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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GALEPHAR PHARMACEUTICAL
RESEARCH, INC., CIPHER
PHARMACEUTICALS INC., AND SUN
PHARMACEUTICAL INDUSTRIES, INC.,

Plaintiffs,

v.

UPSHER-SMITH LABORATORIES, LLC,

Defendant.

No. 2:19-cv-02546-MCA-MAH

**UPSHER-SMITH LABORATORIES, LLC'S ANSWER TO FIRST AMENDED
COMPLAINT & AFFIRMATIVE DEFENSES**

Defendant Upsher-Smith Laboratories, LLC (“USL”), through its undersigned counsel, herein respond to the allegations in the First Amended Complaint of Galephar Pharmaceutical Research, Inc. (“Galephar”); Cipher Pharmaceuticals Inc. (“Cipher”); and Sun Pharmaceutical

Industries, Inc. (“Sun”) (collectively, “Plaintiffs”). USL bases the below responses on its knowledge and on information and belief as to the activities of others. If USL does not specifically admit any of the allegations below, those allegations are denied.

The preamble of the First Amended Complaint contains no allegations of fact to which a response is required.

NATURE OF THE ACTION¹

1. USL states that the allegations set forth in paragraph 1 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL admits that this action purports to arise under the patent laws of the United States, Title 35, United States Code. USL further admits that Plaintiffs purport to seek relief from alleged infringement of U.S. Patents Nos. 7,435,427 (“the ’427 patent”); 8,367,102 (“the ’102 patent”); 8,952,064 (“the ’064 patent”); 9,078,925 (“the ’925 patent”); and 9,089,534 (“the ’534 patent”) (collectively, the “Patents-in-Suit”). USL further admits that it filed ANDA Nos. 212333 and 213571. USL denies any infringement of the Patents-in-Suit and denies any remaining allegations in paragraph 1.

THE PARTIES

2. USL admits upon information and belief, based on the facts alleged in the First Amended Complaint, that Plaintiff Galephar is a corporation organized under the laws of Puerto Rico having its principal place of business at Juncos Industrial Park, Juncos, Puerto Rico 00777-3873.

¹ This Answer reproduces the headings of the First Amended Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the First Amended Complaint.

3. USL admits upon information and belief, based on the facts alleged in the First Amended Complaint, that Plaintiff Cipher is a corporation organized under the laws of Canada, having its principal place of business at 16-5650 Tomken Road, Mississauga, Ontario, Canada.

4. USL admits upon information and belief, based on the facts alleged in the First Amended Complaint, that Plaintiff Sun is an entity organized and existing under the laws of Michigan having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512, USA.

5. Admitted.

JURISDICTION AND VENUE

6. USL states that the allegations set forth in paragraph 6 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL does not contest that the Court has subject matter jurisdiction over this action for the purposes of the instant case, but only to the extent each Plaintiff has standing to bring the claims as set forth in the First Amended Complaint. USL denies the remaining allegations in paragraph 6.

7. USL states that the allegations set forth in paragraph 7 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL does not contest personal jurisdiction for purposes of the instant action only. USL denies the remaining allegations in paragraph 7.

8. USL states that the allegations set forth in paragraph 8 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL admits that it submitted Abbreviated New Drug Application (“ANDA”) Nos. 212333 and 213571 that contain a paragraph IV certification and that it seeks approval from FDA to engage in the manufacture, use, sale, offer for sale, or importation of isotretinoin capsules, USP (10 mg, 20

mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. USL denies the remaining allegations in paragraph 8.

9. USL states that the allegations set forth in paragraph 9 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL does not contest personal jurisdiction for purposes of the instant action only. Answering further, USL admits that it has an office at 840 Headquarters Plaza, North Tower—4th Floor, Morristown, NJ 07960 that assisted in the preparation of ANDA Nos. 212333 and 213571. USL denies the remaining allegations in paragraph 9.

