IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DELCOR ASSET CORPORATION and MYLAN PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-1653-RGA
GLENMARK PHARMACEUTICALS LIMITED, GLENMARK PHARMACEUTICALS INC., USA and STIEFEL WEST COAST, LLC,	)	
Defendants.	)	

GLENMARK'S ANSWER,
AFFIRMATIVE DEFENSES, COUNTERCLAIMS, AND CROSSCLAIMS

Defendants Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (collectively, "Glenmark"), by and through the undersigned attorneys, answer the Complaint of Plaintiffs Delcor Asset Corporation ("Delcor") and Mylan Pharmaceuticals Inc. ("Mylan") (collectively, "Plaintiffs"), as follows. This pleading is based upon Glenmark's knowledge as to its own activities, and upon information and belief as to the activities of others. Pursuant to Fed. R. Civ. P. 8(b)(3), Glenmark denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. Glenmark admits that the Complaint purports to bring an action for infringement of the '237 and '747 patents and that the action purports to arise under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Glenmark admits that this action purports to relate to Glenmark's ANDA No. 210778, which Glenmark further admits was filed to obtain approval to market a

generic version of Evoclin® (clindamycin phosphate aerosol, foam 1%). Glenmark otherwise denies the remaining allegations of paragraph 1.

THE PARTIES

2. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 2 and therefore denies the same.

3. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 3 and therefore denies the same.

4. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 4 and therefore denies the same.

5. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 5 and therefore denies the same.

6. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 6 and therefore denies the same.

7. Glenmark admits that Glenmark Pharmaceuticals Limited is a company organized and existing under the laws of India, and having a principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400 099, Maharashtra, India. Glenmark further admits that Glenmark Pharmaceuticals Limited developed and owns ANDA No. 210778.

8. Glenmark admits that Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark further admits that

Glenmark Pharmaceuticals Inc., USA is the authorized U.S. agent for ANDA No. 210778. Glenmark is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 8 and therefore denies the same.

JURISDICTION AND VENUE

9. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest subject matter jurisdiction over Plaintiffs' infringement claims against Glenmark under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only. Glenmark otherwise denies the remaining allegations of paragraph 9.

10. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 10 and therefore denies the same.

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Delcor and Mylan. Glenmark further admits that Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware. Glenmark otherwise denies the allegations of paragraph 11.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Delcor and Mylan. Glenmark further admits that Glenmark Pharmaceuticals Limited is a company organized and existing under the laws of India, and having a principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400 099, Maharashtra, India. Glenmark otherwise denies the allegations of paragraph 12.

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest that venue is proper in this judicial district for the purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Delcor and Mylan. Glenmark further admits that Glenmark Pharmaceuticals Inc., USA is incorporated in Delaware and Glenmark Pharmaceuticals Limited is incorporated in India. Glenmark is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 13 and therefore denies the same.

THE PATENTS-IN-SUIT

14. Glenmark admits that a purported copy of the '237 patent is attached to Plaintiffs' Complaint as Exhibit A, and that on its face, the '237 patent is titled "Pharmaceutical Foam" and bears an issuance date of November 28, 2006. Glenmark denies that the '237 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 14.

15. Glenmark admits that on its face, the claims of the '237 patent are directed to pharmaceutical compositions containing, *inter alia*, clindamycin phosphate and a base. Glenmark otherwise denies the remaining allegations of paragraph 15.

16. Glenmark admits that a purported copy of the '747 patent is attached to Plaintiffs' Complaint as Exhibit B, and that on its face, the '747 patent is titled "Pharmaceutical Foam" and bears an issuance date of May 20, 2008. Glenmark denies that the '747 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 16.

17. Glenmark admits that on its face, the claims of the '747 patent are directed to methods of treating a bacteria-mediated disease using pharmaceutical compositions containing, *inter alia*, clindamycin phosphate and a base. Glenmark otherwise denies the remaining allegations of paragraph 17.

18. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 18 and therefore denies the same.

19. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 19 and therefore denies the same.

20. On information and belief, Glenmark admits that Mylan is the holder of NDA No. 050801, which was approved for Evoclin®. Glenmark is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 20 and therefore denies the same.

