minocycline HCl extended release tablets is covered by the '838 patent, and Medicis has the right to enforce the '838 patent.

26. In June 2008 a request for reexamination was filed on the '838 patent. In August 2008, the USPTO granted the request for reexamination.

27. On June 1, 2010, the USPTO issued the Ex Parte Reexamination Certificate, reaffirming the validity of original claims 3, 4, 12, and 13, and issuing new claims 19-34. Ex. A at 4-14.

28. Although the Ex Parte Reexamination Certificate incorrectly identifies Norwest Bank Arizona, National Association, n/k/a Wells Fargo Bank Arizona, as the Assignee of the '838 patent, the USPTO issued a Certificate of Correction on October 12, 2010, indicating that the correct assignee of the '838 patent is Medicis. Ex. A at 15.

29. The FDA listed the '838 patent in the Orange Book on December 3, 2008 for SOLODYN® minocycline HCl extended release tablets in their 45 mg, 90 mg, and 135 mg strengths, on August 14, 2009 for SOLODYN® minocycline HCl extended release tablets in their 65 mg and 115 mg strengths, and on September 6, 2010 for SOLODYN® minocycline HCl extended release tablets in their 55 mg, 80 mg, and 105 mg strengths. On June 24, 2010, Medicis submitted updated information to the FDA regarding the claims of the '838 patent in the Reexamination Certificate.

30. On information and belief, Defendants submitted the Alkem ANDA to the FDA after the '838 patent was listed in the Orange Book.

31. Medicis is the owner of all rights, title and interest in the '705 patent, entitled "Minocycline Oral Dosage Forms for the Treatment of Acne." The USPTO duly and legally issued the '705 patent on September 7, 2010, to Mitchell Wortzman, R. Todd Plott, Kuljit Bhatia, and Bhiku Patel, which was assigned to Medicis. A true and correct copy of the '705 patent is attached as Exhibit B.

32. The use of SOLODYN® minocycline HCl extended release tablets is covered by the '705 patent, and Medicis has the right to enforce the '705 patent.

33. The FDA listed the '705 patent in the Orange Book by September 16, 2010 for SOLODYN® in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg and 135 mg strengths.

34. On information and belief, Defendants submitted the Alkem ANDA to the FDA after the '705 patent was listed in the Orange Book.

35. Medicis is the owner of all rights, title and interest in the '804 patent, entitled "Method for the Treatment of Acne." The USPTO duly and legally issued the '804 patent on September 18, 2012, to Mitchell Wortzman, R. Todd Plott, Kuljit Bhatia, and Bhiku Patel, which was assigned to Medicis. A true and correct copy of the '804 patent is attached as Exhibit C.

36. The use of SOLODYN® minocycline HCl extended release tablets is covered by the '804 patent, and Medicis has the right to enforce the '804 patent.

37. The FDA listed the '804 patent in the Orange Book by October 16, 2012 for SOLODYN® in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg and 135 mg strengths.

38. On information and belief, Defendants submitted the Alkem ANDA to the FDA after the '804 patent was listed in the Orange Book.

COUNT I
(INFRINGEMENT OF THE '838 PATENT BY DEFENDANTS)

39. The allegations of ¶¶ 1-38 are incorporated herein by reference.

40. On information and belief, Alkem filed the Alkem ANDA under 21 U.S.C. § 355(j) to obtain approval to commercially manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent.

41. On or about October 29, 2012, Medicis received a letter (“Alkem Notice Letter”), dated October 26, 2012, from Alkem, stating that Alkem had filed the Alkem ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notified Medicis that the Alkem ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is not infringed, invalid and/or unenforceable.

42. On information and belief, TPN and Ascend participated in, contributed to, aided, and/or abetted Alkem's submission of the Alkem ANDA and its Paragraph IV allegations, and the Paragraph IV certifications to the FDA contained therein.

43. Defendants have infringed one or more claims of the '838 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their submission of the Alkem ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths, which are covered by one or more of the following claims of the '838 patent: claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34.

44. Defendants are jointly and severally liable for any infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent. Defendants' participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Alkem ANDA and its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct, contributory, and/or induced infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c).

45. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Alkem ANDA would infringe directly or contribute to or induce the infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent.

46. Pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A), an order should be entered requiring that Alkem amend its Paragraph IV certification in the Alkem ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification").

47. Under 35 U.S.C. § 271(e)(4), an order should be entered providing that the effective date of any FDA approval of the Alkem ANDA be a date that is not earlier than the expiration of the '838 patent, or any later expiration of exclusivity for the '838 patent to which Medicis becomes entitled.

48. Medicis will be irreparably harmed if Defendants are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent. Pursuant to 35 U.S.C. § 283, a permanent injunction should be entered preventing further infringement. Medicis does not have an adequate remedy at law.

49. To the extent Defendants commercialize their product, they will become liable for damages under 35 U.S.C. § 284.

COUNT II
(INFRINGEMENT OF THE '705 PATENT BY DEFENDANTS)

50. The allegations of ¶¶ 1-49 are incorporated herein by reference.

51. On information and belief, Alkem filed the Alkem ANDA under 21 U.S.C. § 355(j) to obtain approval to commercially manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets for the treatment of acne before the expiration of the '705 patent.

52. On or about October 29, 2012, Medicis received the Alkem Notice Letter, dated October 26, 2012, stating that Alkem had filed the Alkem ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths for the treatment of acne before the expiration of the '705 patent. The letter notified Medicis that the Alkem ANDA was submitted with a Paragraph IV certification that the '705 patent purportedly is not infringed and/or invalid.

