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

ALKERMES PHARMA IRELAND LIMITED, Plaintiff, v. NANJING DELOVA BIOTECH CO., LTD. Defendant.	C.A. No.:3-23-9763

ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

Defendant Nanjing Delova Biotech Co. Ltd., ("Delova") responds to the Complaint of Plaintiff Alkermes Pharma Ireland Limited ("Alkermes" or "Plaintiff") as follows:

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 Delova's filing of New Drug Application ("NDA") No. 217593 ("Delova'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. 9,974,746 (the "'746 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.

ANSWER:

Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit Plaintiff purports to bring an action for infringement of United States Patent Nos. 9,974,746 (the "'746 patent"), 10,709,713 (the "'713 patent"), 10,881,663 (the "'663 patent"), and 11,458,145 (the "'145 patent") under the patent laws of the United States but deny that Plaintiff is entitled to such relief. Delova lacks knowledge or information sufficient to form a belief as to whether Plaintiff owns the Patents-in-Suit and, on that basis, denies that allegation. Delova admits that Delova submitted a New Drug Application ("NDA") No. 217593 ("Delova's NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for the matters described in Delova's NDA and the product that is described in Delova's NDA ("Delova's Proposed NDA Product"). Defendant denies the remaining allegations of paragraph 1 of the Complaint.

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.

ANSWER:

Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, on that basis, denies them.

3. On information and belief, Delova is a limited company organized under the laws of China, having a principal place of business at 7th Floor, Building 6, No. 699-18, Xuanwu Avenue, Xuanwu District, Nanjing, Jiangsu, China.

ANSWER:

Admitted.

4. 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.

ANSWER:

Paragraph 4 contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest that this Court has subject matter jurisdiction over this action. Defendant denies the remaining allegations of paragraph 4 of the Complaint.

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

ANSWER:

Denied.

6. Delova sent Plaintiff a letter dated July 10, 2023 ("Delova's Notice Letter") stating that Delova filed Delova'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.

ANSWER:

Delova admits it filed Delova's NDA seeking approval of the matters described therein. Delova's Notice Letter is a document that speaks for itself. Delova denies the remaining allegations of paragraph 6 of the Complaint.

7. This Court thus has personal jurisdiction over Delova 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).

ANSWER:

Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, for the purposes of this action only, Delova does not contest personal jurisdiction. Delova denies the remaining allegations of paragraph 7 of the Complaint.

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

ANSWER:

Denied

9. On information and belief, Delova 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.

ANSWER:

Denied.

10. On information and belief, this Judicial District is a likely destination for the Proposed Drug Product.

ANSWER:

Denied.

11. On information and belief, Delova intends a future course of conduct that includes acts of patent infringement in this Judicial District.

ANSWER:

Denied.

12. In addition to the foregoing, this Court has personal jurisdiction over Delova because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiff's claims arise under federal law; (b) Delova is a foreign defendant not subject to general personal

jurisdiction in the courts of any state; and (c) on information and belief, Delova 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 Delova satisfies due process.

ANSWER:

Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Delova does not contest personal jurisdiction in this judicial district. Delova denies the remaining allegations of paragraph 12 of the Complaint.

13. Venue is proper in this district for Delova pursuant to at least 28 U.S.C. § 1391 because, inter alia, Delova is a limited company existing under the laws of China with headquarters in Nanjing, Jiangsu, China and may be sued in any judicial district.

ANSWER:

Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Delova does not contest venue in this judicial district. Delova denies the remaining allegations of paragraph 13 of the Complaint.

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

ANSWER:

Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Delova does not contest venue in this judicial district. Delova denies the remaining allegations of paragraph 14 of the Complaint.

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

ANSWER:

Defendant admits, on information and belief, that NDA No. 210583 was approved for intravenous meloxicam injection, 30 mg/mL under the trademark ANJESO®. Delova admits that

ANJESO® is the Reference Listed Drug for Delova's NDA. Defendant denies any remaining allegations of paragraph 15 of the Complaint.

16. 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.

ANSWER:

Defendant admits, on information and belief, that the intravenous meloxicam injection, 30 mg/mL "has been sold" in the United States under the trademark ANJESO® and drugs@FDA lists February 20, 2020 as the approval date for the RLD NDA. Defendant denies the remaining allegations of paragraph 16, including any implication that ANJESO® product is currently sold in the United States.

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

ANSWER:

Defendant admits, on information and belief, that the Patents-in-Suit were listed in the Orange Book in connection with ANJESO®. Defendants deny the remaining allegations of paragraph 17 of the Complaint.