21. Glenmark admits that, on its face, the Evoclin® Prescribing Information revised in January 2012 states Evoclin® is indicated for acne vulgaris in patients 12 years and older. Glenmark otherwise denies the remaining allegations of paragraph 21.

22. Glenmark admits that the ’237 and ’747 patents are listed in the Orange Book in connection with Evoclin®. Glenmark is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 22 and therefore denies the same.

ACTS GIVING RISE TO THIS ACTION

23. Glenmark admits that it submitted ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of Evoclin® (“Glenmark’s ANDA Product”). Glenmark further admits that it sent Mylan and Stiefel West Coast, LLC (“Stiefel”) a Notice Letter dated September 29, 2017, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, notifying Mylan and Stiefel that Glenmark’s ANDA No. 210778 includes Paragraph IV Certifications with respect to the ’237 and ’747 patents. Glenmark otherwise denies the remaining allegations of paragraph 23.

24. Glenmark admits that in the Notice Letter, Glenmark notified Mylan and Stiefel that Glenmark’s ANDA No. 210778 includes Paragraph IV Certifications certifying 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 Glenmark’s ANDA Product in or into the United States. Glenmark otherwise denies the remaining allegations of paragraph 24.

25. Glenmark admits that the active ingredient in Glenmark’s ANDA Product is clindamycin phosphate. On information and belief, Glenmark admits clindamycin phosphate is the active ingredient in Evoclin® and that clindamycin phosphate is recited on the face of one or more claims of the ’237 and ’747 patents. Glenmark otherwise denies the remaining allegations in paragraph 25.

26. Glenmark admits that, pursuant to 21 U.S.C. § 355(j)(2)(A), Glenmark’s ANDA No. 210778 refers to Evoclin® as the listed drug for Glenmark’s ANDA Product and contains bioequivalence data with respect to Evoclin®. Glenmark is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 26 and therefore denies the same.

27. Glenmark admits that it is seeking approval to market Glenmark’s ANDA Product for the same indication provided in the Evoclin® Prescribing Information revised in January 2012. Glenmark otherwise denies the remaining allegations in paragraph 27.

28. Glenmark admits that it is seeking approval to market Glenmark’s ANDA Product for acne vulgaris in patients 12 years and older. Glenmark otherwise denies the remaining allegations in paragraph 28.

29. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the ’237 and ’747 patents at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 29.

30. Glenmark admits that it filed ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Glenmark's ANDA Product before the expiration date of the '237 and '747 patents. Glenmark otherwise denies the remaining allegations of paragraph 30.

31. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 31.

32. Glenmark admits that it filed ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Product before the expiration date of the '237 and '747 patents. Glenmark otherwise denies the remaining allegations of paragraph 32.

33. Glenmark denies the allegations of paragraph 33.

34. Glenmark admits that the proposed labeling accompanying ANDA No. 210778 states that Glenmark's ANDA Product is indicated for acne vulgaris in patients 12 years and older. Glenmark otherwise denies the remaining allegations in paragraph 34.

35. Glenmark admits the allegations of paragraph 35.

36. Glenmark is without sufficient knowledge and information to form a belief as to the allegations of paragraph 36 and therefore denies the same.

37. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 37.

38. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that Plaintiffs assert that there is an actual case or controversy. Glenmark otherwise denies the remaining allegations of paragraph 38.

39. Glenmark admits that Delcor and Mylan commenced this action within 45 days of Mylan and Stiefel's receipt of Glenmark's Notice Letter. Glenmark otherwise denies the remaining allegations of paragraph 39.

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

40. Glenmark restates its answers to paragraphs 1−39 as if fully set forth herein.

41. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 41.

42. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '237 patent at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 42.

43. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 43.

44. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 44.

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

45. Glenmark restates its answers to paragraphs 1−44 as if fully set forth herein.

46. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that the Complaint purports to arise under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* and under the Declaratory Judgment Act, including 28 U.S.C. §§ 2201 and 2202, and that Plaintiffs assert that there is an actual case or controversy. Glenmark does not contest subject matter jurisdiction over Plaintiffs' infringement

claims against Glenmark under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only. Glenmark further admits that it filed ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, import, use, offer for sale, and/or sale of Glenmark's ANDA Product before the expiration date of the '237 patent. Glenmark otherwise denies the remaining allegations of paragraph 46.

