

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

MYLAN INSTITUTIONAL LLC
and APICORE US LLC,

Plaintiffs,

v.

HONG KONG KING-FRIEND
INDUSTRIAL CO., LTD.,

Defendant.

Civil Action No.

**MYLAN INSTITUTIONAL LLC AND APICORE US
LLC’S COMPLAINT FOR PATENT INFRINGEMENT
AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT**

Plaintiffs Mylan Institutional LLC (“Mylan Institutional”) and Apicore US LLC (“Apicore”) (collectively “Plaintiffs”) for their Complaint for Patent Infringement and Declaratory Judgment of Patent Infringement against Defendant Hong Kong King-Friend Industrial Co., Ltd. (“HKKF” or “Defendant”) herein allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and a declaratory judgment of patent infringement arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq.*, involving U.S. Patent No. 9,353,050 (the “’050 Patent”), U.S. Patent No. 10,626,086 (the “’086 Patent”), and U.S. Patent No. 10,752,580 (the “’580 Patent”) (collectively, the “Patents-in-Suit”).

2. On information and belief, HKKF has used, offered to sell, sold, and/or imported into the United States and intends to continue to manufacture, use, offer to sell, sell, and/or import

into the United States an isosulfan blue for injection product that is the subject of its Abbreviated New Drug Application (“ANDA”) No. 213130 (“the HKKF ANDA Product”) submitted to the U.S. Food and Drug Administration (“FDA”), prior to the expiration of the Patents-in-Suit.

3. On information and belief, the HKKF ANDA Product infringes or would infringe at least one claim of the ’050 Patent.

4. On information and belief, the HKKF ANDA Product infringes or would infringe at least one claim of the ’086 Patent.

5. On information and belief, the HKKF ANDA Product infringes or would infringe at least one claim of the ’580 Patent.

THE PARTIES

6. Mylan Institutional is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 1718 Northrock Court, Rockford, Illinois 61103.

7. Mylan Institutional is a pharmaceutical company that develops and commercializes injectable and other pharmaceutical products.

8. Apicore is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

9. Apicore is a pharmaceutical company that provides innovative solutions to the pharmaceutical industry in the field of active pharmaceutical ingredient manufacturing, including a high purity isosulfan blue product that is superior to the product of other methods of isosulfan blue synthesis.

10. On information and belief, HKKF is a company organized and existing under the laws of Hong Kong, China. On information and belief, HKKF has a principal place of business at Room 501 5/F. 113 Argyle Street, Mongkok, Kowloon, Hong Kong, China.

11. On information and belief, HKKF has registered address at Room 2702 27/F., Omega Plaza, 32 Dundas Street, Mongkok, Kowloon, Hong Kong, China.

12. On information and belief, HKKF has a principal place of business at 1/16 Xuefu Road, Nanjing High-Tech Zone Nanjing P.R. China 210061.

JURISDICTION AND VENUE

13. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq.*

14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq.*

15. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this case involves an actual controversy within the Court's jurisdiction and seeks a declaratory judgment that the '050, '086 and '580 Patents will be infringed.

16. This Court has personal jurisdiction over HKKF by virtue of actions HKKF has taken for the purpose of engaging in injury-causing and wrongful marketing conduct in Texas and this District. *See Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

17. HKKF has taken the significant and costly step of requesting FDA approval to engage in the marketing of the HKKF ANDA Product described in ANDA No. 213130 purposefully directed at Texas and this District.

18. The FDA approved HKKF's ANDA No. 213130 on November 3, 2021. HKKF has very recently engaged in the marketing and commercial launch of the HKKF ANDA Product

described in ANDA No. 213130 in the United States without any limitations or any advance notice to Plaintiffs.

19. HKKF's ANDA conduct is therefore suit-related and has a substantial connection with Texas and this District because HKKF's ANDA filing is tightly tied, in purpose and planned effect, to the deliberate making of sales in Texas and this District and the suit relates to whether that in-State activity will infringe the Patents-in-Suit.

20. On information and belief, HKKF knows and intends that its ANDA Product described in ANDA No. 213130 will displace sales of Mylan Institutional's ISB product causing injury to Plaintiffs in Texas and in this District.

21. It is a proper exercise of judicial power in this District to stop HKKF's planned, non-speculative harmful conduct.

22. In the alternative, personal jurisdiction is proper in this District pursuant to Rule 4(k) of the Federal Rules of Civil Procedure because (1) this claim arises under federal law, (2) on information and belief, HKKF is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) exercising jurisdiction is consistent with the United States Constitution and laws.

23. Venue is proper in this District. (28 U.S.C. § 1391(b), 28 U.S.C. § 1400(b)).

24. In the alternative, venue is proper in this District because HKKF is a "defendant not resident in the United States" and therefore "may be sued in any judicial district" pursuant to 28 U.S.C. § 1391(c)(3).