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

ANSWER:

Defendant admits, on information and belief, that Plaintiff's intravenous meloxicam injection, 30 mg/mL "was" indicated for a medical purpose as stated in the approved label for ANJESO®. On information and belief, Defendant denies the remaining allegations of paragraph 31, including any implication that ANJESO® product is currently sold in the United States.

A. The '746 Patent

19. Plaintiff owns U.S. Patent No. 9,974,746. On May 22, 2018, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '746 patent, entitled "Reduction of flake-like aggregation in nanoparticulate active agent compositions." A copy of the '746 patent is attached as Exhibit A. The '746 patent is listed in the Orange Book for ANJESO®.

ANSWER:

Defendant admits that the cover page of the '746 patent indicates it issued on May 22, 2018, but specifically denies it was duly and lawfully issued. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '746 patent, on that basis, deny them. Defendant admits that what purports to be a copy of the '746 patent is attached to the Complaint as Exhibit A. The '746 patent is a document that speaks for itself. Defendant admits that the '746 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendant denies the remaining allegations of paragraph 19 of the Complaint.

B. The '713 Patent

20. 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 B. The '713 patent is listed in the Orange Book for ANJESO®.

ANSWER:

Defendant admits that the cover page of the '713 patent indicates it issued on July 14, 2020, but specifically denies it was duly and lawfully issued. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '713 patent, on that basis, deny them. Defendant admits that what purports to be a copy of the '713 patent is attached to the Complaint as Exhibit B. The '713 patent is a document that speaks for itself. Defendant admits that the '713 patent was listed in the Orange Book for NDA No. 210583, but

said NDA is "discontinued." Defendant denies the remaining allegations of paragraph 20 of the Complaint.

C. The '663 Patent

21. 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 C. The '663 patent is listed in the Orange Book for ANJESO®

ANSWER:

Defendant admits that the cover page of the '663 patent indicates it issued on January 5, 2021, but specifically denies it was duly and lawfully issued. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '663 patent, on that basis, deny them. Defendant admits that what purports to be a copy of the '663 patent is attached to the Complaint as Exhibit C. The '663 patent is a document that speaks for itself. Defendant admits that the '663 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendant denies the remaining allegations of paragraph 21 of the Complaint.

D. The '145 Patent

22. 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 D. The '145 patent is listed in the Orange Book for ANJESO®.

ANSWER:

Defendant admits that the cover page of the '145 patent indicates it issued on October 4, 2022, but specifically denies it was duly and lawfully issued. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '145 patent, on that basis, denies them. Defendant admits that what purports to be a copy of the

'145 patent is attached to the Complaint as Exhibit D. The '145 patent is a document that speaks for itself. Defendant admits that the '145 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendant denies the remaining allegations of paragraph 22 of the Complaint.

23. On information and belief, as set forth in Delova's Notice Letter, Delova filed Delova'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.

ANSWER:

Delova admits it filed Delova's NDA seeking approval of the matters described therein. Delova denies the remaining allegations of paragraph 23 of the Complaint.

24. Delova'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").

ANSWER:

Delova admits that Delova's Notice Letter notified Plaintiff of its Delova's NDA certification that the claims of each of the Patents-in- Suit are invalid, unenforceable, and/or will not be infringed by Delova's Proposed NDA Product. Delova's Notice Letter is a document that speaks for itself. Delova denies the remaining allegations of paragraph 24 of the Complaint.

25. On or about July 10, 2023, Delova's Notice Letter was sent to Plaintiff, in which Delova represented that it had filed Delova'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®.

ANSWER:

Delova admits it filed Delova's NDA seeking approval of the matters described therein. Delova's Notice Letter is a document that speaks for itself. Delova denies the remaining allegations of paragraph 24 of the Complaint.

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

ANSWER:

Denied.

27. In Delova's Notice Letter, Delova states that the established name for its Proposed Drug Product is "meloxicam injection."

ANSWER:

Admitted.

28. In Delova's Notice Letter, Delova included a "Detailed Statement of the Factual and Legal Basis for Delova's NDA Paragraph IV Certification" ("Detailed Statement") of the Patents-in-Suit, which is required to set forth the basis for its Paragraph IV Certification.

ANSWER:

Delova admits that its Notice Letter included a "Detailed Statement of the Factual and Legal Basis for Delova's NDA Paragraph IV Certification" ("Detailed Statement") of the Patents-in-Suit. The remaining allegations of the paragraph are legal conclusions, to which no response is required. Delova denies the remaining allegations of paragraph 28 of the Complaint.