47. Glenmark admits that it filed ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Product before the expiration date of the '237 patent. Glenmark otherwise denies the remaining allegations of paragraph 47.

48. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 48.

49. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 49.

50. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 50.

51. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '237 patent at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 51.

52. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 52.

53. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 53.

54. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 54.

55. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the ’237 patent at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 55.

56. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 56.

57. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 57.

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

58. Glenmark restates its answers to paragraphs 1−57 as if fully set forth herein.

59. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 59.

60. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the ’237 patent at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 60.

61. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 61.

62. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 62.

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

63. Glenmark restates its answers to paragraphs 1−62 as if fully set forth herein.

64. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that the Complaint purports to arise under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* and under the Declaratory Judgment Act, including 28 U.S.C. §§ 2201 and 2202, and that Plaintiffs assert that there is an actual case or controversy. Glenmark does not contest subject matter jurisdiction over Plaintiffs' infringement claims against Glenmark under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only. Glenmark further admits that it filed ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, import, use, offer for sale, and/or sale of Glenmark's ANDA Product before the expiration date of the '747 patent. Glenmark otherwise denies the remaining allegations of paragraph 64.

65. Glenmark admits that it filed ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Product before the expiration date of the '747 patent. Glenmark otherwise denies the remaining allegations of paragraph 65.

66. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 66.

67. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 67.

68. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 68.

69. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '747 patent at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 69.

70. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 70.

71. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 71.

72. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 72.

73. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '747 patent at the time of filing the ANDA No. 210778. Glenmark otherwise denies the remaining allegations of paragraph 73.

74. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 74.

75. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 75.

RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief to which no response is required. To the extent any response is required, Glenmark denies that Plaintiffs are entitled to any remedy or relief. Further, Glenmark prays that the Plaintiffs' Complaint be dismissed in its entirety, that Plaintiffs take nothing by way of the allegations complained of in the Complaint, and

that Glenmark be awarded its costs, including reasonable attorneys' fees incurred in defense of this action, and for all other appropriate relief.

GLENMARK'S AFFIRMATIVE DEFENSES

Glenmark asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Glenmark does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Glenmark reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

The '237 patent is unenforceable for patent misuse. Statements in the specification and prosecution history of the '237 patent limit the scope of the claims to compositions that contain a "base." The '237 patent was issued as a result of the applicant's statements during prosecution and amendment of all claims to add the "base" limitation. The applicant argued, "with the addition of a base, the composition is unexpectedly stable and efficacious." April 27, 2006 Reply to Office Action at 2, 11, 12. The applicant further argued that it "surprisingly demonstrated that the addition of a base (such as potassium hydroxide), will generate the desired pH of the formulation without degradation of the active agent." *Id.* at 11. The applicant defined "base" during prosecution and in the '237 patent specification as "bicarbonates, carbonates, and hydroxides such as alkali or alkaline earth metal hydroxide as well as transition metal hydroxides." *Id*. at 12; '237 patent at col. 6, ll. 56−60. Glenmark's Notice Letter and the face of ANDA No. 210778 show that Glenmark's ANDA Product does not contain a "base" or an equivalent of a "base" as that term is used in the intrinsic record of the '237 patent. Based upon Glenmark's Notice Letter, setting forth detailed reasons, and ANDA No. 210778, Plaintiffs are aware that Glenmark's ANDA Product

does not infringe, has not infringed, and would not, if marketed, sold, or used, infringe any valid and enforceable claim of the ’237 patent either directly or indirectly, and either literally or under the doctrine of equivalents. Despite this information, Plaintiffs filed the present suit with no objectively reasonable bases for doing so. As such, Plaintiffs have attempted to broaden the scope of the ’237 patent to encompass compositions that do not contain a “base” with intended anticompetitive effects.