10. USL states that the allegations set forth in paragraph 10 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL does not contest personal jurisdiction for purposes of the instant action only. Answering further, USL admits that, if approved by FDA, it would offer to sell and sell isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) throughout the United States, including in New Jersey. USL denies the remaining allegations in paragraph 10.

11. USL states that the allegations set forth in paragraph 11 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL does not contest venue for purposes of the instant action only.

12. USL states that the allegations set forth in paragraph 12 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL does not contest venue for purposes of the instant action only.

BACKGROUND

The FDA Marketing Approval Process

13. USL states that the allegations set forth in paragraph 13 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states

that the Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the “Hatch-Waxman Amendments” or “Hatch-Waxman”), and as further amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”), sets forth a statutory framework that FDA follows for the approval of both brand-name and generic drugs. USL denies the remaining allegations in paragraph 13.

14. USL states that the allegations set forth in paragraph 14 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that, under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by FDA. *See* 21 U.S.C. § 355. USL denies the remaining allegations in paragraph 14.

15. USL states that the allegations set forth in paragraph 15 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that an NDA includes, among other things, the number of any patent that the NDA holder asserts 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 party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). Answering further, the decision to submit patent information to FDA rests solely with the NDA holder. USL denies the remaining allegations in paragraph 15.

16. USL states that the allegations set forth in paragraph 16 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states

that upon approval of the NDA, FDA publishes patent information for the approved drug in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” *See* 21 U.S.C. § 355(j)(7)(A)(iii). USL denies the remaining allegations in paragraph 16.

17. USL states that the allegations set forth in paragraph 17 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that, under Hatch-Waxman, a generic manufacturer may submit an ANDA to FDA, and the generic manufacturer must, among other things, show that its generic drug is “bioequivalent” to the listed reference drug. *See* 21 U.S.C. § 355(j). USL denies the remaining allegations in paragraph 17.

Plaintiffs’ Patents Covering ABSORICA® Isotretinoin Capsules for the Treatment of Severe Recalcitrant Nodular Acne

18. USL admits that the “INDICATIONS AND USAGE” section of the Prescribing Information states that ABSORICA® is “indicated for the treatment of severe recalcitrant nodular acne.” USL denies that the Patents-in-Suit were duly and legally issued. USL states that the remaining allegations set forth in paragraph 18 are legal conclusions as to which no response is necessary; therefore, denied.

A. The ’427 Patent

19. USL admits that Exhibit A purports to be a copy of the ’427 patent, titled “Pharmaceutical Semi-Solid Composition of Isotretinoin.” USL admits that, on its face, the ’427 patent lists Francis Vanderbist, Cecile Servais, and Philippe Baudier as inventors. USL admits that, on its face, the ’427 patent issued on October 14, 2008. USL denies the remaining allegations in paragraph 19.

20. USL admits that, on its face, the ’427 patent lists Galephar M/F as an assignee; otherwise, denied.

21. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 21 and therefore denies the same.

22. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 22 and therefore denies the same.

23. Upon information and belief, USL admits that Sun is the holder of NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules. Otherwise, denied.

24. USL admits that the '427 patent appears to be listed in the Orange Book corresponding to NDA No. 021-951. The remaining allegations set forth in paragraph 24 are legal conclusions as to which no response is necessary; therefore, denied.

25. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 25 and therefore denies the same.

B. The '102 Patent

26. USL admits that Exhibit B purports to be a copy of the '102 patent, titled "Pharmaceutical Semi-Solid Composition of Isotretinoin." USL admits that, on its face, the '102 patent lists Francis Vanderbist, Cecile Servais, and Philippe Baudier as inventors. USL admits that, on its face, the '102 patent issued on February 5, 2013. USL denies the remaining allegations in paragraph 26.

27. USL admits that, on its face, the '102 patent lists Galephar Pharmaceutical Research, Inc. as an assignee; otherwise, denied.

28. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 28 and therefore denies the same.

29. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 29 and therefore denies the same.

30. Upon information and belief, USL admits that Sun is the holder of NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, 30 mg, and 40 mg capsules. Otherwise, denied.

31. USL admits that the '102 patent appears to be listed in the Orange Book corresponding to NDA No. 021-951. The remaining allegations set forth in paragraph 31 are legal conclusions as to which no response is necessary; therefore, denied.

32. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 32 and therefore denies the same.

C. The '064 Patent

33. USL admits that Exhibit C purports to be a copy of the '064 patent, titled "Pharmaceutical Semi-Solid Composition of Isotretinoin." USL admits that, on its face, the '064 patent lists Francis Vanderbist, Cecile Servais, and Philippe Baudier as inventors. USL admits that, on its face, the '064 patent issued on February 10, 2015. USL denies the remaining allegations in paragraph 33.

34. USL admits that, on its face, the '064 patent lists Galephar Pharmaceutical Research, Inc. as an assignee; otherwise, denied.

35. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 35 and therefore denies the same.

36. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 36 and therefore denies the same.

37. Upon information and belief, USL admits that Sun is the holder of NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, 30 mg, and 40 mg capsules. Otherwise, denied.

38. USL admits that the '064 patent appears to be listed in the Orange Book corresponding to NDA No. 021-951. The remaining allegations set forth in paragraph 38 are legal conclusions as to which no response is necessary; therefore, denied.

39. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 39 and therefore denies the same.

D. The '534 Patent

40. USL admits that Exhibit D purports to be a copy of the '534 patent, titled "Pharmaceutical Semi-Solid Composition of Isotretinoin." USL admits that, on its face, the '534 patent lists Francis Vanderbist, Cecile Servais, and Philippe Baudier as inventors. USL admits that, on its face, the '534 patent issued on July 28, 2015. USL denies the remaining allegations in paragraph 40.

41. USL admits that, on its face, the '534 patent lists Galephar Pharmaceutical Research, Inc. as an assignee; otherwise, denied.

42. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 42 and therefore denies the same.

43. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 43 and therefore denies the same.

44. Upon information and belief, USL admits that Sun is the holder of NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, 30 mg, and 40 mg capsules. Otherwise, denied.

45. USL admits that the '534 patent appears to be listed in the Orange Book corresponding to NDA No. 021-951. The remaining allegations set forth in paragraph 45 are legal conclusions as to which no response is necessary; therefore, denied.

46. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 46 and therefore denies the same.

E. The '925 Patent

47. USL admits that Exhibit E purports to be a copy of the '925 patent, titled "Pharmaceutical Semi-Solid Composition of Isotretinoin." USL admits that, on its face, the '925 patent lists Arthur M. DeBoeck, Francis Vanderbist, Cecile Servais, and Philippe Baudier as inventors. USL admits that, on its face, the '925 patent issued on July 14, 2015. USL denies the remaining allegations in paragraph 47.

48. USL admits that, on its face, the '925 patent lists Galephar Pharmaceutical Research, Inc. as an assignee; otherwise, denied.

49. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 49 and therefore denies the same.

50. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 50 and therefore denies the same.

51. Upon information and belief, USL admits that Sun is the holder of NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, 30 mg, and 40 mg capsules. Otherwise, denied.

52. USL admits that the '925 patent appears to be listed in the Orange Book corresponding to NDA No. 021-951. The remaining allegations set forth in paragraph 52 are legal conclusions as to which no response is necessary; therefore, denied.

53. USL is without sufficient information to form a belief as to the allegations set forth in paragraph 53 and therefore denies the same.

Acts Giving Rise to This Action

54. Admitted.

55. USL admits the first sentence of paragraph 55. Answering further, USL states that the paragraph IV certification stated that USL does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning the non-infringement, invalidity, and enforceability of any of the Patents in Suit. Otherwise, denied.

