IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DELCOR ASSET CORPORATION and MYLAN PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
GLENMARK PHARMACEUTICALS LIMITED, GLENMARK PHARMACEUTICALS INC., USA and STIEFEL WEST COAST, LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Delcor Asset Corporation and Mylan Pharmaceuticals Inc. (collectively, "Delcor" or "Plaintiffs"), by their attorneys, for their Complaint against Defendants Glenmark Pharmaceuticals Limited ("Glenmark Ltd.") and Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") (Glenmark Ltd. and Glenmark USA are collectively referred to herein as "Glenmark"), and Involuntary Party Stiefel West Coast, LLC ("Stiefel"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 7,141,237 ("the '237 patent") and 7,374,747 ("the '747 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to Abbreviated New Drug Application ("ANDA") No. 210778, filed by Glenmark with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Evoclin® (clindamycin phosphate aerosol, foam 1%) prior to the expiration of the '237 and '747 patents.

THE PARTIES

2. Plaintiff Delcor Asset Corporation is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

3. Plaintiff Mylan Pharmaceuticals Inc. is a company organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. On information and belief, Involuntary Party Stiefel is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 3160 Porter Drive, Palo Alto, California 94304. On information and belief, Stiefel has a registered agent in Delaware, which agent is Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

5. Stiefel has been joined as an involuntary party in this action, pursuant to Rule 19(a) of the Federal Rules of Civil Procedure. *See Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 468 (1926) ("If the owner of a patent, being within the jurisdiction, refuses or is unable to join an exclusive licensee as co-plaintiff, the licensee may make him a party defendant by process, and he will be lined up by the court in the party character which he should assume."); *AsymmetRx, Inv. v. Biocare Med.*, 582 F.3d 1314, 1322 (Fed. Cir. 2009) ("A patentee that does not voluntarily join an action prosecuted by its exclusive licensee can be joined as a defendant . . . ."); *Int'l Rediscount Corp. v. Hartford Accident & Indem. Co.*, 425 F. Supp. 669, 674-75 (D. Del. 1997) ("An involuntary plaintiff is a party who is obligated to assist in prosecuting an action or to permit its name to be used but refuses to do so and who is thereafter joined . . . If a party is subject

to service, however, it is not joined as an 'involuntary plaintiff.' Rather, it is served, joined as a defendant, and then realigned by the Court in the 'character which [it] should assume.'").

6. On information and belief, Stiefel is subject to service in Delaware because it is registered to do business in the State of Delaware as a Limited Liability Company and has a registered agent in Delaware for service of process. After Stiefel has been served with the complaint, Plaintiffs will respectfully request that the Court realign Stiefel as a co-plaintiff pursuant to *Independent Wireless*, *AsymmetRx*, and *Int'l Rediscount*.

7. On information and belief, Defendant Glenmark Ltd. is a company organized and existing under the laws of India, with its principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400 099, Maharashtra, India. On information and belief, Glenmark Ltd. developed and owns ANDA No. 210778.

8. On information and belief, Defendant Glenmark USA is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 750 Corporate Drive, Mahwah NJ 07430. On information and belief, Glenmark USA is the authorized U.S. agent for ANDA No. 210778. On information and belief, Glenmark USA and Glenmark Ltd. collaborate to develop, manufacture, and market pharmaceutical products in the United States.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and 28 U.S.C. §§ 2201 and 2202.

10. Stiefel is a limited liability company organized and existing under the laws of the State of Delaware and therefore subject to the general personal jurisdiction of this court.

11. Glenmark USA is a corporation organized and existing under the laws of the State of Delaware and therefore subject to the general personal jurisdiction of this court.

12. Glenmark Ltd., which is organized and existing under the laws of India, with its principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400 099, Maharashtra, India, is subject to personal jurisdiction of this court pursuant to at least Fed. R. Civ. P. 4(k)(2).

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b) because Glenmark USA and Stiefel are incorporated in Delaware and Glenmark Ltd. is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

THE PATENTS-IN-SUIT

14. The '237 patent, titled "Pharmaceutical Foam," was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on November 28, 2006. A true and correct copy of the '237 patent is attached as Exhibit A.

15. As set forth in greater detail in the '237 patent, the claims of the '237 patent, incorporated by reference herein, are directed to, *inter alia*, pharmaceutical compositions containing clindamycin phosphate and other components such as a base.