PATENTS-IN-SUIT

25. Mylan Institutional's highly pure isosulfan blue is the Reference Standard product as designated by the FDA because the isosulfan blue Reference Listed Drug product previously

sold by Covidien is no longer commercially available. *See* Exhibit D (FDA webpage showing that Mylan Institutional's isosulfan blue is the Reference Standard).

26. A “[r]eference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an *in vivo* bioequivalence study required for approval.” 21 CFR 314.3; *see also*

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079086.htm>, Section 1.4 (defining “Reference Standard”).

27. The '050 Patent, entitled “Process for Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on May 31, 2016. The named inventors of the '050 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the '050 Patent. Apicore is the exclusive licensee of the '050 Patent. A true and correct copy of the '050 Patent is attached hereto as Exhibit A.

28. The '086 Patent, entitled “Process for Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on April 21, 2020. The named inventors of the '086 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the '086 Patent. Apicore is the exclusive licensee of the '086 patent. A true and correct copy of the '086 Patent is attached hereto as Exhibit B.

29. The '580 Patent, entitled “Process for Preparation of Isosulfan Blue,” was duly and legally issued by the USPTO on August 25, 2020. The named inventors of the '580 Patent are Ravishanker Kovi, Satyam Nampalli, and Peter Xavier Tharial. Mylan Institutional is the assignee of the '580 Patent. Apicore is the exclusive licensee of the '580 patent. A true and correct copy of the '580 Patent is attached hereto as Exhibit C.

30. Mylan Institutional is the lawful owner of the Patents-in-Suit and has all right, title and interest in and to the Patents-in-Suit.

31. Apicore is an exclusive licensee of each of the Patents-in-Suit.

ACTS GIVING RISE TO THIS ACTION

32. Neither Mylan Institutional nor Apicore has authorized or licensed HKKF to make, use, sell, offer for sale, and/or import into the United States any of the inventions claimed in the Patents-in-Suit.

33. On information and belief, HKKF submitted ANDA No. 213130 to the FDA seeking approval to engage in the commercial manufacture, use, marketing, offer for sale, and sale of an isosulfan blue product.

34. HKKF received approval of its ANDA No. 213130 on November 3, 2021. HKKF has very recently engaged in the marketing and commercial launch of the HKKF ANDA Product described in ANDA No. 213130 in the United States without any limitations or any advance notice to Plaintiffs.

35. On November 5, 2021, counsel for Mylan Institutional sent HKKF a letter requesting that HKKF and its affiliates refrain from commercially selling, offering to sell, or importing the HKKF ANDA Product while the parties resolve Mylan Institutional's patent rights. HKKF did not agree to the request.

36. On information and belief, HKKF instead launched its ANDA Product into the market on or around November 8, 2021.

37. On information and belief, HKKF was aware of the '050 Patent, the '086 Patent and the '580 Patent prior to the launch of its ANDA Product.

38. On information and belief, HKKF was aware of the '050 Patent, the '086 Patent and the '580 Patent prior to the commencement of this action.

COUNT I

Infringement of the '050 Patent

39. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

40. On information and belief, HKKF has infringed (literally and/or under the doctrine of equivalents) the '050 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the HKKF ANDA Product.

41. The HKKF ANDA Product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

42. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the HKKF ANDA, would be compared to Mylan Institutional's ISB product in *in vivo* bioequivalence studies required by FDA.

43. Apicore's isosulfan blue API and Mylan Institutional's ISB product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

44. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the HKKF ANDA for ISB is likely to have at least the same purity as the Apicore isosulfan blue API used in Mylan Institutional's ISB product.

45. On information and belief, the HKKF ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB product for HKKF's ANDA Product to have been approved by the FDA.

46. On information and belief, HKKF infringes at least claim 1 of the '050 Patent because the isosulfan blue API used in the HKKF ANDA Product has a purity of at least 99.0% by HPLC.

47. On information and belief, HKKF had knowledge of the '050 Patent at least as early as November 5, 2021.

48. HKKF has had constructive notice of the '050 Patent as of its date of issuance on May 31, 2016.

49. On information and belief, HKKF is and was aware of the existence of the '050 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '050 Patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

50. Plaintiffs will be substantially and irreparably damaged and harmed if HKKF's infringement of the '050 Patent is not enjoined by this Court.

51. HKKF's infringement of the '050 Patent has caused Plaintiff substantial harm.

COUNT II

Infringement of the '086 Patent

52. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

53. On information and belief, HKKF has infringed (literally and/or under the doctrine of equivalents) the '086 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the HKKF ANDA Product.

54. The HKKF ANDA Product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

55. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the HKKF ANDA, would be compared to Mylan Institutional's ISB product in *in vivo* bioequivalence studies required by FDA.