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

ANSWER:

Denied.

30. In its Detailed Statement, Delova did not set forth any information or details supporting its positions of noninfringement of the Patents-in-Suit.

ANSWER:

Denied.

31. Delova's Notice Letter and Detailed Statement were deficient for, at least, failing to set forth Delova's noninfringement positions regarding the Patents-in-Suit.

ANSWER:

Denied.

32. Delova's Notice Letter contained an "Offer of Confidential Access." The terms to the Offer of Confidential Access were unreasonable, and Plaintiff made numerous attempts to negotiate access on more reasonable terms.

ANSWER:

Denied.

33. Only after protracted negotiations, Delova accepted Plaintiff's revisions to Delova's Offer of Confidential Access. Thereafter, belatedly and selectively, Delova produced a set of highly technical documents 43 days after the date on Delova's Notice Letter.

ANSWER:

Denied.

34. Despite repeated requests, Delova refused to produce Delova's NDA in full and included unnecessary redactions to substantial portions of its already limited disclosure.

ANSWER:

Denied.

35. On August 22, 2023, Delova sent or caused to be sent an email to Plaintiff's Counsel containing noninfringement positions. This email was sent 43 days after the date on Delova's Notice Letter. This was the first time Delova provided Plaintiff with its noninfringement positions for the Patents-in-Suit. Such positions should have been provided in Delova's Detailed Statement.

ANSWER:

Delova admits that it sent an e-mail on August 22, 2023, that speaks for itself. Delova denies the remaining allegations of paragraph 35.

36. 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.

ANSWER:

Denied.

37. Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act ("FFDCA"), Delova filed Delova'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 the Proposed Drug Product before the Patents-in-Suit expire.

ANSWER:

Delova admits it filed Delova's NDA seeking approval of the matters described therein. Delova denies the remaining allegations of paragraph 37 of the Complaint.

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

ANSWER:

Delova admits it filed Delova's NDA seeking approval of the matters described therein. Delova denies the remaining allegations of paragraph 38 of the Complaint.

39. In connection with the filing of Delova's NDA as described above, Delova 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 Delova's Paragraph IV Certification.

ANSWER:

Admitted.

40. On or about July 10, 2023, Delova sent written notice of Delova's Paragraph IV Certification to Plaintiff (i.e., Delova's Notice Letter) regarding the Patents-in-Suit. Delova's Notice Letter alleged that the claims of the Patents-in-Suit will not be infringed by the activities described in Delova's NDA. Delova's Notice Letter also informed Plaintiff that Delova seeks approval to market the Proposed Drug Product before the Patents-in-Suit expire. Delova specifically directed Delova's Notice Letter to Plaintiff.

ANSWER:

Delova admits that by letter dated July 10, 2023, Delova notified Plaintiff of its NDA certification that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Delova's Proposed NDA Product. Delova's Notice Letter is a document that speaks for itself. Delova denies the remaining allegations of paragraph 40 of the Complaint.

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

ANSWER:

Denied.

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

ANSWER:

Paragraph 42 contains legal conclusions to which no response is required. Delova denies the remaining allegations of paragraph 42 of the Complaint.

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

ANSWER:

Defendant incorporates by reference its responses to paragraphs 1-42 as if fully set forth herein.

44. Delova, by the submission of its Paragraph IV Certification as part of Delova'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 the Proposed Drug Product, prior to the expiration of the '746 patent.

ANSWER:

Delova admits it filed Delova's NDA seeking approval of the matters described therein. Delova denies the remaining allegations of paragraph 44 of the Complaint.

45. Delova's NDA has been pending before the FDA since at least July 10, 2023, the date appearing on Delova's Notice Letter to Plaintiff.

ANSWER:

Admitted.

46. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '746 patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

47. Delova's submission of Delova's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Proposed Drug Product, prior to the expiration of the '746 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

48. There is a justiciable controversy between the parties hereto as to the infringement of the '746 patent.

ANSWER:

Denied.

49. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant will infringe one or more claims of the '746 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Proposed Drug Product in the United States.

ANSWER:

Denied.

50. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Delova will induce infringement of one or more claims of the '746 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the Proposed Drug Product in the United States. On information and belief, upon FDA approval of Delova's NDA, Defendant will intentionally encourage acts of direct infringement with knowledge of the '746 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Denied.

51. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant will contributorily infringe one or more claims of the '746 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Proposed Drug Product in the United

States. On information and belief, Defendant has had and continues to have knowledge that the Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '746 patent and that there is no substantial non-infringing use for the Proposed Drug Product.

ANSWER:

Denied.

52. Plaintiff will be substantially and irreparably damaged and harmed if Defendant's infringement of the '746 patent is not enjoined.

ANSWER:

Denied.

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

ANSWER:

Denied.

54. Delova did not contest the validity of any of the claims of the '746 patent in Delova's Notice Letter. If Delova had a factual or legal basis to contest the validity of the claims of the '746 patent, it was required by applicable regulations to state such a basis in Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

55. Delova did not provide any information or detail in Delova's Notice Letter supporting its opinion that the claims of the '746 patent are not infringed. If Delova had a factual or legal basis to contest the infringement of the claims of the '746 patent, it was required by applicable regulations to state such a basis in Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Defendant incorporates by reference its responses to paragraphs 1-57 as if fully set forth herein.

58. Delova, by the submission of its Paragraph IV Certification as part of Delova'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 the Proposed Drug Product, prior to the expiration of the '713 patent.

ANSWER:

Denied.

59. Delova's NDA has been pending before the FDA since at least July 10, 2023, the date appearing on Delova's Notice Letter to Plaintiff.

ANSWER:

Admitted.

60. 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.

ANSWER:

Denied.

61. Delova's submission of Delova's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the 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).

ANSWER:

Denied.

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

ANSWER:

Denied.

63. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States.

ANSWER:

Denied.

64. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States. On information and belief, upon FDA approval of Delova's NDA, Defendant will intentionally encourage acts of direct infringement with knowledge of the '713 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Denied.

65. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States. On information and belief, Defendant has had and continues to have knowledge that the 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 the Proposed Drug Product.

ANSWER:

Denied.

66. Plaintiff will be substantially and irreparably damaged and harmed if Defendant's infringement of the '713 patent is not enjoined.

ANSWER:

Denied.

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

ANSWER:

Denied.

68. Delova did not contest the validity of any of the claims of the '713 patent in Delova's Notice Letter. If Delova 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 Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

69. Delova did not provide any information or detail in Delova's Notice Letter supporting its opinion that the claims of the '713 patent are not infringed. If Delova had a factual or legal basis to contest the infringement of the claims of the '713 patent, it was required by applicable regulations to state such a basis in Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

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

ANSWER:

Denied

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

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ANSWER:

Defendant incorporates by reference its responses to paragraphs 1-70 as if fully set forth herein.

72. Delova, by the submission of its Paragraph IV Certification as part of Delova'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 the Proposed Drug Product, prior to the expiration of the '663 patent.

ANSWER:

Denied.

73. Delova's NDA has been pending before the FDA since at least July 10, 2023, the date appearing on Delova's Notice Letter to Plaintiff.

ANSWER:

Admiited.

74. 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.

ANSWER:

Denied.

75. Delova's submission of Delova's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the 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).

ANSWER:

Denied.

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

ANSWER:

Denied.

77. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States.

ANSWER:

Denied.

78. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States. On information and belief, upon FDA approval of Delova's NDA, Defendant will intentionally encourage acts of direct infringement with knowledge of the '663 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Denied.

79. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States. On information and belief, Defendant has had and continues to have knowledge that the 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 the Proposed Drug Product.

ANSWER:

Denied.

80. Plaintiff will be substantially and irreparably damaged and harmed if Defendant's infringement of the '663 patent is not enjoined.

ANSWER:

Denied.

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

ANSWER:

Denied.

82. 82. Delova did not contest the validity of any of the claims of the '663 patent in Delova's Notice Letter. If Delova 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 Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

83. Delova did not provide any information or detail in Delova's Notice Letter supporting its opinion that the claims of the '663 patent are not infringed. If Delova had a factual or legal basis to contest the infringement of the claims of the '663 patent, it was required by applicable regulations to state such a basis in Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Defendant incorporates by reference its responses to paragraphs 1-84 as if fully set forth herein.

86. Delova, by the submission of its Paragraph IV Certification as part of Delova'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 the Proposed Drug Product, prior to the expiration of the '145 patent.

ANSWER:

Denied.

87. Delova's NDA has been pending before the FDA since at least July 10, 2023, the date appearing on Delova's Notice Letter to Plaintiff.

ANSWER:

Admitted

88. 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.

ANSWER:

Denied.

89. Delova's submission of Delova's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the 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).

ANSWER:

Denied.