56. On information and belief, admitted.

57. Admitted.

58. USL states that the allegations set forth in paragraph 58 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that its paragraph IV certification recites that USL's ANDA No. 212333 contains bioavailability or bioequivalence data. USL denies the remaining allegations in paragraph 58.

59. USL states that the allegations set forth in paragraph 59 are legal conclusions as to which no responsive pleading is necessary; therefore, denied.

60. USL admits that it provided an Offer of Confidential Access ("OCA") to ANDA No. 212333 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). The OCA speaks for itself. Otherwise, denied.

61. USL denies that Plaintiffs negotiated in good faith. On January 9, 2019, Sun's counsel "decline[]d the Offer made in USL's [OCA] letter" and stated that it was "not hereby requesting access to any USL Confidential Information." Sun's January 9, 2019 letter, nevertheless, went on to request that its outside and in-house counsel be granted full and unfettered access to USL's ANDA No. 212333. On January 11, 2019, USL proposed that access to ANDA No. 212333 be limited to two of Sun's in-house counsel, provided those attorneys agreed to have no direct, indirect, formal, or informal involvement in (i) patent prosecution

relating to any isotretinoin drug product, (ii) submissions to FDA relating to any isotretinoin drug product, (iii) product development of any isotretinoin drug product, and (iv) competitive decision making with respect to any isotretinoin drug product. USL again inquired regarding this proposal on January 15, 2019. One week later, on January 22, 2019, Sun's counsel rejected USL's proposal, other than to agree that Sun's in-house counsel would not directly or formally engage in patent prosecution or any Citizen's Petition. On January 25, 2019, USL promptly responded, stating that it would agree—as requested by Plaintiffs—to drop the product development and competitive decision making bars. USL also agreed—as requested by Plaintiffs—that the patent prosecution bar be limited to direct or formal activity. USL did not agree to Plaintiffs requested modification to the FDA bar. USL also offered to provide Plaintiffs' outside counsel—while the parties negotiated the scope of access for in-house counsel—access to USL's ANDA No. 212333, provided they agreed to a patent prosecution and FDA bar. On January 28, 2019, USL reiterated its offer to provide Plaintiffs' outside counsel access to USL's ANDA No. 212333. On January 30, 2019, Sun provided no counteroffer, asked USL to “reconsider” its January 22, 2019 proposal, and then filed suit that same day. Plaintiffs commenced this action without reviewing USL's ANDA No. 212333, despite being on notice—based on USL's Notice Letter—that USL's isotretinoin drug product does not have a component with an HLB value of 10 or greater (as required by all of the claims of the Patents-in-Suit). Otherwise, denied.

62. USL states that the allegations set forth in paragraph 62 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that 21 U.S.C. § 355(c)(3)(C) provides that FDA “approval shall be made effective immediately,

unless, before the expiration of 45 days after the date on which the [paragraph IV certification] is received, an action is brought for infringement.” Otherwise, denied.

63. USL states that the allegations set forth in paragraph 63 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL denies—as set forth in paragraph 61, above—that Plaintiffs had no means of obtaining information contained in USL’s ANDA No. 212333.

64. USL states that the allegations set forth in paragraph 64 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that this action was commenced within 45 days of Sun and Galephar’s receipt of the paragraph IV certification. Otherwise, denied.

65. USL states that the allegations set forth in paragraph 65 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA No. 212333, pursuant to 21 U.S.C. § 355(j); that USL’s ANDA contains a paragraph IV certification to the Patents-in-Suit; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

66. USL states that the allegations set forth in paragraph 66 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA No. 212333, pursuant to 21 U.S.C. § 355(j); that USL’s ANDA contains a paragraph IV certification to the Patents-in-Suit; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

67. Admitted.

68. USL admits the first sentence of paragraph 68. Answering further, USL states that the paragraph IV certification stated the USL does not waive, and expressly reserves, the right to raise additional defenses and arguments concerning the non-infringement, invalidity, and enforceability of any of the Patents-in-Suit. Otherwise, denied.