16. The '747 patent, titled "Pharmaceutical Foam," was duly and legally issued by the USPTO on May 20, 2008. A true and correct copy of the '747 patent is attached as Exhibit B.

17. As set forth in greater detail in the '747 patent, the claims of the '747 patent, incorporated by reference herein, are directed to, *inter alia*, methods of treating bacteria-mediated diseases using pharmaceutical compositions containing clindamycin phosphate and other components such as a base.

18. Stiefel is the assignee of the '237 and '747 patents.

19. Delcor Asset Corporation is the exclusive licensee of the '237 and '747 patents.

20. Mylan Pharmaceuticals Inc. is the holder of approved New Drug Application No. 050801 for clindamycin phosphate aerosol, foam 1% (the "Evoclin® NDA"), which is marketed under the name Evoclin® in the United States.

21. Evoclin® is indicated for the treatment of acne vulgaris. The approved usage of Evoclin® is described in the Evoclin® Prescribing Information.

22. The '237 and '747 patents are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as covering Evoclin® and its approved uses.

ACTS GIVING RISE TO THIS ACTION

23. In a letter dated September 29, 2017 purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Notice Letter"), Glenmark notified Mylan Pharmaceuticals Inc. and Stiefel that it had submitted ANDA No. 210778 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A) seeking approval to engage in the commercial manufacture, use, or sale of its proposed clindamycin phosphate aerosol, foam 1% (the "ANDA Product"), as a generic version of Evoclin® in/into the United States, prior to the expiration of the '237 and '747 patents.

24. In the Notice Letter, Glenmark notified Plaintiffs that ANDA No. 210778 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '237 and '747 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Product in/into the United States ("Paragraph IV Certification").

25. On information and belief, the active ingredient of the ANDA Product is clindamycin phosphate, which is the same active ingredient in Evoclin® and the same active

ingredient used in the compositions and methods of described in one or more claims of the ’237 and ’747 patents.

26. On information and belief, Glenmark asserts in ANDA No. 210778 that the ANDA Product is bioequivalent to Evoclin®, refers to and relies upon the Evoclin® NDA, and contains data that, according to Glenmark, demonstrate the bioequivalence of the ANDA Product to Evoclin®.

27. On information and belief, Glenmark is seeking approval to market the ANDA Product for the same Approved Indication as Evoclin®.

28. On information and belief, Glenmark is seeking approval to market the ANDA Product for the treatment of acne vulgaris.

29. Glenmark had knowledge of the ’237 and ’747 patents when it submitted and filed ANDA No. 210778.

30. On information and belief, Glenmark intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in/into the United States promptly upon receiving FDA approval and prior to the expiration of the ’237 and ’747 patents.

31. On information and belief, Glenmark intends to and will actively induce infringement of the ’237 and ’747 patents upon receiving FDA approval of ANDA No. 210778 and prior to the expiration of the ’237 and ’747 patents.

32. On information and belief, Glenmark will commercially manufacture, use, offer for sale, and/or sell the ANDA Product throughout the United States, import the ANDA Product into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the ’237 and ’747 patents.

33. On information and belief, Glenmark will knowingly accompany the ANDA Product with prescribing information that will contain instructions for use that substantially copy the instructions for Evoclin®.

34. On information and belief, Glenmark's prescribing information for the ANDA Product will instruct users to administer the ANDA Product to treat patients with acne vulgaris.

35. On information and belief, Glenmark has knowledge and/or an expectation that the ANDA Product will be used in accordance with its prescribing information.

36. On information and belief, Glenmark knows that the prescribing information that will accompany the ANDA Product will induce and/or contribute to others using the ANDA Product in the manner set forth in the prescribing information.

37. On information and belief, Glenmark knows that the ANDA Product is especially made or adapted for use in a way that would infringe the '237 and '747 patents and is not suitable for substantial non-infringing use. On information and belief, Glenmark knowingly has taken and intends to take active steps to, and will, induce and/or contribute to infringement of one or more claims of the '237 and '747 patents, including without limitation claim 1 of the '237 and '747 patents.

38. An actual case or controversy exists between Delcor and Glenmark with respect to infringement of each of the '237 and '747 patents.

