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. 20-804 (RGA)
ACTAVIS LLC, APOTEX CORP., APOTEX INC., BRECKENRIDGE PHARMACEUTICAL, INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., FRESENIUS KABI USA, LLC and SANDOZ INC.,	)	
Defendants.	)	

PLAINTIFFS' FIRST AMENDED 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 Applications ("ANDAs") and the New Drug Applications ("NDAs") filed pursuant to 21 U.S.C. § 355(b)(2) ("B2 NDAs") 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, generic versions 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

A. Plaintiffs

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.

B. Actavis LLC

5. On information and belief, Defendant Actavis LLC ("Actavis") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis 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, Actavis assembled and caused to be submitted to the FDA NDA No. 207970 pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") (hereinafter "the Actavis B2 NDA") concerning a proposed drug product, Cabazitaxel Injection, 10 mg/mL (hereinafter "Actavis's Proposed B2 NDA Product"). The Actavis B2 NDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

7. By letters dated December 22, 2014 and April 23, 2015, Actavis notified Plaintiffs that, as a part of its B2 NDA, it had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), with respect to, *inter alia*, the '170 patent and the '592 patent, both of which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's Proposed B2 NDA Product.

8. Plaintiffs filed suit against Actavis for infringement of the '170 patent and the '592 patent within 45 days of receiving these Notice Letters. *See Sanofi-Aventis US LLC et al. v. Actavis LLC et al.*, C.A. No. 15-cv-776-MAS-LHG (D.N.J.); *Sanofi-Aventis US LLC et al. v. Actavis LLC et al.*, C.A. No. 15-cv-3107-MAS-LHG (D.N.J.).

9. On information and belief, the FDA has granted tentative approval to the Actavis B2 NDA.

10. Actavis committed acts of infringement of the '110 and '777 patents by submitting and maintaining NDA No. 207970 with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of NDA No. 207970 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiffs.

11. This Court has personal jurisdiction over Actavis. On information and belief, Actavis is organized and existing under the laws of the State of Delaware. On information and belief, Actavis maintains an agent for service of process at 3411 Silverside Road Tatnall Building Ste. 104, Wilmington DE 19810.

12. On information and belief, Actavis 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, Actavis 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, Actavis 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.

13. On information and belief, Actavis has consented to jurisdiction and venue in this Judicial District by participating in one or more prior cases arising out of the filing of its ANDAs or B2 NDAs and has filed counterclaims in such cases. *See, e.g.*, *CyDex Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 17-1832-LPS (D. Del. Mar. 22, 2018), D.I. 14; *Astellas Pharma Inc., et al. v. Actavis Elizabeth LLC, Actavis LLC, et al.*, C.A No. 16-905-JFB-CJB (D. Del. Dec. 16, 2016), D.I. 16; *Millennium Pharmaceuticals, Inc. v. Actavis LLC*, C.A. No. 16-223-CFC (D. Del. Apr. 25, 2016), D.I. 7; *Cephalon, Inc. v. Dr. Reddy's Labs., Ltd., Actavis LLC, et al.*, C.A. No. 15-179-GMS (D. Del. Mar. 17, 2015), D.I. 13.

14. Actavis is also subject to personal jurisdiction in the State of Delaware because it 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.

15. On information and belief, upon approval of the Actavis B2 NDA, Actavis and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Actavis's Proposed B2 NDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

16. On information and belief, upon approval of the Actavis B2 NDA, Actavis and/or its subsidiaries, affiliates or agents will place Actavis's Proposed B2 NDA 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.

C. Apotex Inc. and Apotex Corp.

17. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

18. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

19. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

20. On information and belief, Apotex Inc. itself and through its wholly owned subsidiary and agent Apotex Corp. is in the business of developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States, including in this Judicial District.

21. Apotex Inc. and Apotex Corp. are collectively referred to hereafter as "Apotex" unless otherwise noted.

22. On information and belief, Apotex Inc. assembled and caused to be submitted to the FDA ANDA No. 207736 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "the Apotex ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "Apotex's Proposed ANDA Product"). The Apotex ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

23. By letters dated December 4, 2014 and January 28, 2015, Apotex Inc. notified Plaintiffs that, as a part of its ANDA, Apotex Inc. had filed certifications 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 '170 patent and the '592 patent, both of which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Apotex's Proposed ANDA Product.