56. Apicore's isosulfan blue API and Mylan Institutional's ISB product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

57. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the HKKF ANDA for ISB is likely to have at least the same purity as the Apicore isosulfan blue API used in Mylan Institutional's ISB product.

58. On information and belief, the HKKF ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB product for HKKF's ANDA Product to have been approved by the FDA.

59. On information and belief, HKKF infringes at least claim 1 of the '086 Patent because the isosulfan blue API used in the HKKF ANDA Product has a purity of at least 99.0% by HPLC.

60. On information and belief, HKKF had knowledge of the '086 Patent at least as early as November 5, 2021.

61. HKKF has had constructive notice of the '086 Patent as of its date of issuance on April 21, 2020.

62. On information and belief, HKKF is and was aware of the existence of the '086 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '086 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

63. Plaintiffs will be substantially and irreparably damaged and harmed if HKKF's infringement of the '086 Patent is not enjoined by this Court.

64. HKKF's infringement of the '086 Patent has caused Plaintiff substantial harm.

COUNT III

Infringement of the '580 Patent

65. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

66. On information and belief, HKKF has infringed (literally and/or under the doctrine of equivalents) the '580 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the HKKF ANDA Product.

67. The HKKF ANDA Product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

68. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the HKKF ANDA, would be compared to Mylan Institutional's ISB product in *in vivo* bioequivalence studies required by FDA.

69. Apicore's isosulfan blue API and Mylan Institutional's ISB product, are at least 99% pure by HPLC as defined in the Patents-in-Suit.

70. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the HKKF ANDA for ISB is likely to have at least the same purity as the Apicore isosulfan blue API used in Mylan Institutional's ISB product.

71. On information and belief, the HKKF ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB product for HKKF's ANDA Product to have been approved by the FDA.

72. On information and belief, HKKF infringes at least claim 1 of the '580 Patent because the isosulfan blue API used in the HKKF ANDA Product has a purity of at least 99.0% by HPLC.

73. On information and belief, HKKF had knowledge of the '580 Patent at least as early as November 5, 2021.

74. HKKF has had constructive notice of the '580 Patent as of its date of issuance on August 25, 2020.

75. On information and belief, HKKF is and was aware of the existence of the '580 Patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '580 Patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

76. Plaintiffs will be substantially and irreparably damaged and harmed if HKKF's infringement of the '580 Patent is not enjoined by this Court.

77. HKKF's infringement of the '580 Patent has caused Plaintiff substantial harm.

COUNT IV

Declaratory Judgment of Infringement of the '050 Patent

78. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

79. On information and belief, HKKF will infringe (literally and/or under the doctrine of equivalents) the '050 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the HKKF ANDA Product.

80. The HKKF ANDA product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

81. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the HKKF ANDA, would be compared to Mylan Institutional's ISB product in *in vivo* bioequivalence studies required by FDA.

82. Apicore's isosulfan blue API and Mylan Institutional's ISB product are at least 99% pure by HPLC as defined in the Patents-in-Suit.

83. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the

HKKF ANDA for ISB is likely to have at least the same purity as the Apicore isosulfan blue API used in Mylan Institutional's ISB product.

84. On information and belief, the HKKF ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB product for HKKF's ANDA Product to have been approved by the FDA.

85. On information and belief, HKKF infringes at least claim 1 of the '050 Patent because the isosulfan blue API used in the HKKF ANDA Product has a purity of at least 99.0% by HPLC.

86. On information and belief, HKKF had knowledge of the '050 Patent at least as early as November 5, 2021.

87. HKKF has had constructive notice of the '050 Patent as of its date of issuance on May 31, 2016.

88. Plaintiffs will be substantially and irreparably damaged and harmed if HKKF's infringement of the '050 Patent is not enjoined by this Court.

89. HKKF's infringement of the '050 Patent will cause Plaintiffs substantial harm.

COUNT V

Declaratory Judgment of Infringement of the '086 Patent

90. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

91. On information and belief, HKKF will infringe (literally and/or under the doctrine of equivalents) the '086 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the HKKF ANDA Product.

92. The HKKF ANDA product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

93. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the HKKF ANDA, would be compared to Mylan Institutional's ISB product in *in vivo* bioequivalence studies required by FDA.

94. Apicore's isosulfan blue API and Mylan Institutional's ISB product are at least 99% pure by HPLC as defined in the Patents-in-Suit.

95. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the HKKF ANDA for ISB is likely to have at least the same purity as the Apicore isosulfan blue API used in Mylan Institutional's ISB product.

96. On information and belief, the HKKF ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB product for HKKF's ANDA Product to have been approved by the FDA.

97. On information and belief, HKKF infringes at least claim 1 of the '086 Patent because the isosulfan blue API used in the HKKF ANDA Product has a purity of at least 99.0% by HPLC.