39. This action is being commenced within 45 days of receipt of the Notice Letter.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 7,141,237

40. Delcor repeats and realleges the allegations of paragraphs 1-39 as if fully set forth herein.

41. Glenmark's submission of ANDA No. 210778 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the ANDA Product in/into the United States prior to the expiration of the '237 patent constitutes infringement of one or more claims of the '237 patent under 35 U.S.C. § 271(e)(2)(A), including without limitation claim 1.

42. Glenmark had knowledge of the '237 patent when it submitted ANDA No. 210778. Glenmark's infringement has been, and continues to be, deliberate.

43. Plaintiffs will be substantially and irreparably harmed if Glenmark's infringement of the '237 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

44. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants an award of Plaintiffs' reasonable attorney fees.

COUNT II

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,141,237

45. Delcor repeats and realleges the allegations of paragraphs 1-44 as if fully set forth herein.

46. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. Glenmark has taken immediate and active steps, through the submission of ANDA No. 210778, to obtain approval from the FDA to commercially manufacture, import, use, offer for sale, and/or sell the ANDA Product prior to the expiration of the '237 patent.

47. On information and belief, after obtaining FDA approval, Glenmark plans to commercially manufacture, use, offer for sale, and/or sell the ANDA Product in the United States, import the ANDA Product into the United States, and/or induce or contribute to such acts prior to the expiration of the '237 patent.

48. Upon FDA approval of ANDA No. 210778, Glenmark will infringe one or more of the claims of the ’237 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c), including without limitation claim 1, by making, using, selling, offering for sale, and/or importing the ANDA Product in/into the United States and/or inducing or contributing to such acts prior to the expiration of the ’237 patent, unless enjoined by this Court. Accordingly, an actual and immediate controversy exists between the parties regarding infringement of the ’237 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

49. Upon FDA approval of ANDA No. 210778, use of the ANDA Product as directed by the instructions to be included with the ANDA Product will directly infringe at least one of the claims of the ’237 patent, including without limitation claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (a), unless enjoined by this Court.

50. Glenmark has taken and intends to take active steps to induce or contribute to the direct infringement of one or more claims of the ’237 patent under 35 U.S.C. § 271 (b) and/or § 271 (c) after ANDA No. 210778 is approved, including without limitation claim 1, unless enjoined by this Court.

51. Glenmark has knowledge of the ’237 patent and, by the prescribing information that will be included with ANDA Product, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’237 patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

52. Glenmark’s offering for sale, sale, and/or importation of the ANDA Product in/into the United States with the prescribing information for the ANDA Product will actively induce infringement of at least one of the claims of the ’237 patent, including without limitation claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b).

53. The use of the ANDA Product constitutes a material part of at least one of the claims of the ’237 patent; Glenmark knows that the ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ’237 patent either literally or under the doctrine of equivalents; and Glenmark knows that the ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

54. Glenmark’s manufacture, use, sale, offering for sale, and/or importation of the ANDA Product in/into the United States will contributorily infringe at least one of the claims of the ’237 patent, including without limitation claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (c).

55. Glenmark had knowledge of the ’237 patent when it submitted ANDA No. 210778. Glenmark’s infringement of the ’237 patent will be deliberate.

56. Plaintiffs will be substantially and irreparably harmed if Glenmark’s infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

57. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants an award of Plaintiffs’ reasonable attorney fees.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 7,374,747

58. Delcor repeats and realleges the allegations of paragraphs 1-57 as if fully set forth herein.

59. Glenmark’s submission of ANDA No. 210778 containing a Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the ANDA Product in/into the United States prior to the expiration of the ’747 patent constitutes infringement of at least one of the claims of the ’747 patent under 35 U.S.C. § 271(e)(2)(A), including without limitation claim 1.

60. Glenmark had knowledge of the ’237 patent when it submitted ANDA No. 210778. Glenmark’s infringement has been, and continues to be, deliberate.

61. Plaintiffs will be substantially and irreparably harmed if Glenmark’s infringement of the ’747 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

62. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants an award of Plaintiffs’ reasonable attorney fees.

COUNT IV

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,374,747

63. Delcor repeats and realleges the allegations of paragraphs 1-62 as if fully set forth herein.

64. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. Glenmark has taken immediate and active steps, through the submission of ANDA No. 210778, to obtain approval from the FDA to commercially manufacture, import, use, offer for sale, and/or sell the ANDA Product prior to the expiration of the ’747 patent.