24. Plaintiffs filed suit against Apotex for infringement of the '170 patent and the '592 patent within 45 days of receiving these Notice Letters. *See Sanofi-Aventis US LLC et al. v. Apotex Corp. et al.*, C.A. No. 15-cv-287-MAS-LHG (D.N.J.); *Sanofi-Aventis US LLC et al. v. Apotex Corp. et al.*, C.A. No. 15-cv-1835-MAS-LHG (D.N.J.).

25. On information and belief, the FDA has granted tentative approval to the Apotex ANDA.

26. On information and belief, and consistent with their past practices, Apotex Inc. and Apotex Corp. acted collaboratively in the preparation and submission of ANDA No. 207736 and Apotex's Proposed ANDA Product, and both intend to directly benefit from and have a financial stake in the approval of the ANDA.

27. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207736, Apotex Inc. and Apotex Corp. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug product that is the subject of NDA No. 207736 throughout the United States, and/or import such drug product into the United States, including in this Judicial District.

28. Apotex committed acts of infringement of the '110 and '777 patents by submitting and maintaining ANDA No. 207736 with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 207736 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiffs.

29. This Court has personal jurisdiction over Apotex Corp. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Apotex Corp. maintains a corporate agent for service of process at 3411 Silverside Road Tatnall Building Ste. 104, Wilmington DE 19810.

30. On information and belief, Apotex Corp. 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, Apotex Corp. 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, Apotex Corp. 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.

31. On information and belief, Apotex Corp. holds an active wholesale pharmacy license for the State of Delaware under License No. A4-0001921. On information and belief, Apotex Corp. also holds an active controlled substance distributor/manufacturer license for the State of Delaware under License No. DM-0008873.

32. On information and belief, Apotex Corp. has consented to jurisdiction and venue in this Judicial 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.*, *Pfizer Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-747-CFC (D. Del. Jul. 8, 2019), D.I. 10; *Vanda Pharm. Inc. v. Apotex Inc. et al.*, C.A. No. 19-685-CFC (D. Del. May 7, 2019), D.I. 9; *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, C.A. No. 19-313-RGA (D. Del. Apr. 19, 2019), D.I. 13; *Genentech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-123-RGA (D. Del. Mar. 14, 2019), D.I. 10; *Genentech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-120-RGA (D. Del. Mar. 14, 2019), D.I. 10; *Genzyme Corp. et al. v. Apotex Corp. et al.*, C.A. No. 18-1795-CFC (D. Del. Jan 18, 2019), D.I. 13; *AstraZeneca AB et al. v. Apotex Inc. et al.*, C.A. No. 18-2010-RGA (D. Del. Jan 2, 2019), D.I. 8.

33. Apotex Corp. is also subject to personal jurisdiction in the State of Delaware because Apotex Corp. 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.

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

35. On information and belief, upon approval of the Apotex ANDA, Apotex Corp. and/or its subsidiaries, affiliates or agents will place Apotex'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.

36. This Court has personal jurisdiction over Apotex Inc. On information and belief, Apotex Inc. 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, Apotex Inc. 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, Apotex Inc. 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.

37. On information and belief, Apotex Inc. has consented to jurisdiction and venue in this Judicial 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.*, *Pfizer Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-747-CFC (D. Del. Jul. 8, 2019), D.I. 10; *Vanda Pharm. Inc. v. Apotex Inc. et al.*, C.A. No. 19-685-CFC (D. Del. May 7, 2019), D.I. 9; *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, C.A. No. 19-313-RGA (D. Del. Apr. 19, 2019), D.I. 13; *Genentech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-123-RGA (D. Del. Mar. 14, 2019). D.I. 10; *Genentech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-120-RGA (D. Del. Mar. 14, 2019), D.I. 10; *Genzyme Corp. et al. v. Apotex Corp. et al.*, C.A. No. 18-1795 (D. Del. Jan 18, 2019), D.I. 13; *AstraZeneca AB et al. v. Apotex Inc. et al.*, C.A. No. 18-2010-RGA (D. Del. Jan 2, 2019), D.I. 8.

38. Apotex Inc. is also subject to personal jurisdiction in the State of Delaware because Apotex Inc. 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.

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

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

41. On information and belief, upon approval of the Apotex ANDA, Apotex Inc. and/or its subsidiaries, affiliates or agents will place Apotex'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.

D. Breckenridge Pharmaceutical, Inc.

42. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. (hereinafter "Breckenridge") is a corporation organized and existing under the laws of Florida, having a principal place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida 33487. On information and belief, Breckenridge 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.

