IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC and SANOFI MATURE IP,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HONG KONG KING-FRIEND INDUSTRIAL COMPANY LTD.,	)	
Defendants	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC (hereinafter "Sanofi U.S.") and Sanofi Mature IP (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by the above-named defendant to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of cabazitaxel injection, for intravenous infusion, a generic version of Plaintiffs' JEVTANA® KIT (hereinafter "JEVTANA®"), prior to the expiration of U.S. Patent Nos. 10,583,110 ("the '110 patent") and 10,716,777 ("the '777 patent").

THE PARTIES

2. Plaintiff Sanofi U.S. is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Plaintiff Sanofi Mature IP is a company organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

4. Plaintiffs are owned by Sanofi, a global research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve human health.

5. On information and belief, Defendant Hong Kong King-Friend Industrial Company Ltd. ("HKF") is a corporation organized and existing under the laws of Hong Kong, with a place of business at Room 501,5/F.113 Argyle Street, Mongkok, Kowloon, Hong Kong. On information and belief, HKF is in the business of, among other things, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States, including in this Judicial District.

6. On information and belief, HKF assembled and caused to be submitted to the FDA ANDA No. 214506 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA")) (hereinafter "the HKF ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "HKF's Proposed ANDA Product"). The HKF ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

7. By a letter dated October 22, 2020, HKF notified Plaintiffs that, as a part of its ANDA, HKF had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to, *inter alia*, the '110 patent and the '777 patent, both of which are listed in the FDA's Approved Drug Products with Therapeutic

Equivalence Evaluations (the "Orange Book") for JEVTANA®, asserting that the '110 patent and the '777 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of HKF's Proposed ANDA Product.

8. On information and belief, the FDA has made a threshold determination that the HKF ANDA is substantially complete.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over HKF. On information and belief, HKF directly or through its alter ego, affiliates, or agents develops, formulates, manufactures, markets, imports, and sells pharmaceutical products, including generic drug products, throughout the United States, including in Delaware. On information and belief, HKF regularly conducts and solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from services or things used or consumed in the State of Delaware. On information and belief, HKF transacts business within the state of Delaware related to Plaintiffs' claims, and has engaged in systematic, pervasive, and continuous business contacts within the State of Delaware.

11. HKF is also subject to personal jurisdiction in the State of Delaware because, by submitting and maintaining the HKF ANDA with the intent to make, use, offer to sell, and/or sell the drug product that is subject of ANDA No. 201023 in this Judicial District, HKF has committed, aided, abetted, contributed to, and/or participated in the commission of tortious acts of patent infringement under 35 U.S.C. § 271(e)(2) that have led and/or will lead to foreseeable harm and injury to Plaintiff Sanofi U.S., which is a Delaware company.

12. In the alternative, HKF. is subject to jurisdiction throughout the United States, and specifically in the State of Delaware, pursuant to Fed. R. Civ. P. 4(k)(2).

13. On information and belief, upon approval of the HKF ANDA, HKF and/or its subsidiaries, affiliates or agents will market, sell and/or distribute HKF's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

14. On information and belief, upon approval of the HKF ANDA, HKF and/or its subsidiaries, affiliates or agents will place HKF's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

15. Venue is proper in this Judicial District under 28 U.S.C. § 1391.

JEVTANA® AND THE PATENTS-IN-SUIT

16. Sanofi U.S. holds approved NDA No. 201023 for cabazitaxel injection, 60 mg/1.5 mL (40 mg/mL), which is prescribed and sold in the United States under the trademark JEVTANA® KIT. The FDA approved NDA No. 201023 on June 17, 2010. JEVTANA® is approved for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

17. United States Patent No. 10,583,110 (copy attached as Exhibit A) is entitled "Antitumoral Use of Cabazitaxel" and was duly and legally issued by the United States Patent and Trademark Office on March 10, 2020. It is owned by Sanofi Mature IP. The '110 patent is directed to methods for increasing survival of prostate cancer patients with cabazitaxel, including the use of JEVTANA® in accordance with the labeling approved by the FDA.

18. United States Patent No. 10,716,777 (copy attached as Exhibit B) is entitled "Antitumoral Use of Cabazitaxel" and was duly and legally issued by the United States Patent and Trademark Office on July 21, 2020. It is owned by Sanofi Mature IP. The '777 patent is a continuation of the '110 patent and relies on the same provisional patent applications. The '777 patent is directed to methods for increasing survival of prostate cancer patients with cabazitaxel, including the use of JEVTANA® in accordance with the labeling approved by the FDA.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,583,110 BY HKF'S ANDA UNDER 35 U.S.C. § 271(e)

19. Plaintiffs incorporate each of the preceding paragraphs 1–18 as if fully set forth herein.

20. By submitting and maintaining the HKF ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product throughout the United States prior to expiration of the '110 patent, HKF committed an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2).