65. On information and belief, after obtaining FDA approval, Glenmark plans to commercially manufacture, use, offer for sale, and/or sell the ANDA Product in the United States, import the ANDA Product into the United States, and/or induce or contribute to such acts prior to the expiration of the ’747 patent.

66. Upon FDA approval of ANDA No. 210778, Glenmark will infringe one or more of the claims of the ’747 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c), including without limitation claim 1, by making, using, selling, offering for sale, and/or importing the ANDA Product in/into the United States and/or inducing or contributing to such acts prior to the expiration of the ’747 patent, unless enjoined by this Court. Accordingly, an actual and immediate controversy

exists between the parties regarding infringement of the ’747 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

67. Upon FDA approval of ANDA No. 210778, use of the ANDA Product as directed by the instructions to be included with the ANDA Product will directly infringe at least one of the claims of the ’747 patent, including without limitation claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (a), unless enjoined by this Court.

68. Glenmark has taken and intends to take active steps to induce or contribute to the direct infringement of one or more claims of the ’747 patent under 35 U.S.C. § 271 (b) and/or § 271 (c) after ANDA No. 210778 is approved, including without limitation claim 1, unless enjoined by this Court.

69. Glenmark has knowledge of the ’747 patent and, by the prescribing information that will be included with ANDA Product, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’747 patent, including without limitation claim 1, either literally or under the doctrine of equivalents.

70. Glenmark’s offering for sale, sale, and/or importation of the ANDA Product in/into the United States with the prescribing information for the ANDA Product will actively induce infringement of at least one of the claims of the ’747 patent, including without limitation claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b).

71. The use of the ANDA Product constitutes a material part of at least one of the claims of the ’747 patent; Glenmark knows that the ANDA Product is especially made or adapted for use in infringing at least one of the claims, of the ’747 patent either literally or under the doctrine of equivalents; and Glenmark knows that the ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

72. Glenmark's manufacture, use, offering for sale, sale, and/or importation of the ANDA Product in/into the United States will contributorily infringe at least one of the claims of the '747 patent, including without limitation claim 1, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (c).

73. Glenmark had knowledge of the '747 patent when it submitted ANDA No. 210778. Glenmark's infringement of the '747 patent will be deliberate.

74. Plaintiffs will be substantially and irreparably harmed if Glenmark's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

75. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants an award of Plaintiffs' reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Glenmark has infringed one or more claims of the '237 and '747 patents by the filing of ANDA No. 210778;

(b) A judgment declaring that Glenmark's manufacturing, using, selling, offering for sale, and/or importing the ANDA Product in/into the United States will infringe one or more claims of the '237 and '747 patents;

(c) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 210778 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '237 and '747 patents, inclusive of any extension(s) or additional period(s) of exclusivity;

(d) Injunctive relief preliminarily and permanently enjoining Glenmark, whether alone or through a subsidiary company, from making, using, selling, offering for sale, or importing the

ANDA Product in/into the United States until after expiration of the ’237 and ’747 patents, inclusive of any extension(s) or additional period(s) of exclusivity;

(e) A permanent injunction restraining and enjoining Glenmark, whether alone or through a subsidiary company, from making, using, selling, offering for sale, and/or importing a pharmaceutical composition as claimed in the ’237 and ’747 patents, or practicing any methods as claimed in the ’237 and ’747 patents, or from actively inducing or contributing to the infringement of any claim of the ’237 and ’747 patents, until after the expiration of the ’237 and ’747 patents, inclusive of any extension(s) or additional period(s) of exclusivity;

(f) A Declaration that the commercial manufacture, use, sale, offer for sale, and importation in/into the United States of the ANDA Product will directly infringe, induce, and/or contribute to infringement of the ’237 and ’747 patents;

(g) Damages, which this Court should treble pursuant to 35 U.S.C. § 284, if Glenmark, whether alone or through a subsidiary company, infringes the ’237 and ’747 patents by engaging in the commercial manufacture, use, sale, offer for sale, or importation of the ANDA Product in/into the United States prior to the expiration of the ’237 and ’747 patents, inclusive of any extension(s) or additional period(s) of exclusivity;

(h) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

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

Respectfully submitted,

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By: */s/ David E. Moore*

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Dated: November 15, 2017
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