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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 **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Alkermes Pharma Ireland Limited ("Alkermes" or "Plaintiff"), for its Complaint against defendant Nanjing Delova Biotech Co., Ltd. ("Delova" or "Defendant"), 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 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.

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, 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.

JURISDICTION AND VENUE

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.

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.

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.

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).

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.

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.

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

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

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.

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.

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.

BACKGROUND

The Patents-in-Suit and ANJESO® Drug Product

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.

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.

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

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

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®.

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®.

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®.

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®.

Delova's Infringing NDA Submission

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.

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").

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®.

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

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

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.

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

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

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.

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.

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.

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.

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.

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.

ACTS GIVING RISE TO THIS SUIT

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.

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.

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.

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.

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.

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

COUNT I
Infringement of the '746 Patent

43. Plaintiff repeats and realleges the allegations of the preceding paragraphs 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.

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.

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.

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).

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

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.

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.

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.

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

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

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).

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).

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.

COUNT II
Infringement of the '713 Patent

57. Plaintiff repeats and realleges the allegations of the preceding paragraphs 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.

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.

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.

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).

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

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.

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.

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.

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

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

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).

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).

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.

COUNT III
Infringement of the '663 Patent

71. Plaintiff repeats and realleges the allegations of the preceding paragraphs 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.

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.

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.

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).

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

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.

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.

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.

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

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

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).

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).

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.

COUNT IV
Infringement of the '145 Patent

85. Plaintiff repeats and realleges the allegations of the preceding paragraphs 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.

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.

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.

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).

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

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.

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.

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.

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

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

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).

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).

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

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

B. A Judgment that Defendant's making, using, offering to sell, selling, or importing the 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 Delova'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 Defendant and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing the 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 Defendant, its 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 the Proposed Drug Product will directly infringe, induce and/or contribute to infringement of each of the Patents-in-Suit;

G. To the extent that Defendant has 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 Defendant engages in the commercial manufacture, use, importation into the United States, sale, and/or offer for sale of the 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.

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