21. On information and belief, HKF intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product with proposed labeling immediately and imminently upon final approval.

22. On information and belief, the proposed labeling for HKF's Proposed ANDA Product will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '110 patent.

23. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing

treatment regimen." (JEVTANA® label at § 1, copy attached as Exhibit C). The JEVTANA® label describes the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients, and therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '110 patent. (JEVTANA® label at § 14).

24. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 20 mg/m^2 who require dose reduction should receive 15 mg/m^2, and patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 15 mg/m^2, 20 mg/m^2, or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '110 patent.

25. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA® with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist (ranitidine 50 mg or equivalent H_2 antagonist)." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the premedications recited in the '110 patent claims in accordance with the claimed methods of the '110 patent.

26. Thus, on information and belief, the use of HKF's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '110 patent under 35 U.S.C. § 271(a).

27. On information and belief, HKF has actual knowledge of the '110 patent and will actively induce direct infringement of at least one claim of the '110 patent under 35 U.S.C. § 271(b) when the HKF ANDA is approved and HKF's Proposed ANDA Product is marketed, sold, distributed, and/or imported.

28. The foregoing acts by HKF constitute and/or will constitute infringement of the '110 patent and/or active inducement of infringement of the '110 patent under 35 U.S.C. § 271(b).

29. If HKF's infringement of the '110 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,583,110 BY HKF'S PROPOSED ANDA PRODUCT UNDER 35 U.S.C. § 271(b)

30. Plaintiffs incorporate each of the preceding paragraphs 1–29 as if fully set forth herein.

31. On information and belief, HKF intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product with proposed labeling immediately and imminently upon final approval and prior to the expiration of the '110 patent. Therefore, a case or controversy exists between HKF and Plaintiffs as to infringement of the '110 patent.

32. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product would infringe one or more claims of the '110 patent.

33. On information and belief, the proposed labeling for HKF's Proposed ANDA Product will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '110 patent.

34. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1). The JEVTANA® label describes the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients, and therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '110 patent. (JEVTANA® label at § 14).

35. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 20 mg/m^2 who require dose reduction should receive 15 mg/m^2, and patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 15 mg/m^2, 20 mg/m^2, or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '110 patent.

36. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA® with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist (ranitidine 50 mg or equivalent H_2 antagonist)." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the premedications recited in the '110 patent claims in accordance with the claimed methods of the '110 patent.

37. Thus, on information and belief, the use of HKF's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '110 patent under 35 U.S.C. § 271(a).

38. On information and belief, HKF has actual knowledge of the '110 patent and will actively induce direct infringement of at least one claim of the '110 patent under 35 U.S.C. § 271(b) when the HKF ANDA is approved and HKF's Proposed ANDA Product is marketed, sold, distributed, and/or imported.

39. The foregoing acts by HKF constitute and/or will constitute active inducement of infringement of the '110 patent under 35 U.S.C. § 271(b).

40. If HKF's infringement of the '110 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,716,777 BY HKF'S ANDA UNDER 35 U.S.C. § 271(e)

41. Plaintiffs incorporate each of the preceding paragraphs 1–40 as if fully set forth herein.

42. By submitting and maintaining the HKF ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product throughout the United States prior to expiration of the '777 patent, HKF committed an act of infringement of one or more claims of the '777 patent under 35 U.S.C. § 271(e)(2).

43. On information and belief, HKF intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product with proposed labeling immediately and imminently upon final approval.

44. On information and belief, the proposed labeling for HKF's Proposed ANDA Product will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '777 patent.

45. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1). The JEVTANA® label describes the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients, and therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '777 patent. (JEVTANA® label at § 14).

46. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 20 mg/m^2 or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '777 patent.

47. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA® with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or equivalent steroid), H_2 antagonist (ranitidine 50 mg or equivalent H_2 antagonist)." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer

the H_2 antagonist recited in the '777 patent claims in accordance with the claimed methods of the '777 patent.

48. Thus, on information and belief, the use of HKF's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '777 patent under 35 U.S.C. § 271(a).