69. Admitted.

70. Admitted.

71. USL states that the allegations set forth in paragraph 71 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that its paragraph IV certification recites that USL's ANDA No. 213571 contains bioavailability or bioequivalence data. USL denies the remaining allegations of paragraph 71.

72. USL states that the allegations set forth in paragraph 72 are legal conclusions as to which no responsive pleading is necessary; therefore, denied.

73. USL states that the allegations set forth in paragraph 73 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that 21 U.S.C. § 355(c)(3)(C) provides that FDA "approval shall be made effective immediately, unless, before the expiration of 45 days after the date on which the [paragraph IV certification] is received, an action is brought for infringement." Otherwise, denied.

74. USL states that the allegations set forth in paragraph 74 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL denies that Plaintiffs had no means of obtaining information contained in USL's ANDA No. 213571 before Plaintiffs filed their First Amended Complaint. Indeed, USL produced ANDA No. 213571 to Plaintiffs on September 26, 2019, more than one month before Plaintiffs filed the First Amended Complaint against the 40 mg on November 6, 2019.

75. USL states that the allegations set forth in paragraph 75 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL denies that Plaintiffs commenced an action against ANDA No. 213571 within 45 days of Sun's and Galephar's receipt of the paragraph IV certification. USL denies that Plaintiffs have triggered any stay of FDA's approval of ANDA No. 213571. USL further denies all remaining allegations in paragraph 75.

76. USL states that the allegations set forth in paragraph 76 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA No. 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDA contains a paragraph IV certification to the Patents-in-Suit; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

77. USL states that the allegations set forth in paragraph 77 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA No. 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDA contains a paragraph IV certification to the Patents-in-Suit; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

COUNT I

(Infringement of U.S. Patent No. 7,435,427 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

78. Paragraph 78 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-77 as if fully set forth herein.

79. USL denies that submission of ANDA Nos. 212333 and 213571 are acts of infringement; otherwise admitted.

80. Denied.

81. USL admits that it became aware of the '427 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

COUNT II

(Declaratory Judgment of Infringement of the '427 Patent Under 35 U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

86. Paragraph 86 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-85 as if fully set forth herein.

87. USL states that the allegations set forth in paragraph 87 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '427 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

88. USL states that the allegations set forth in paragraph 88 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '427 patent

under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

89. USL states that the allegations set forth in paragraph 89 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '427 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

90. USL states that the allegations set forth in paragraph 90 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '427 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

91. Denied.

92. Denied.

93. Denied.

COUNT III

**(Declaratory Judgment of Infringement of the '427 Patent Under 35 U.S.C. § 271(b) and (c)
by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg,
and 40 mg))**

94. Paragraph 94 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-93 as if fully set forth herein.

95. USL states that the allegations set forth in paragraph 95 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '427 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

96. USL states that the allegations set forth in paragraph 96 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '427 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

97. USL admits that it became aware of the '427 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

98. USL admits that it became aware of the '427 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

COUNT IV

(Infringement of U.S. Patent No. 8,367,102 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

114. Paragraph 114 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-113 as if fully set forth herein.

115. USL denies that submission of ANDA Nos. 212333 and 213571 are acts of infringement; otherwise admitted.

116. Denied.

117. USL admits that it became aware of the '102 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

COUNT V

(Declaratory Judgment of Infringement of the '102 Patent Under 35 U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

122. Paragraph 122 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-121 as if fully set forth herein.

123. USL states that the allegations set forth in paragraph 123 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '102 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

124. USL states that the allegations set forth in paragraph 124 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '102 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

125. USL states that the allegations set forth in paragraph 125 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '102 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin

capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit.

Otherwise, denied.

126. USL states that the allegations set forth in paragraph 126 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '102 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit.

Otherwise, denied.