SECOND DEFENSE

The ’747 patent is unenforceable for patent misuse. The applicant’s statements during the prosecution of the ’237 patent apply to the ’747 patent, and the scope of the claims of the ’747 patent are limited to methods of using compositions that contain a “base.” The ’747 patent specification likewise defines “base” as “bicarbonates, carbonates, and hydroxides such as alkali or alkaline earth metal hydroxide as well as transition metal hydroxides.” ’747 patent at col. 6, ll. 56−60. Glenmark’s Notice Letter and the face of ANDA No. 210778 show that Glenmark’s ANDA Product does not contain a “base” or an equivalent of a “base” as that term is used in the intrinsic record of the ’747 patent. Based upon Glenmark’s Notice Letter, setting forth detailed reasons, and ANDA No. 210778, Plaintiffs are aware that Glenmark’s ANDA Product does not infringe, has not infringed, and would not, if marketed, sold, or used, infringe any valid and enforceable claim of the ’747 patent either directly or indirectly, and either literally or under the doctrine of equivalents. Despite this information, Plaintiffs filed the present suit with no objectively reasonable bases for doing so. As such, Plaintiffs have attempted to broaden the scope of the ’747 patent to encompass methods of using compositions that do not contain a “base” with intended anticompetitive effects.

THIRD DEFENSE

Claims of the ’237 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FOURTH DEFENSE

Claims of the ’747 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FIFTH DEFENSE

Claims of the ’747 patent are invalid under the doctrine of obviousness-type double patenting and/or the expiration date of the ’747 patent is incorrectly listed in the Orange Book. The Orange Book lists the ’747 patent’s expiration date as August 9, 2026 and lists the ’237 patent’s expiration date as January 23, 2024. Any differences between the subject matter claimed in the ’747 patent and the subject matter claimed in the ’237 patent would have been obvious at the time the alleged invention was made to a person having ordinary skill in the art to which the claimed subject matter pertains.

SIXTH DEFENSE

Plaintiffs’ purported claim for relief in the Complaint is barred for failure to properly join the patent owner of the ’237 and ’747 patents as an indispensable party.

SEVENTH DEFENSE

Claims of the ’237 and ’747 patents are barred in whole or in part by the doctrine of prosecution history estoppel and/or judicial estoppel.

EIGHTH DEFENSE

Plaintiffs’ purported claim for relief in the Complaint is barred due to Plaintiffs’ lack of standing.

NINTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

TENTH DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS AND CROSSCLAIMS

Defendants and Counterclaim-Plaintiffs Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (collectively, "Glenmark"), by way of counterclaim against Plaintiffs-Counterclaim Defendants Delcor Asset Corporation ("Delcor") and Mylan Pharmaceuticals Inc. ("Mylan") (collectively, "Plaintiffs"), and crossclaim against Defendant-Crossclaim Defendant Stiefel West Coast, LLC ("Stiefel"), state as follows:

THE PARTIES

1. Glenmark Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400 099, Maharashtra, India.

2. Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

3. On information and belief, Delcor 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.

4. On information and belief, Mylan 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.

5. On information and belief, 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.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims and Crossclaims pursuant to 28 U.S.C. §§ 1331, 1337, 1338, 1367, 2201, and 2202.

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs commenced and continue to maintain this action against Glenmark in this judicial district.

8. This Court has personal jurisdiction over Stiefel because Stiefel is a limited liability company organized and existing under the laws of the State of Delaware and has a registered agent in Delaware for service of process.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1400(b) for purposes of this case.

FACTUAL BACKGROUND

A. FDA Approval of New Brand Name Drugs.

10. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

11. Under the FDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

12. An NDA must include, among other things, the number of any patent that allegedly 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 user. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b)(1), (c)(2).

13. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

14. The FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)−(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval Of New Generic Drugs.

15. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments to the FDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. § 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs for the purpose of decreasing the cost of pharmaceuticals through increased competition.

16. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

17. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

18. A "Paragraph IV Certification" asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

19. An applicant submitting an ANDA containing a Paragraph IV Certification must notify both the patent holder and NDA holder of each of its Paragraph IV Certifications. *See* 21 U.S.C. § 355(j)(2)(B).

20. Upon receiving notice of the Paragraph IV Certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A). The patent holder's filing of an infringement suit against the generic manufacturer triggers a 30-month period, beginning on the date of the patent holder's receipt of the Paragraph IV Certifications, in which the FDA will not approve the ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. The Patents-in-Suit & Glenmark's ANDA.