49. On information and belief, HKF has actual knowledge of the '777 patent and will actively induce direct infringement of at least one claim of the '777 patent under 35 U.S.C. § 271(b) when the HKF ANDA is approved and HKF's Proposed ANDA Product is marketed, sold, distributed, and/or imported.

50. The foregoing acts by HKF constitute and/or will constitute infringement of the '777 patent and/or active inducement of infringement of the '777 patent under 35 U.S.C. § 271(b).

51. If HKF's infringement of the '777 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,716,777 BY HKF'S PROPOSED ANDA PRODUCT UNDER 35 U.S.C. § 271(b)

52. Plaintiffs incorporate each of the preceding paragraphs 1–51 as if fully set forth herein.

53. On information and belief, HKF intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product with proposed labeling immediately and imminently upon final approval and prior to the expiration of the '777 patent. Therefore, a case or controversy exists between HKF and Plaintiffs as to infringement of the '777 patent.

54. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of HKF's Proposed ANDA Product would infringe one or more claims of the '777 patent.

55. On information and belief, the proposed labeling for HKF's Proposed ANDA Product will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '777 patent.

56. The JEVTANA® label states that the indication is "treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen." (JEVTANA® label at § 1). The JEVTANA® label describes the pivotal TROPIC clinical study in which cabazitaxel was shown to prolong overall survival of these patients, and therefore instructs physicians that JEVTANA® increases survival and encourages physicians to administer the drug to those patients for that purpose in accordance with the claimed methods of the '777 patent. (JEVTANA® label at § 14).

57. The recommended dose of cabazitaxel in the JEVTANA® label is 20 mg/m^2 administered as a one-hour intravenous infusion every three weeks. A dose of 25 mg/m^2 "can be used in select patients." Patients at 25 mg/m^2 who require dose reduction should receive 20 mg/m^2. (JEVTANA® label at § 2). The JEVTANA® label therefore instructs and encourages physicians to administer 20 mg/m^2 or 25 mg/m^2 of cabazitaxel in accordance with the claimed methods of the '777 patent.

58. The JEVTANA® label instructs physicians to "[p]remedicate at least 30 minutes prior to each dose of JEVTANA® with the following intravenous medications to reduce the risk and/or severity of hypersensitivity: antihistamine (dexchlorpheniramine 5 mg, or diphenhydramine 25 mg or equivalent antihistamine), corticosteroid (dexamethasone 8 mg or

equivalent steroid), H_2 antagonist (ranitidine 50 mg or equivalent H_2 antagonist)." (JEVTANA® label at § 2.1). The JEVTANA® label therefore instructs and encourages physicians to administer the H_2 antagonist recited in the '777 patent claims in accordance with the claimed methods of the '777 patent.

59. Thus, on information and belief, the use of HKF's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '777 patent under 35 U.S.C. § 271(a).

60. On information and belief, HKF has actual knowledge of the '777 patent and will actively induce direct infringement of at least one claim of the '777 patent under 35 U.S.C. § 271(b) when the HKF ANDA is approved and HKF's Proposed ANDA Product is marketed, sold, distributed, and/or imported.

61. The foregoing acts by HKF constitute and/or will constitute active inducement of infringement of the '777 patent under 35 U.S.C. § 271(b).

62. If HKF's infringement of the '777 patent is not permanently enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that HKF's submission and maintenance of the HKF ANDA constituted an act of infringement of the '110 patent;

B. A judgment (or a declaration) that HKF's making, using, offering to sell, or selling in the United States or importing into the United States of HKF's Proposed ANDA Product will infringe the '110 patent;

C. A permanent injunction restraining and enjoining HKF, its affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity

or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of HKF's Proposed ANDA Product until the expiration of the '110 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '110 patent are or become entitled;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the HKF ANDA shall be a date that is not earlier than the expiration date of the '110 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '110 patent are or become entitled;

E. A judgment that HKF's submission and maintenance of the HKF ANDA constituted an act of infringement of the '777 patent;

F. A judgment (or a declaration) that HKF's making, using, offering to sell, or selling in the United States or importing into the United States of HKF's Proposed ANDA Product will infringe the '777 patent;

G. A permanent injunction restraining and enjoining HKF, its affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of HKF's Proposed ANDA Product until the expiration of the '777 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '777 patent are or become entitled;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the HKF ANDA shall be a date that is not earlier than the expiration date of the '777 patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '777 patent are or become entitled;

I. Damages, including monetary and other relief, to Plaintiffs if HKF engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of HKF's Proposed ANDA Product prior to the expiration date of the '110 patent and/or the '777 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

J. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

K. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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