127. Denied.

128. Denied.

129. Denied.

COUNT VI

(Declaratory Judgment of Infringement of the '102 Patent Under 35 U.S.C. § 271(b) and (c) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

130. Paragraph 130 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-129 as if fully set forth herein.

131. USL states that the allegations set forth in paragraph 131 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '102 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

132. USL states that the allegations set forth in paragraph 132 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '102 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

133. USL admits that it became aware of the '102 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

134. USL admits that it became aware of the '102 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

135. Denied.

136. Denied.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Denied.

147. Denied.

148. Denied.

149. Denied.

COUNT VII

(Infringement of U.S. Patent No. 8,952,064 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

150. Paragraph 150 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-149 as if fully set forth herein.

151. USL denies that submission of ANDA Nos. 212333 and 213571 are acts of infringement; otherwise admitted.

152. Denied.

153. USL admits that it became aware of the '064 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

154. Denied.

155. Denied.

156. Denied.

157. Denied.

COUNT VIII

(Declaratory Judgment of Infringement of the '064 Patent Under 35 U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

158. Paragraph 158 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-157 as if fully set forth herein.

159. USL states that the allegations set forth in paragraph 159 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '064 patent

under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

160. USL states that the allegations set forth in paragraph 160 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '064 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

161. USL states that the allegations set forth in paragraph 161 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '064 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

162. USL states that the allegations set forth in paragraph 162 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '064 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

163. Denied.

164. Denied.

165. Denied.

COUNT IX

**(Declaratory Judgment of Infringement of the '064 Patent Under 35 U.S.C. § 271(b) and (c)
by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg,
and 40 mg))**

166. Paragraph 166 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-165 as if fully set forth herein.

167. USL states that the allegations set forth in paragraph 167 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '064 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

168. USL states that the allegations set forth in paragraph 168 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '064 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

169. USL admits that it became aware of the '064 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

170. USL admits that it became aware of the '064 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

171. Denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

176. Denied.

177. Denied.

178. Denied.

179. Denied.

180. Denied.

181. Denied.

182. Denied.

183. Denied.

184. Denied.

185. Denied.

COUNT X

(Infringement of U.S. Patent No. 9,078,925 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

186. Paragraph 186 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-185 as if fully set forth herein.

187. USL denies that submission of ANDA Nos. 212333 and 213571 are acts of infringement; otherwise admitted.

188. Denied.

189. USL admits that it became aware of the '925 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

190. Denied.

191. Denied.

192. Denied.

193. Denied.

COUNT XI

(Declaratory Judgment of Infringement of the '925 Patent Under 35 U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

194. Paragraph 194 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-193 as if fully set forth herein.

195. USL states that the allegations set forth in paragraph 195 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '925 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

196. USL states that the allegations set forth in paragraph 196 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '925 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

197. USL states that the allegations set forth in paragraph 197 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '925 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin

capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit.

Otherwise, denied.

198. USL states that the allegations set forth in paragraph 198 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '925 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit.

Otherwise, denied.

199. Denied.

200. Denied.

201. Denied.

COUNT XII

(Declaratory Judgment of Infringement of the '925 Patent Under 35 U.S.C. § 271(b) and (c) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30 mg))

202. Paragraph 202 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-201 as if fully set forth herein.

203. USL states that the allegations set forth in paragraph 203 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '925 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

204. USL states that the allegations set forth in paragraph 204 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '925 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

205. USL admits that it became aware of the '925 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

206. USL admits that it became aware of the '925 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

207. Denied.

208. Denied.

209. Denied.

210. Denied.

211. Denied.

212. Denied.

213. Denied.

214. Denied.

215. Denied.

216. Denied.

217. Denied.

218. Denied.

219. Denied.

220. Denied.

221. Denied.

COUNT XIII

(Infringement of U.S. Patent No. 9,089,534 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

