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. _____
MSN PHARMACEUTICALS, INC. and MSN LABORATORIES PRIVATE 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 defendants 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 No. 10,583,110 ("the '110 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 MSN Pharmaceuticals, Inc. ("MSN Pharmaceuticals") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 343 Thornall Street, Suite 678, Edison, New Jersey 08837.

6. On information and belief, Defendant MSN Laboratories Private Limited ("MSN Labs") is an Indian private limited company, having a place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

7. On information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Labs.

8. MSN Pharmaceuticals and MSN Labs are collectively referred to hereafter as "MSN" unless otherwise noted.

9. On information and belief, MSN Labs itself and through its wholly owned subsidiary MSN Pharmaceuticals 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.

10. On information and belief, MSN assembled and caused to be submitted to the FDA ANDA No. 210685 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA")) (hereinafter "the MSN ANDA") concerning a proposed drug

product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "MSN's Proposed ANDA Product"). The MSN ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

11. By a letter dated May 1, 2020 (the "Notice Letter"), MSN notified Plaintiffs that, as a part of its ANDA, MSN 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 the '110 patent, which was listed in the Orange Book for JEVTANA®, asserting that the '110 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of MSN's Proposed ANDA Product.

12. On information and belief, and consistent with their past practices, MSN Pharmaceuticals and MSN Labs acted collaboratively in the preparation and submission of ANDA No. 210685 and MSN's Proposed ANDA Product, and both intend to directly benefit from and have a financial stake in the approval of the ANDA.

13. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 210685, MSN Pharmaceuticals and MSN Labs will work in concert with one another to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 210685 throughout the United States, and/or import such drug product into the United States, including in this Judicial District.

JURISDICTION AND VENUE

14. 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).

15. This Court has personal jurisdiction over MSN Pharmaceuticals. On information and belief, MSN Pharmaceuticals is a corporation organized and existing under the

laws of the State of Delaware. On information and belief, MSN Pharmaceuticals maintains an agent for service of process at 221 North Broad Street, Suite 3-A, Middletown, DE 19709.

16. On information and belief, MSN Pharmaceuticals 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, MSN Pharmaceuticals 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, MSN Pharmaceuticals 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.

17. On information and belief, MSN Pharmaceuticals has consented to jurisdiction and venue in this District by participating in one or more prior cases arising out of the filing of its ANDAs and has filed counterclaims in such cases. *See, e.g.*, *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc. et al.*, C.A. No. 19-926-CFC (D. Del. May 28, 2019), D.I. 8; *Genentech, Inc. et. al. v. MSN Laboratories Private Limited et. al.*, C.A. No. 19-205-RGA (D. Del. Feb. 22, 2019), D.I. 9; *Boehringer Ingelheim Pharmaceuticals Inc. et al., v. MSN Laboratories Private Ltd. et al.*, C.A. No. 18-1785-CFC-SRF (D. Del. Jan. 11, 2019), D.I. 12; *Biogen International GmbH v. MSN Laboratories Private Ltd. et al.*, C.A. No. 18-337-MN (D. Del. Mar. 26, 2018), D.I. 8.

18. MSN Pharmaceuticals is also subject to personal jurisdiction in the State of Delaware because by submitting and maintaining the MSN ANDA with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 210685 in this

Judicial District, MSN Pharmaceuticals 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.

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

20. On information and belief, upon approval of the MSN ANDA, MSN Pharmaceuticals and/or its subsidiaries, affiliates, or agents will place MSN'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.

21. This Court has personal jurisdiction over MSN Labs. On information and belief, MSN Labs 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, MSN Labs 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, MSN Labs 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.

22. On information and belief, MSN Labs has consented to jurisdiction and venue in this District by participating in in one or more prior cases arising out of the filing of its ANDAs and has filed counterclaims in such cases. *See, e.g.*, *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc. et al*., C.A. No. 19-926-CFC (D. Del. May 28, 2019), D.I. 8; *Genentech, Inc. et. al. v. MSN Laboratories Private Limited et. al.*, C.A. No. 19-205-RGA (D. Del. Feb. 22, 2019). D.I. 9; *Boehringer Ingelheim Pharmaceuticals Inc. et al., v. MSN Laboratories Private Ltd. et al.*, C.A. No. 18-1785-CFC-SRF (D. Del. Jan. 11, 2019), D.I. 12; *Biogen International GmbH v. MSN Laboratories Private Ltd. et al*., C.A. No. 18-337-MN (D. Del. Mar. 26, 2018), D.I. 8.

23. MSN Labs is also subject to personal jurisdiction in the State of Delaware because by submitting and maintaining the MSN ANDA with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 210685 in this Judicial District, MSN Labs 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.

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

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

26. On information and belief, upon approval of the MSN ANDA, MSN Labs and/or its subsidiaries, affiliates, or agents will place MSN'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.

27. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because MSN Pharmaceuticals is, among other things, incorporated in the State of Delaware and therefore "resides" in this Judicial District and/or has committed acts of infringement in this Judicial District and has a regular and established place of business in this Judicial District. MSN Labs is a foreign corporation that may be sued in any Judicial District. 28 U.S.C. § 1391(c)(3). Moreover, MSN has litigated previous disputes in the District of Delaware.

JEVTANA® AND THE PATENT-IN-SUIT

28. 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.

29. United States Patent No. 10,583,110 (copy attached as Exhibit A) is entitled "Novel 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 the survival of patients with prostate cancer with cabazitaxel, including the use of JEVTANA® in accordance with the labeling approved by the FDA.

COUNT I: INFRINGEMENT OF THE PATENT-IN-SUIT UNDER 35 U.S.C. § 271(e)

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

31. By submitting the MSN 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 MSN's Proposed ANDA Product throughout the United States prior to expiration of the '110 patent, MSN committed an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2).

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

33. On information and belief, the proposed labeling for MSN'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, copy attached as Exhibit B). 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 MSN'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. In the Notice Letter, MSN has not contested the infringement of any claim of the '110 patent.

39. On information and belief, MSN 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 MSN's ANDA is approved and MSN's Proposed ANDA Product is marketed, sold, distributed, and/or imported.

40. The foregoing acts by MSN 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).

41. If MSN'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 UNDER 35 U.S.C. § 271(B)

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

43. On information and belief, MSN intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN'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 MSN and Plaintiffs as to infringement of the '110 patent.

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

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

46. 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).

47. 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.

48. 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.

49. Thus, on information and belief, the use of MSN'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).

50. In the Notice Letter, MSN has not contested the infringement of any claim of the '110 patent.

51. On information and belief, MSN 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 MSN ANDA is approved and MSN's Proposed ANDA Product is marketed, sold, distributed, and/or imported.

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

53. If MSN'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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

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

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

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

F. 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

G. 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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