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

ANSWER:

Denied.

91. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States.

ANSWER:

Denied.

92. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States. On information and belief, upon FDA approval of Delova's NDA, Defendant will intentionally encourage acts of direct infringement with knowledge of the '145 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Denied.

93. Unless enjoined by this Court, upon FDA approval of Delova's NDA, Defendant 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 the Proposed Drug Product in the United States. On information and belief, Defendant has had and continues to have knowledge that the 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 the Proposed Drug Product.

ANSWER:

Denied.

94. Plaintiff will be substantially and irreparably damaged and harmed if Defendant's infringement of the '145 patent is not enjoined.

ANSWER:

Denied.

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

ANSWER:

Denied.

96. Delova did not contest the validity of any of the claims of the '145 patent in Delova's Notice Letter. If Delova 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 Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

97. Delova did not provide any information or detail in Delova's Notice Letter supporting its opinion that the claims of the '145 patent are not infringed. If Delova had a factual or legal basis to contest the infringement of the claims of the '145 patent, it was required by applicable regulations to state such a basis in Delova's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Denied.

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

ANSWER:

Denied.

SEPARATE DEFENSES

Without prejudice to the admissions and denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Delova asserts the following

separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

First Separate Defense
(Non-infringement of the '746 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Delova's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '746 Patent.

Second Separate Defense
(Invalidity of the '746 Patent)

The claims of the '746 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Third Separate Defense
(Non-infringement of the '713Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Delova's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '713 Patent.

Fourth Separate Defense
(Invalidity of the '713 Patent)

The claims of the '713 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited

to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Fifth Separate Defense
(Non-infringement of the '663 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Delova's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '663 Patent.

Sixth Separate Defense
(Invalidity of the '663 Patent)

The claims of the '663 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Seventh Separate Defense
(Non-infringement of the '145 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Delova's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '145 Patent.

Eighth Separate Defense
(Invalidity of the '145 Patent)

The claims of the '145 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited

to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Ninth Separate Defense
(No Injury or Damage)

Plaintiff may not seek injunctive relief against Defendants because Plaintiff's alleged damages are not immediate or irreparably, and Plaintiff therefore has an adequate remedy at law.

Reservation of Defenses

Defendants reserve the right to assert additional defenses pending further investigation and discovery.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

The remainder of Plaintiff's complaint recites a prayer for relief for which no response is required. To the extent a response is required, Defendant denies that Plaintiff is entitled to any judgment or relief against Defendant and, therefore, specifically denies paragraphs (A) through (L) of Plaintiff's Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Delova respectfully requests that this Court enter judgment in its favor and against Plaintiff as follows:

A. Dismissing the Complaint with prejudice, denying each and every Request for Relief contained therein, and ordering that Plaintiff take nothing thereby;

B. Declaring that the manufacture, use, sale, offer for sale, or importation of Delova's Proposed NDA Product described in Delova's NDA No. 217593 does not and will not infringe any valid and/or enforceable claim of the '746 patent;

C. Declaring the claims of the '746 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

D. Declaring that the manufacture, use, sale, offer for sale, or importation of Delova's Proposed NDA Product described in Delova's NDA No. 217593 does not and will not infringe any valid and/or enforceable claim of the '713 patent;

E. Declaring the claims of the '713 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

F. Declaring that the manufacture, use, sale, offer for sale, or importation of Delova's Proposed NDA Product described in Delova's NDA No. 217593 does not and will not infringe any valid and/or enforceable claim of the '663 patent;

G. Declaring the claims of the '663 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

H. Declaring that the manufacture, use, sale, offer for sale, or importation of Delova's Proposed NDA Product described in Delova's NDA No. 217593 does not and will not infringe any valid and/or enforceable claim of the '145 patent;

I. Declaring the claims of the '145 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

J. Permanently enjoining Plaintiff or any of its assignees or successors from asserting that the commercial manufacture, use, sale, offer for sale, or importation of Delova's Proposed NDA Product described in Delova's NDA No. 217593 infringes or will infringe any claim of the Orange Book Patents;

K. Awarding Delova its costs and expenses in this action;

L. Declaring that this is an exceptional case under 35 U.S.C. §285 and/or other applicable laws and awarding Delova its attorneys' fees, costs and expenses in this action;

M. An order allowing Delova to launch its Proposed NDA Product, if it chooses to do so, upon FDA approval; and

N. Awarding Delova such further relief this Court may deem just and proper.

HILL WALLACK LLP

/s/ Eric I. Abraham

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