22. On information and belief, Stiefel purports to be the owner of all title, right, and interest in and to U.S. Patent Nos. 7,141,237 ("the '237 patent") and 7,374,747 ("the '747 patent")

by assignment and therefore has the full right to sue and recover for the infringement thereof. The ’237 patent issued from application 10/763,379 (“the ’379 application”). The ’747 patent issued from application 11/463,573 (“the ’573 application”), which was a divisional of the ’379 application.

23. Statements during the prosecution of the ’379 application limit the claims to compositions that contain a “base” as that term is used in the intrinsic record. During prosecution, the patent applicant in the ’379 application overcame a final rejection by amending all independent claims to require “a base” and argued that “with the addition of a base, the composition is unexpectedly stable and efficacious.” April 27, 2006 Reply to Office Action at 2, 11, 12. The patent applicant further argued that it “surprisingly demonstrated that the addition of a base (such as potassium hydroxide), will generate the desired pH of the formulation without degradation of the active agent.” *Id.* at 11.

24. During prosecution of the ’379 application, the patent applicant defined “base” as “bicarbonates, carbonates, and hydroxides such as alkali or alkaline earth metal hydroxide as well as transition metal hydroxides.” *Id*. at 12. The ’237 and ’747 patent specifications also define “base” as “bicarbonates, carbonates, and hydroxides such as alkali or alkaline earth metal hydroxide as well as transition metal hydroxides.” ’237 patent at col. 6, ll. 56−60; ’747 patent at col. 6, ll. 56−60.

25. The claims of the ’573 application, which was a divisional of the ’379 application, included the “base” limitation, and all the claims of the ’747 patent issued with the “base” limitation.

26. Every claim of the ’237 and ’747 patents requires a “base.”

27. Glenmark's ANDA Product does not contain a "base" or an equivalent to a "base." As detailed in Glenmark's Notice Letter and the face of ANDA No. 210778, Glenmark's ANDA Product contains clindamycin phosphate as the active ingredient and the following inactive ingredients: cetyl alcohol, stearyl alcohol, polysorbate 60, ethanol absolute, propylene glycol, purified water, and propane/butane/isobutene. Glenmark specifically articulated in its Notice Letter that none of the ingredients in Glenmark's ANDA Product is a "base" or an equivalent of a "base" as used in the intrinsic record, and thus Glenmark's ANDA Product could not infringe any claim of the '237 or '747 patents.

28. Glenmark's ANDA Product only contains ingredients that could objectively correspond to claim limitations other than the "base" limitation. Each claim of the '237 and '747 patents requires, *inter alia*, (1) clindamycin; (2) a C_1–C_6 alcohol; (3) a C_{14}–C_{22} alcohol; (4) water; (5) a surfactant; (6) an aerosol propellant; and (7) a base. Additional claims add an emollient. Glenmark's ANDA Product consists of (1) clindamycin; (2) a C_2 alcohol, ethanol; (3) a C_{16} alcohol, cetyl alcohol and a C_{18} alcohol, stearyl alcohol; (4) purified water; (5) a surfactant, polysorbate 60; (6) an aerosol propellant, propane/butane/isobutane; and (7) an emollient, propylene glycol. No remaining ingredient exists in Glenmark's ANDA Product to satisfy the "base" limitation.

29. On information and belief, Delcor purports to be the exclusive licensee of the '237 and '747 patents.

30. On information and belief, FDA lists Mylan as the holder of NDA No. 050801.

31. On information and belief, NDA No. 050801 covers Mylan's Evoclin® product. Evoclin® is a clindamycin foam indicated for treatment of acne vulgaris in patients 12 years and older.

32. On information and belief, Mylan and Perrigo are the only two companies that market topical clindamycin foam in the United States.

33. On information and belief, Perrigo has a license to the ’237 and ’747 patents and pays a royalty for use of the ’237 and ’747 patents.

34. On information and belief, Mylan lists the ’237 and ’747 patents in the Orange Book in connection with NDA No. 050801.

35. By listing the ’237 and ’747 patents in the Orange Book, Plaintiffs created a reasonable apprehension that they and/or Stiefel would file a patent infringement suit against applicants seeking regulatory approval for a generic version of Evoclin®.