43. On information and belief, Breckenridge assembled and caused to be submitted to the FDA ANDA No. 207619 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "the Breckenridge ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "Breckenridge's Proposed ANDA Product"). The Breckenridge ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

44. By letters dated December 2, 2014 and January 26, 2015, Breckenridge notified Plaintiffs that, as a part of its ANDA, Breckenridge had filed certifications 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 '170 patent and the '592 patent, both of which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Breckenridge's Proposed ANDA Product.

45. Plaintiffs filed suit against Breckenridge for infringement of the '170 patent and the '592 patent within 45 days of receiving these Notice Letters. *See Sanofi-Aventis US LLC et al. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 15-cv-289-MAS-LHG (D.N.J.); *Sanofi-Aventis US LLC et al. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 15-cv-1836-MAS-LHG (D.N.J.).

46. On information and belief, the FDA has granted tentative approval to the Breckenridge ANDA.

47. Breckenridge committed acts of infringement of the '110 and '777 patents by submitting and maintaining ANDA No. 207619 with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 207619 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiffs.

48. This Court has personal jurisdiction over Breckenridge. On information and belief, Breckenridge 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,

Breckenridge 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, Breckenridge 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.

49. On information and belief, Breckenridge maintains an agent for service of process at 1209 Orange Street, Wilmington DE 19801.

50. On information and belief, Breckenridge has consented to jurisdiction and venue in this Judicial 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.*, *Onyx Therapeutics, Inc. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 19-71-LPS (D. Del. Mar. 1, 2019), D.I. 13; *Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc. et al.*, C.A. No. 18-1043-KAJ (D. Del. Aug. 13, 2018), D.I. 85; *Onyx Therapeutics, Inc. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 18-262-LPS (D. Del. Apr. 11, 2018), D.I. 10; *Pfizer Inc., et al. v. Breckenridge Pharmaceutical, Inc. et al.*, C.A. No. 17-1532-LPS (D. Del. Nov. 27, 2017), D.I. 10; *Bayer Intellectual Property GmbH et al. v. Breckenridge Pharmaceutical, Inc.*, C.A. No. 17-1129-TBD (D. Del. Nov. 9, 2017), D.I. 28.

51. Breckenridge is also subject to personal jurisdiction in the State of Delaware because Breckenridge 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.

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

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

E. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Limited

54. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

55. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, India.

56. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd.

57. On information and belief, Dr. Reddy's Laboratories, Ltd., itself and through its wholly owned subsidiary and agent Dr. Reddy's Laboratories, Inc., is in the business of developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States, including in this Judicial District.

58. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. are collectively referred to hereafter as "DRL" unless otherwise noted.

59. On information and belief, Dr. Reddy's Laboratories, Inc. as United States agent for Dr. Reddy's Laboratories, Ltd., assembled and caused to be submitted to the FDA ANDA No. 207718 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "the DRL ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "DRL's Proposed ANDA Product"). The DRL ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

60. By letters dated March 18, 2015 and March 10, 2016, Dr. Reddy's Laboratories, Inc. notified Plaintiffs that, as a part of its ANDA, Dr. Reddy's Laboratories, Inc had filed certifications 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 '170 patent and the '592 patent, both of which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of DRL's Proposed ANDA Product.

61. Plaintiffs filed suit against DRL for infringement of the '170 patent and the '592 patent within 45 days of receiving these Notice Letters. *See Sanofi-Aventis US LLC et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 15-cv-2522-MAS-LHG (D.N.J.); *Sanofi-Aventis US LLC et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 16-cv-2259-MAS-LHG (D.N.J.).

62. On information and belief, and consistent with their past practices, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. acted collaboratively in the

preparation and submission of ANDA No. 207718 and DRL's Proposed ANDA Product, and both intend to directly benefit from and have a financial stake in the approval of the ANDA.

63. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207718, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. 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. 207718 throughout the United States, and/or import such drug product into the United States, including in this Judicial District.

64. DRL committed acts of infringement of the '110 and '777 patents by submitting and maintaining ANDA No. 207718 with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of ANDA No. 207718 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiffs.

65. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. On information and belief, Dr. Reddy's Laboratories, Inc. 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, Dr. Reddy's Laboratories, Inc. 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, Dr. Reddy's Laboratories, Inc. 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.

66. On information and belief, Dr. Reddy's Laboratories, Inc. holds an active wholesale pharmacy license for the State of Delaware under License No. A4-0002524. On information and belief, Dr. Reddy's Laboratories, Inc. also holds an active controlled substance distributor/manufacturer license for the State of Delaware under License No. DM-0013148.

