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

ALKERMES PHARMA IRELAND LIMITED, Plaintiff, v. SLAYBACK PHARMA LLC and SLAYBACK PHARMA INDIA LLP. Defendants.	)	C.A. No.: 3:23-3794 **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Alkermes Pharma Ireland Limited ("Alkermes" or "Plaintiff"), for its Complaint against defendants Slayback Pharma LLC ("Slayback") and Slayback Pharma India LLP ("Slayback India") (collectively, "Defendants"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100, *et seq*., arising from Slayback's filing of New Drug Application ("NDA") No. 218395 ("Slayback's NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market an infringing version of ANJESO® (meloxicam injection, 30 mg/mL) at a dose of 30 mg (the "Proposed Drug Product") prior to the expiration of United States Patent Nos. 10,463,673 (the "'673 patent"), 10,471,067 (the "'067 patent"), 10,709,713 (the "'713 patent"), 10,881,663 (the "'663 patent"), and 11,458,145 (the "'145 patent") (collectively, the "Patents-in-Suit"), all owned by Plaintiff.

THE PARTIES

2. Plaintiff is an entity organized and existing under the laws of Ireland, with a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland, D04 C5Y6.

3. On information and belief, Slayback is an entity organized and existing under the laws of the State of Delaware, having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540.

4. On information and belief, Slayback India is a limited liability partnership organized under the laws of India, having a principal place of business at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU – Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana, 500072, India.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 35 U.S.C. § 271, 28 U.S.C. §§ 1331, 1338, 2201, and/or 2202.

6. On information and belief, Slayback has its principal place of business in New Jersey at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540.

7. On information and belief, Slayback, either directly or through one or more of its subsidiaries or agents, manufactures, markets, imports, distributes, and/or sells pharmaceutical drug products, including drug products, throughout the United States, including in this Judicial District.

8. Slayback is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005359.

9. Slayback is registered with the State of New Jersey's Division of Revenue & Enterprise Services as a business in the State of New Jersey under Entity ID No. 0400399320.

10. Slayback's website states it is "a New Jersey-based company focused on complex generic and specialty pharmaceutical products." Slayback Pharma LLC, https://slayback-pharma.com/about-us/ (last visited July 14, 2023).

11. Slayback sent Plaintiff a letter dated June 1, 2023 ("Slayback's Notice Letter") stating that Slayback filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, or sale within the United States, including, on information and

belief, in this Judicial District, of the Proposed Drug Product prior to the expiration of the Patents-in-Suit.

12. This Court thus has personal jurisdiction over Slayback because, *inter alia*, it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement under 35 U.S.C. § 271(e)(2).

13. This Court has personal jurisdiction over Slayback because, *inter alia*, Slayback: (1) has a principal place of business in New Jersey; and (2) has purposefully availed itself of the privilege of doing business in New Jersey by registering with the State of New Jersey's Division of Revenue & Enterprise Services as a business operating in New Jersey under Entity ID No. 0400399320 and registering with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005359.

14. This Court also has personal jurisdiction over Slayback because, *inter alia*, Slayback: (1) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (2) imports generic versions of branded pharmaceutical products for sale and use throughout the United States, including in New Jersey; and (3) on information and belief, derives substantial revenue from the sale of its products in this Judicial District.

15. On information and belief, this court has jurisdiction over Slayback India. On information and belief, Slayback India is in the business of, *inter alia*, developing, manufacturing, marketing, importing, distributing, and/or selling pharmaceutical drug products, including generic drug products.

16. On information and belief, Slayback India directly or indirectly develops, manufactures, markets, distributes, and/or sells pharmaceutical drug products, including generic drug products, throughout the United States, including in this Judicial District.

17. On information and belief, Slayback India purposefully has conducted and continues to conduct business in this Judicial District in concert with Slayback.

18. On information and belief, this Judicial District is a likely destination for Slayback's Proposed Drug Product.

19. On information and belief, Slayback and Slayback India intend a future course of conduct that includes acts of patent infringement in this Judicial District.

20. On information and belief, Slayback and Slayback India operate as interrelated corporate entities.

21. On information and belief, Slayback is the parent corporation of Slayback India.

22. On information and belief, Slayback and Slayback India each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including in this Judicial District.

23. In addition to the foregoing, this Court has personal jurisdiction over Slayback India because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiff's claims arise under federal law; (b) Slayback India is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) on information and belief, Slayback India has sufficient contacts with the United States as a whole, including, but not

limited to, preparing and submitting NDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Slayback India satisfies due process.

24. This Court has personal jurisdiction over Defendants also because they have taken advantage of the jurisdiction of this Court by filing claims and/or counterclaims in this Court. On information and belief, Defendants have previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases. For example, Defendants have previously been sued in this Judicial District and have availed themselves of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and have not challenged personal jurisdiction. *See, e.g.*, *Valeant Pharms. North America, LLC et al v. Zydus Pharms. USA, Inc. et al*, Civil Action No. 18-13635 (BRM)(LDW); *Kythera Biopharmaceuticals, Inc. v. Slayback Pharma LLC*, Civil Action No. 18-16012 (BRM)(TJB). Defendants have also consented to personal jurisdiction in additional suits brought in New Jersey. *See, e.g.*, *Bausch & Lomb , Inc. et al v. Slayback Pharma LLC et al*, Civil Action No. 21-16766 (RK)(RLS).