36. Glenmark submitted ANDA No. 210778 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic version of Evoclin® (“Glenmark’s ANDA Product”) for the treatment of acne vulgaris in patients 12 years and older before the expiration of the ’237 and ’747 patents.

37. Glenmark’s ANDA No. 210778 includes Paragraph IV Certifications certifying 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 Glenmark’s ANDA Product in or into the United States.

38. By letter dated September 29, 2017, Glenmark sent Mylan and Stiefel a Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, notifying Mylan and Stiefel that Glenmark’s ANDA No. 210778 includes Paragraph IV Certifications with respect to the ’237 and ’747 patents. A true and correct copy of Glenmark’s Notice Letter is attached as Exhibit A.

39. Glenmark's Notice Letter contained a Detailed Statement setting forth the factual and legal basis for why Glenmark's ANDA Product does not infringe, has not infringed, and would not, if marketed, sold, or used, infringe any valid and enforceable claim of the '237 or '747 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

40. As part of the Notice Letter, Glenmark provided Mylan and Stiefel with an offer of confidential access to ANDA No. 210778.

41. Plaintiffs accepted Glenmark's offer of confidential access and had access to Glenmark's ANDA. From the ANDA, Plaintiffs had the opportunity to confirm that Glenmark's ANDA Product did not infringe.

42. Plaintiffs initiated the present action by filing a Complaint against Glenmark on November 15, 2017.

FIRST COUNTERCLAIM/CROSSCLAIM
DECLARATION OF NON-INFRINGEMENT OF THE '237 PATENT

43. Glenmark restates and incorporates the allegations of paragraphs 1−42 as if fully set forth herein.

44. The manufacture, use, or sale of Glenmark's ANDA Product would not infringe any valid and enforceable claim of the '237 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

45. A present, genuine, justiciable controversy exists between Glenmark and Plaintiffs and Stiefel regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Glenmark's ANDA Product would infringe any valid or enforceable claim of the '237 patent.

46. Glenmark is entitled to a declaration that the manufacture, use, or sale of Glenmark's ANDA Product would not infringe any valid or enforceable claims of the '237 patent.

SECOND COUNTERCLAIM/CROSSCLAIM
DECLARATION OF NON-INFRINGEMENT OF THE '747 PATENT

47. Glenmark restates and incorporates the allegations of paragraphs 1−46 as if fully set forth herein.

48. The manufacture, use, or sale of Glenmark's ANDA Product would not infringe any valid and enforceable claim of the '747 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

49. A present, genuine, justiciable controversy exists between Glenmark and Plaintiffs and Stiefel regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Glenmark's ANDA Product would infringe any valid or enforceable claim of the '747 patent.

50. Glenmark is entitled to a declaration that the manufacture, use, or sale of Glenmark's ANDA Product would not infringe any valid or enforceable claims of the '747 patent.

THIRD COUNTERCLAIM
MONOPOLIZATION AND ATTEMPTED MONOPOLIZATION

51. Glenmark restates and incorporates the allegations of paragraphs 1−50 as if fully set forth herein.

52. By filing ANDA No. 210778 to obtain approval to market Glenmark's ANDA Product, Glenmark is or will become a direct competitor to Mylan.

53. For antitrust purposes, the relevant product market is the market for treatment with topical clindamycin foam. The relevant geographic market for the product market is the United States.

54. Glenmark's Notice Letter and the face of ANDA No. 210778 unequivocally show that the manufacture, use, or sale of Glenmark's ANDA Product would not infringe any claim of the '237 or '747 patents either directly or indirectly, and either literally or under the doctrine of equivalents. On information and belief, Plaintiffs initiated this suit, fully aware that Glenmark's

ANDA Product would not infringe any claim of the ’237 or ’747 patents either directly or indirectly, and either literally or under the doctrine of equivalents. Accordingly, Plaintiffs’ infringement action against Glenmark is both objectively and subjectively baseless.