222. Paragraph 222 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-221 as if fully set forth herein.

223. USL denies that submission of ANDA Nos. 212333 and 213571 are acts of infringement; otherwise admitted.

224. Denied.

225. USL admits that it became aware of the '534 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

226. Denied.

227. Denied.

228. Denied.

229. Denied.

COUNT XIV

(Declaratory Judgment of Infringement of the '534 Patent Under 35 U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg))

230. Paragraph 230 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-229 as if fully set forth herein.

231. USL states that the allegations set forth in paragraph 231 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '534 patent

under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

232. USL states that the allegations set forth in paragraph 232 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '534 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

233. USL states that the allegations set forth in paragraph 233 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '534 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

234. USL states that the allegations set forth in paragraph 234 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that it submitted ANDA Nos. 212333 and 213571, pursuant to 21 U.S.C. § 355(j); that USL's ANDAs contain a paragraph IV certification to the '534 patent; and that USL seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of isotretinoin capsules, USP (10 mg, 20 mg, 30 mg, and 40 mg) prior to the expiration of the Patents-in-Suit. Otherwise, denied.

235. Denied.

236. Denied.

237. Denied.

COUNT XV

**(Declaratory Judgment of Infringement of the '534 Patent Under 35 U.S.C. § 271(b) and (c)
by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, 30 mg,
and 40 mg))**

238. Paragraph 238 contains no allegations of fact to which a response is required. To the extent an answer is required, USL incorporates its responses to paragraphs 1-237 as if fully set forth herein.

239. USL states that the allegations set forth in paragraph 239 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '534 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

240. USL states that the allegations set forth in paragraph 240 are legal conclusions as to which no responsive pleading is necessary, but to the extent a response is required, USL states that Plaintiffs' First Amended Complaint is for alleged patent infringement of the '534 patent under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a)-(c). USL denies that Plaintiffs are entitled to any relief.

241. USL admits that it became aware of the '534 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

242. USL admits that it became aware of the '534 patent at least as early as the date that USL submitted its ANDA No. 212333. Otherwise, denied.

243. Denied.

244. Denied.

245. Denied.

246. Denied.

247. Denied.

248. Denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Denied.

254. Denied.

255. Denied.

256. Denied.

257. Denied.

[ALLEGED] PRAYER FOR RELIEF

USL denies that Plaintiffs are entitled to judgment and any relief sought by the First Amended Complaint in paragraphs (a) through (g) of its prayer for relief.

AFFIRMATIVE DEFENSES

USL, without prejudice to the denials set forth in its Answer, alleges the following defenses to Plaintiffs' First Amended Complaint. USL reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery.

FIRST DEFENSE
(Non-infringement)

USL incorporates the file history for each of the Patents-in-Suit and ANDA Nos. 212333 and 213571 by reference.

The manufacture, use, sale, offer for sale, or importation of USL's ANDA Products that are the subject of USL's ANDA Nos. 212333 and 213571 have not infringed, do not infringe, and will not infringe any valid and enforceable claim of the Patents-in-Suit directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. Indeed, USL's isotretinoin drug products do not have a component with an HLB value of 10 or greater (as required by all of the claims of the Patents-in-Suit). *See, e.g.*, ANDA No. 212333, 1.12.11 at 2, 3.2.P.1 at 9, 3.2.P.2 at 11-12; ANDA No. 213571, 1.12.11 at 2, 3.2.P.1 at 7, 3.2.P.2 at 10-12.

Amendment and argument estoppel preclude Plaintiffs from recapturing claim scope through the doctrine of equivalents.

SECOND DEFENSE
(Failure to State a Claim)

The First Amended Complaint fails to state a claim upon which relief may be granted and must be dismissed, especially to the extent USL has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Patents-in-Suit directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

THIRD DEFENSE
(Not an Exceptional Case)

Plaintiffs are not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, or pursuant to the Court's inherent power.

FOURTH DEFENSE
(No Willful Infringement)

Plaintiffs' claims for enhanced damages, if any, and an award of fees and costs against USL have no basis in fact or law and should be denied.

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