25. Venue is proper in this district for Slayback pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Slayback has a regular and established place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District.

26. Venue is proper in this Court as to Slayback for the reasons set forth above and for other reasons that will be presented to the Court if such venue is challenged.

27. Venue is proper in this district as to Slayback India pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Slayback India is a limited liability partnership existing under the laws of India and may be sued in any judicial district.

BACKGROUND

The Patents-in-Suit and ANJESO® Drug Product

28. NDA No. 210583 (the "RLD NDA") was for ANJESO®–intravenous meloxicam injection, 30 mg/mL. ANJESO® is the Reference Listed Drug for Slayback's NDA.

29. The RLD NDA was approved on February 20, 2020. Intravenous meloxicam injection, 30 mg/mL, has been sold in the United States under the trademark ANJESO® pursuant to the RLD NDA.

30. The Patents-in-Suit were each listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Valuations* (the "Orange Book").

31. ANJESO® was indicated for management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.

A. The '673 Patent

32. Plaintiff owns U.S. Patent No. 10,463,673. On November 5, 2019, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '673 patent, entitled "Nanoparticulate meloxicam formulations." A copy of the '673 patent is attached as **Exhibit A**. The '673 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

B. **The ’067 Patent**

33. Plaintiff owns U.S. Patent No. 10,471,067. On November 12, 2019, the USPTO duly and lawfully issued the ’067 patent, entitled “Nanoparticulate meloxicam formulations.” A copy of the ’067 patent is attached as **Exhibit B**. The ’067 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

C. **The ’713 Patent**

34. Plaintiff owns U.S. Patent No. 10,709,713. On July 14, 2020, the USPTO duly and lawfully issued the ’713 patent, entitled “Nanoparticulate meloxicam formulations.” A copy of the ’713 patent is attached as **Exhibit C**. The ’713 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

D. **The ’663 Patent**

35. Plaintiff owns U.S. Patent No. 10,881,663. On January 5, 2021, the USPTO duly and lawfully issued the ’663 patent, entitled “Method of treating pain in elderly patients with mild renal impairment.” A copy of the ’663 patent is attached as **Exhibit D**. The ’663 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

E. **The ’145 Patent**

36. Plaintiff owns U.S. Patent No. 11,458,145. On October 4, 2022, the USPTO duly and lawfully issued the ’145 patent, entitled “Methods of administering intravenous meloxicam in a bolus dose.” A copy of the ’145 patent is attached as **Exhibit E**. The ’145 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

Slayback's Infringing NDA Submission

37. On information and belief, as set forth in Slayback's Notice Letter, Slayback filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, or sale of its Proposed Drug Product prior to the expiration of the Patents-in-Suit.

38. Slayback's NDA includes a certification with respect to each of the Patents-in-Suit under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification").

39. On or about June 1, 2023, Slayback's Notice Letter was sent to Plaintiff, in which Slayback represented that it had filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, or sale of its Proposed Drug Product prior to the expiration of the Patents-in-Suit that are listed in the Orange Book for ANJESO®.

40. Under statute, Slayback has committed an act of infringement by filing Slayback's NDA with a Paragraph IV Certification.

41. In Slayback's Notice Letter, Slayback included a "Detailed Statement of the Factual and Legal Basis for Slayback Pharma LLC's Assertion of Invalidity, Unenforceability, or Non-Infringement" of the Patents-in-Suit, which sets forth the basis for its Paragraph IV Certification.

42. In Slayback's Notice Letter, Slayback states that the established name for its Proposed Drug Product is "meloxicam injection, 30 mg/mL."

43. In its Detailed Statement, Slayback did not set forth any grounds for invalidity or unenforceability of the Patents-in-Suit.

44. Slayback's Notice Letter contained an "Offer of Confidential Access." The terms to the Offer of Confidential Access were unreasonable, and Plaintiff attempted to negotiate access on more reasonable terms.

45. Only after a protracted negotiation regarding its Offer of Confidential Access, Slayback belatedly produced a multi-thousand page volume of confidential documents 41 days after the date on Slayback's Notice Letter.

46. On information and belief, fact and expert discovery will show that the Proposed Drug Product infringes one or more claims of the Patents-in-Suit.

ACTS GIVING RISE TO THIS SUIT

47. Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act ("FFDCA"), Slayback filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product before the Patents-in-Suit expire.

48. On information and belief, following FDA approval of Slayback's NDA, Defendants will make, use, sell, or offer to sell Slayback's Proposed Drug Product throughout the United States, or import such products into the United States.

49. In connection with the filing of Slayback's NDA as described above, Slayback provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the activities described in Slayback's Paragraph IV Certification.