53. On information and belief, TPN and Ascend participated in, contributed to, aided, and/or abetted Alkem's submission of the Alkem ANDA and its Paragraph IV allegations, and the Paragraph IV certifications to the FDA contained therein.

54. Defendants have infringed one or more claims of the '705 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their submission of the Alkem ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths, which are covered by one or more claims of the '705 patent.

55. Defendants are jointly and severally liable for any infringement of one or more claims of the '705 patent. Defendants' participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Alkem ANDA and its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct, contributory, and/or induced infringement of one or more claims of the '705 patent under §§ 271(e)(2)(A), 271(b), and/or 271(c).

56. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Alkem ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '705 patent.

57. Pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A), an order should be entered requiring that Alkem amend its Paragraph IV certification in the Alkem ANDA to a Paragraph III certification.

58. Under 35 U.S.C. § 271(e)(4), an order should be entered providing that the effective date of any FDA approval of the Alkem ANDA be a date that is not earlier than the expiration of the '705 patent, or any later expiration of exclusivity for the '705 patent to which Medicis becomes entitled.

59. Medicis will be irreparably harmed if Defendants are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more claims of the '705 patent. Pursuant to 35 U.S.C. § 283, a permanent injunction should be entered preventing further infringement. Medicis does not have an adequate remedy at law.

60. To the extent Defendants commercialize their product, they will become liable for damages under 35 U.S.C. § 284.

COUNT III
(INFRINGEMENT OF THE '804 PATENT BY DEFENDANTS)

61. The allegations of ¶¶ 1-60 are incorporated herein by reference.

62. On information and belief, Alkem filed the Alkem ANDA under 21 U.S.C. § 355(j) to obtain approval to commercially manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets for the treatment of acne before the expiration of the '804 patent.

63. On or about October 29, 2012, Medicis received the Alkem Notice Letter, dated October 26, 2012, stating that Alkem had filed the Alkem ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths for the treatment of acne before the expiration of the '804 patent. The letter notified Medicis that the Alkem ANDA was submitted with a Paragraph IV certification that the '804 patent purportedly is not infringed and/or invalid.

64. On information and belief, TPN and Ascend participated in, contributed to, aided, and/or abetted Alkem's submission of the Alkem ANDA and its Paragraph IV allegations, and the Paragraph IV certifications to the FDA contained therein.

65. Defendants have infringed one or more claims of the '804 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their submission of the Alkem ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths, which are covered by one or more claims of the '804 patent.

66. Defendants are jointly and severally liable for any infringement of one or more claims of the '804 patent. Defendants' participation in, contribution to, aiding, abetting,

and/or inducement of the submission of the Alkem ANDA and its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct, contributory, and/or induced infringement of one or more claims of the '804 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c).

67. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Alkem ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '804 patent.

68. Pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A), an order should be entered requiring that Alkem amend its Paragraph IV certification in the Alkem ANDA to a Paragraph III certification.

69. Under 35 U.S.C. § 271(e)(4), an order should be entered providing that the effective date of any FDA approval of the Alkem ANDA be a date that is not earlier than the expiration of the '804 patent, or any later expiration of exclusivity for the '804 patent to which Medicis becomes entitled.

70. Medicis will be irreparably harmed if Defendants are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more claims of the '804 patent. Pursuant to 35 U.S.C. § 283, a permanent injunction should be entered preventing further infringement. Medicis does not have an adequate remedy at law.

71. To the extent Defendants commercialize their product, they will become liable for damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Medicis respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

A. an adjudication that Defendants have infringed directly and/or contributed to and/or induced the infringement of one or more of the following claims of the '838 patent: claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34, under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c), by submitting to the FDA the Alkem ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, or distribution in and/or importation into the United States of generic SOLODYN® minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent;

B. an adjudication that Defendants have infringed directly and/or contributed to and/or induced the infringement of one or more claims of the '705 patent, under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c), by submitting to the FDA the Alkem ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, or distribution in and/or importation into the United States of generic SOLODYN® minocycline HCl extended release tablets for the treatment of acne before the expiration of the '705 patent;

C. an adjudication that Defendants have infringed directly and/or contributed to and/or induced the infringement of one or more claims of the '804 patent, under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c), by submitting to the FDA the Alkem ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, or distribution in and/or importation into the United States of generic SOLODYN® minocycline HCl extended release tablets for the treatment of acne before the expiration of the '804 patent;

D. an order requiring that Defendants amend their Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

E. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Alkem ANDA for generic SOLODYN® minocycline HCl

extended release tablets be a date that is not earlier than the date of the expiration of the '838 patent or any later period of exclusivity to which Medicis is or may become entitled;

F. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Alkem ANDA for generic SOLODYN® minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the '705 patent or any later period of exclusivity to which Medicis is or may become entitled;

G. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Alkem ANDA for generic SOLODYN® minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the '804 patent or any later period of exclusivity to which Medicis is or may become entitled;

H. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the '838 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Alkem ANDA;

I. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the '705 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Alkem ANDA;

J. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the '804 patent, or contributing to or

inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Alkem ANDA;

K. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the '838 patent, and/or contributing to and/or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Alkem ANDA while the litigation is pending;

L. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the '705 patent, and/or contributing to and/or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Alkem ANDA while the litigation is pending;

M. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the '804 patent, and/or contributing to and/or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Alkem ANDA while the litigation is pending;

N. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Alkem ANDA would constitute infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent, and/or inducing and/or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

O. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Alkem ANDA would constitute infringement of one or more claims of the '705 patent, and/or inducing and/or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

P. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Alkem ANDA would constitute infringement of one or more claims of the '804 patent, and/or inducing and/or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c); and

Q. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

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