67. On information and belief, Dr. Reddy's Laboratories, Inc. has consented to jurisdiction and venue in this Judicial 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.*, *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd*, C.A. No. 19-2045-CFC (D. Del. Nov. 20, 2019), D.I. 8; *Boehringer Ingelheim Pharmaceuticals Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-1495-CFC (D. Del. Sep. 4, 2019), D.I. 9; *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 18-1839-CFC (D. Del. Jan. 16, 2019), D.I. 13; *Pfizer Inc. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-750-CFC (D. Del. Jul. 15, 2019), D.I. 12; *Onyx Therapeutics, Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 17-1811-LPS (D. Del. Jan. 23, 2018), D.I. 11; *Viiv Healthcare Co., Shionogi & Co., Ltd., and Viiv Healthcare UK (No. 3) Ltd. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 17-1678-MSG (D. Del. Feb. 12, 2018), D.I. 13.

68. Dr. Reddy's Laboratories, Inc. is also subject to personal jurisdiction in the State of Delaware because Dr. Reddy's Laboratories, Inc. 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.

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

70. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Inc. and/or its subsidiaries, affiliates or agents will place DRL'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.

71. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. On information and belief, Dr. Reddy's Laboratories, Ltd. 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, Dr. Reddy's Laboratories, Ltd. 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, Dr. Reddy's Laboratories, Ltd. 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.

72. On information and belief, Dr. Reddy's Laboratories, Ltd. has consented to jurisdiction and venue in this Judicial 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.*, *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd*, C.A. No. 19-2045-

CFC (D. Del. Nov. 20, 2019), D.I. 8; *Boehringer Ingelheim Pharmaceuticals Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-1495-CFC (D. Del. Sep. 4, 2019), D.I. 9; *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 18-1839-CFC (D. Del. Jan. 16, 2019), D.I. 13; *Pfizer Inc. et al. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 19-750-CFC (D. Del. Jul. 15, 2019), D.I. 12; *Onyx Therapeutics, Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 17-1811-LPS (D. Del. Jan. 23, 2018), D.I. 11; *Viiv Healthcare Co., Shionogi & Co., Ltd., and Viiv Healthcare UK (No. 3) Ltd. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, C.A. No. 17-1678-MSG (D. Del. Feb. 12, 2018), D.I. 13.

73. Dr. Reddy's Laboratories, Ltd. is also subject to personal jurisdiction in the State of Delaware because Dr. Reddy's Laboratories, Ltd. 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.

74. In the alternative, Dr. Reddy's Laboratories, Ltd. is subject to jurisdiction throughout the United States, and specifically in the State of Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

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

76. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Ltd. and/or its subsidiaries, affiliates or agents will place DRL'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.

F. Fresenius Kabi USA, LLC

77. On information and belief, Defendant Fresenius Kabi USA, LLC ("Fresenius") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. On information and belief, Fresenius 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.

78. On information and belief, Fresenius assembled and caused to be submitted to the FDA ANDA No. 207591 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "the Fresenius ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "Fresenius's Proposed ANDA Product"). The Fresenius ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

79. By letters dated November 18, 2014 and April 2, 2015, Fresenius notified Plaintiffs that, as a part of its ANDA, Fresenius had filed certifications 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 '170 patent and the '592 patent, both of which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Fresenius's Proposed ANDA Product.

80. On information and belief, Fresenius assembled and caused to be submitted to the FDA NDA No. 207937 pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the

FDCA) (hereinafter "the Fresenius B2 NDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/3 mL, (hereinafter "Fresenius's Proposed B2 NDA Product"). The Fresenius B2 NDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

81. By letters dated November 3, 2014 and April 2, 2015, Fresenius notified Plaintiffs that, as a part of its B2 NDA, Fresenius had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), with respect to, *inter alia*, the '170 patent and the '592 patent, both of which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Fresenius's Proposed ANDA Product.

82. Plaintiffs filed suit against Fresenius for infringement of the '170 patent and the '592 patent within 45 days of receiving these Notice Letters. *See Sanofi-Aventis US LLC et al. v. Fresenius Kabi USA, LLC*, C.A. No. 14-cv-7869-MAS-LHG (D.N.J.); *Sanofi-Aventis US LLC et al. v. Fresenius Kabi USA, LLC*, C.A. No. 14-cv-8082-MAS-LHG (D.N.J.); *Sanofi-Aventis US LLC et al. v. Fresenius Kabi USA, LLC*, C.A. No. 15-cv-2631-MAS-LHG (D.N.J.).