50. On or about June 1, 2023, Slayback sent written notice of Slayback's Paragraph IV Certification to Plaintiff (i.e., Slayback's Notice Letter) regarding the Patents-in-Suit. Slayback's Notice Letter alleged that the claims of the Patents-in-Suit will not be infringed by the activities described in Slayback's NDA. Slayback's Notice Letter also informed Plaintiff that Slayback seeks approval to market Slayback's Proposed Drug Product before the Patents-in-Suit expire. Slayback specifically directed Slayback's Notice Letter to Plaintiff.

51. Based on a reasonable review of Slayback's Paragraph IV Certification, Slayback's confidential information, and publicly available information, Plaintiff is informed and believes filing of Slayback's NDA infringes and the Proposed Drug Product will infringe valid patent claims of the Patents-in-Suit, and has therefore brought this action.

52. This action is being commenced within the expiration of 45 days from the date Plaintiff received Slayback's Notice Letter.

COUNT I
Infringement of the '673 Patent

53. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

54. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '673 patent.

55. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

56. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '673 patent, either literally or under the doctrine of equivalents.

57. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '673 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

58. There is a justiciable controversy between the parties hereto as to the infringement of the '673 patent.

59. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '673 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

60. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Slayback will induce infringement of one or more claims of the '673 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '673 patent and knowledge that their acts are encouraging infringement.

61. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '673 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug

Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '673 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

62. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '673 patent is not enjoined.

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

64. Slayback did not contest the validity of any of the claims of the '673 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '673 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. *See* 21 CFR § 314.52(c).

65. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
Infringement of the '067 Patent

66. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

67. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '067 patent.

68. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

69. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '067 patent, either literally or under the doctrine of equivalents.

70. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '067 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

71. There is a justiciable controversy between the parties hereto as to the infringement of the '067 patent.

72. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '067 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

73. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '067 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '067 patent and knowledge that their acts are encouraging infringement.

74. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '067 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '067 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

75. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '067 patent is not enjoined.

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

77. Slayback did not contest the validity of any of the claims of the '067 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '067 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. *See* 21 CFR § 314.52(c).

78. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
Infringement of the '713 Patent

79. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

80. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial

manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '713 patent.

81. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

82. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '713 patent, either literally or under the doctrine of equivalents.

83. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '713 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

84. There is a justiciable controversy between the parties hereto as to the infringement of the '713 patent.

85. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '713 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

86. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '713 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's

NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '713 patent and knowledge that their acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '713 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '713 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

88. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '713 patent is not enjoined.

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

90. Slayback did not contest the validity of any of the claims of the '713 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '713 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. *See* 21 CFR § 314.52(c).

91. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
Infringement of the '663 Patent

92. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

93. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '663 patent.

94. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

95. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '663 patent, either literally or under the doctrine of equivalents.

96. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '663 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

97. There is a justiciable controversy between the parties hereto as to the infringement of the '663 patent.

98. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '663 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

99. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '663 patent under 35 U.S.C.

§ 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '663 patent and knowledge that their acts are encouraging infringement.

100. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '663 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '663 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

101. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '663 patent is not enjoined.

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

103. Slayback did not contest the validity of any of the claims of the '663 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '663 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. *See* 21 CFR § 314.52(c).

104. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V
Infringement of the '145 Patent

105. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

106. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '145 patent.

107. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

108. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '145 patent, either literally or under the doctrine of equivalents.

109. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '145 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

110. There is a justiciable controversy between the parties hereto as to the infringement of the '145 patent.

111. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '145 patent under 35 U.S.C. § 271(a) by

making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

112. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '145 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '145 patent and knowledge that their acts are encouraging infringement.

113. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '145 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '145 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

114. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '145 patent is not enjoined.

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

116. Slayback did not contest the validity of any of the claims of the '145 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '145 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. *See* 21 CFR § 314.52(c).

117. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment that Slayback has infringed each of the Patents-in-Suit by submitting Slayback's NDA;

B. A Judgment that Defendants' making, using, offering to sell, selling, or importing Slayback's Proposed Drug Product will infringe one or more claims of each of the Patents-in-Suit;

C. An Order that the effective date of FDA approval of Slayback's NDA be a date which is not earlier than the later of the last date of expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

D. A preliminary injunction enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Slayback's Proposed Drug Product until after the expiration of all of the Patents-in-Suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys, employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing meloxicam formulations or compositions claimed in the Patents-in-Suit, or from actively inducing or contributing to the infringement of any claim of the Patents-in-Suit, until after the expiration of all of the Patents-in-Suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

F. A Judgment that the commercial manufacture, use, importation into the United States, sale, and/or offer for sale of Slayback's Proposed Drug Product will directly infringe, induce and/or contribute to infringement of each of the Patents-in-Suit;

G. To the extent that Defendants have committed any acts with respect to the inventions claimed in any of the Patents-in-Suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiff damages for such acts;

H. If Defendants engage in the commercial manufacture, use, importation into the United States, sale, and/or offer for sale of Slayback's Proposed Drug Product prior to the expiration of all of the Patents-in-Suit, a Judgment awarding damages to Plaintiff resulting from such infringement, together with interest;

I. A Judgment declaring that each of the Patents-in-Suit remains valid and enforceable;

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

K. A Judgment awarding Plaintiff its costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

GIBBONS P.C.

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