55. On information and belief, Mylan, with the collaboration of Delcor, has obtained and/or maintained market power in the relevant product and geographic markets through predatory and anticompetitive acts, which enable it to control prices and exclude competition from the relevant product and geographic markets to the detriment of competition and consumers. On information and belief, through Plaintiffs’ predatory and anticompetitive acts, Plaintiffs have delayed Glenmark’s entry into the relevant market and have maintained pricing for the Evoclin® product that exceeds competitive levels.

56. On information and belief, but for Plaintiffs’ predatory and anticompetitive acts, entry of Glenmark’s ANDA Product would reduce prices in the relevant market and directly benefit consumers.

57. On information and belief, in bringing and/or maintaining allegations of infringement against Glenmark, Plaintiffs were subjectively motivated by an intent to interfere directly with Glenmark’s business relationships through the use of litigation, by precluding, delaying, and/or multiplying the costs of Glenmark’s entry into the relevant market rather than being motivated by the outcome of the litigation.

58. On information and belief, Plaintiffs engaged in the predatory and anticompetitive acts against Glenmark described herein, with the specific intent to obtain and/or maintain Mylan’s dominant market position and monopoly power in the relevant product and geographic markets.

59. On information and belief, Plaintiffs engaged in the predatory and anticompetitive acts against Glenmark described herein, with the specific intent to trigger the 30-month period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) to delay the entry of Glenmark's ANDA Product.

60. The unlawful activities alleged above constitute the willful acquisition or maintenance of Mylan's monopoly power in the relevant product and geographic markets in violation of the prohibition on actual monopolization under 15 U.S.C. § 2.

61. The unlawful activities alleged above also create a dangerous probability of Mylan achieving monopoly power in the relevant product and geographic markets in violation of the prohibition on attempted monopolization under 15 U.S.C. § 2.

62. As a direct and proximate result of Plaintiffs' predatory and anticompetitive conduct, and improperly motivated pursuit of an objectively and subjectively baseless litigation against Glenmark with respect to the '237 and '747 patents, Glenmark is being forced to expend unjustified costs, including the costs of its legal defense. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Plaintiffs' predatory and anticompetitive conduct risks delaying entry of Glenmark's ANDA Product. Plaintiffs' unlawful actions have caused and will continue to cause injury to Glenmark's business and its property.

63. Overall competition in the relevant product and geographic markets has been and will continue to be harmed by Plaintiffs' course of conduct, and consumers of the relevant product have or will be harmed by the reduction in competition and increase of prices if Plaintiffs are permitted to prevent the planned entry of Glenmark's ANDA Product. The injury Glenmark has suffered as a result of Plaintiffs' attempt to monopolize and monopolization accordingly constitutes antitrust injury, for which Glenmark is entitled to recover treble the damages that it has

sustained (including costs and attorneys' fees incurred in connection with Plaintiffs' sham litigation) in accordance with 15 U.S.C. § 15.

64. As a result of Plaintiffs' monopolization and/or attempted monopolization, Glenmark is entitled to have the '237 and '747 patents held unenforceable as against Glenmark in accordance with 15 U.S.C. § 26.

REQUEST FOR RELIEF

WHEREFORE, Defendants and Counterclaim-Plaintiffs Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs-Counterclaim Defendants Delcor Asset Corporation and Mylan Pharmaceuticals Inc., and against Defendant-Crossclaim Defendant Stiefel West Coast, LLC, as follows:

(a) declaring that Glenmark has not infringed any valid and enforceable claim of U.S. Patent No. 7,141,237;

(b) declaring that Glenmark has not infringed any valid and enforceable claim of U.S. Patent No. 7,374,747;

(c) declaring that Plaintiffs have violated Section 2 of the Sherman Antitrust Act (15 U.S.C. § 2) and awarding Glenmark damages (including costs and reasonable attorneys' fees) and that such damages be trebled and permanently enjoining Plaintiffs, their officers, agents, directors, servants, employees, subsidiaries, and assigns, and all those acting under the authority of or in privity with any of them, from asserting or otherwise seeking to enforce U.S. Patent Nos. 7,141,237 and 7,374,747 against Glenmark;

(d) awarding Glenmark its costs and expenses in this action;

(e) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Glenmark its attorneys' fees, costs, and expenses in this action; and

(f) awarding Glenmark any further and additional relief as the Court deems just and proper.

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Dated: January 12, 2018

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