98. On information and belief, HKKF had knowledge of the '086 Patent at least as early as November 5, 2021.

99. HKKF has had constructive notice of the '086 Patent as of its date of issuance on April 21, 2020.

100. Plaintiffs will be substantially and irreparably damaged and harmed if HKKF's infringement of the '086 Patent is not enjoined by this Court.

101. HKKF's infringement of the '086 Patent will cause Plaintiffs substantial harm.

COUNT VI

Declaratory Judgment of Infringement of the '580 Patent

102. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

103. On information and belief, HKKF will infringe (literally and/or under the doctrine of equivalents) the '580 Patent, including at least Claim 1, by making, using, offering to sell and/or selling within the United States and/or importing into the United States the HKKF ANDA Product.

104. The HKKF ANDA product was approved while Mylan Institutional's ISB product was listed as the Reference Standard for isosulfan blue.

105. Because Mylan Institutional's ISB product is listed as the Reference Standard for isosulfan blue, any new ANDA for ISB, including the HKKF ANDA, would be compared to Mylan Institutional's ISB product in *in vivo* bioequivalence studies required by FDA.

106. Apicore's isosulfan blue API and Mylan Institutional's ISB product are at least 99% pure by HPLC as defined in the Patents-in-Suit.

107. On information and belief, because comparison to Mylan Institutional's ISB product as the Reference Standard product would be required, the isosulfan blue API used in the HKKF ANDA for ISB is likely to have at least the same purity as the Apicore isosulfan blue API used in Mylan Institutional's ISB product.

108. On information and belief, the HKKF ANDA Product likely has at least the same or similar purity by HPLC as Mylan Institutional's ISB product for HKKF's ANDA Product to have been approved by the FDA.

109. On information and belief, HKKF infringes at least claim 1 of the '580 Patent because the isosulfan blue API used in the HKKF ANDA Product has a purity of at least 99.0% by HPLC.

110. On information and belief, HKKF had knowledge of the '580 Patent at least as early as November 5, 2021.

111. HKKF has had constructive notice of the '580 Patent as of its date of issuance on August 25, 2020.

112. Plaintiffs will be substantially and irreparably damaged and harmed if HKKF's infringement of the '580 Patent is not enjoined by this Court.

113. HKKF's infringement of the '580 Patent will cause Plaintiffs substantial harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment in its favor and against Defendant HKKF as follows as follows:

(a) A judgment that HKKF has infringed or will infringe the '050 Patent under 35 U.S.C. §§ 271(a), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States the HKKF ANDA Product;

(b) A judgment that HKKF has infringed or will infringe the '086 Patent under 35 U.S.C. §§ 271(a), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States the HKKF ANDA Product;

(c) A judgment that HKKF has infringed or will infringe the '580 Patent under 35 U.S.C. §§ 271(a), (c), and/or (g) by making, using, selling, offering to sell within the United States and/or importing into the United States the HKKF ANDA Product;

(d) A judgment that the '050 Patent is valid and enforceable;

(e) A judgment that the '086 Patent is valid and enforceable;

(f) A judgment that the '580 Patent is valid and enforceable;

(g) An order recalling all units of HKKF ANDA Product that were sold or provided to distributors, wholesalers, or other customers in the United States;

(h) An order temporarily restraining HKKF its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting or attempting to act in concert or privity with them, their successors, and assigns, or acting on their behalf, from engaging in the manufacture, use, offer to sell, and selling in the United States, and/or importation into the United States, of HKKF's ANDA Product for at least 14 days or until Plaintiffs' anticipated motion for preliminary injunction is resolved, subject to any extension of the time period to which Plaintiffs may be entitled;

(i) An order preliminarily and/or permanently enjoining HKKF, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting or attempting to act in concert or privity with them, their successors, and assigns, or acting on their behalf, from infringing, contributorily infringing, or inducing others to infringe the Patents-in-Suit, including engaging in the manufacture, use, offer to sell, and selling in the United States, and/or importation into the United States, of HKKF's ANDA Product until the expiration of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity to which Plaintiffs are or may become entitled;

(j) A judgment awarding Plaintiffs damages or other monetary relief under 35 U.S.C. § 281 as appropriate;

(k) A judgment ordering HKKF to pay damages to Plaintiffs to compensate for its infringement of each of the Patents-in-Suit, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with pre-judgment and post-judgment interest on the damages awarded, with all of these damages to be enhanced in an amount up to treble the amount of the calculated compensatory damages as justified under 35 U.S.C. § 284 as appropriate;

(l) A judgment declaring that infringement of the Patents-in-Suit was willful, and awarding treble damages under 35 U.S.C. § 284 as appropriate;

(m) A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

(n) Such further and other relief as this Court may deem just and proper.

Dated: November 9, 2021

By: /s/ Melissa R. Smith
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