83. On information and belief, the FDA has granted tentative approval to the Fresenius B2 NDA.

84. Fresenius committed acts of infringement of the '110 and '777 patents by submitting and maintaining ANDA No. 207591 and NDA No. 207937 with the intent to make, use, offer to sell, and/or sell the drug products that are the subject of ANDA No. 207591 and NDA No. 207937 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiffs.

85. This Court has personal jurisdiction over Fresenius. On information and belief, Fresenius is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Fresenius maintains an agent for service of process at 251 Little Falls Drive, Wilmington DE 19808.

86. On information and belief, Fresenius 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, Fresenius 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, Fresenius 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.

87. Fresenius has availed itself of the legal protections of the State of Delaware by, among other things, bringing lawsuits in this jurisdiction. *See, e.g.*, *Fresenius Kabi USA, LLC v. Eurohealth Int'l Sarl*, C.A. No. 18-835-LPS (D. Del. Jun. 1, 2018); *Fresenius Kabi USA, LLC v. Sagent Pharm., Inc.*, C.A. No. 17-011-LPS (D. Del. Jan. 4, 2017); *Fresenius Kabi USA, LLC v. B. Braun Med. Inc.*, C.A. No. 16-250-RGA (D. Del. Apr. 11, 2016); *Fresenius Kabi USA, LLC v. Maia Pharm., Inc.*, C.A. No. 16-237-GMS (D. Del. Apr. 7, 2016); *Fresenius Kabi USA, LLC v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 16-169-GMS (D. Del. Mar. 17, 2016).

88. On information and belief, Fresenius has consented to jurisdiction and venue in this Judicial District by participating in one or more prior cases arising out of the filing of its ANDAs or B2 NDAs and has filed counterclaims in such cases. *See, e.g.*, *Millenium*

Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC et al., C.A. No. 19-2252-CFC (D. Del. Feb. 10, 2020), D.I. 8; *Par Pharmaceutical, Inc. et al. v. Fresenius Kabi USA, LLC*, C.A. No. 19-1985-CFC (D. Del. Oct. 29, 2019), D.I. 7; *Spectrum Pharmaceuticals, Inc. et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 18-1533-CFC (D. Del. Nov. 8, 2018), D.I. 14; *Pharmacyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 18-192-CFC (D. Del. Mar. 12, 2018), D.I. 12; *Onyx Therapeutics, Inc. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 16-1012-LPS (D. Del. Jan. 6, 2017), D.I. 19; *Teva Pharm. Int'l GmbH et al. v. Fresenius Kabi USA, LLC*, C.A. No. 17-1201-CFC (D. Del. Sept. 15, 2017), D.I. 10.

89. Fresenius is also subject to personal jurisdiction in the State of Delaware because, among other things, Fresenius 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.

90. On information and belief, upon approval of the Fresenius ANDA and Fresenius B2 NDA, Fresenius and/or its affiliates or agents will market, sell and/or distribute Fresenius's Proposed ANDA Product and Fresenius's Proposed B2 NDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

91. On information and belief, upon the approval of the Fresenius ANDA and Fresenius B2 NDA, Fresenius and/or its affiliates or agents will place Fresenius's Proposed ANDA Product and Fresenius's Proposed B2 NDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this Judicial District.

G. Sandoz Inc.

92. On information and belief, Defendant Sandoz Inc. (hereinafter "Sandoz") is a corporation organized and existing under the laws of Colorado, having a principal place of business at 100 College Road West, Princeton, NJ 08540. On information and belief, Sandoz is a pharmaceutical company 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.

93. On information and belief, Sandoz assembled and caused to be submitted to the FDA NDA No. 208715 pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the FDCA) (hereinafter "the Sandoz B2 NDA") concerning a proposed drug product, Cabazitaxel Injection, 10 mg/mL, 45 mg/4.5 mL, and 60 mg/6 mL (hereinafter "Sandoz's Proposed B2 NDA Product"). The Sandoz B2 NDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

94. By a letter dated August 4, 2016, Sandoz notified Plaintiffs that, as a part of its B2 NDA, Sandoz had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), with respect to, *inter alia*, the '170 patent and the '592 patents, which were listed in the Orange Book for JEVTANA®, asserting that the '170 patent and '592 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Sandoz's Proposed B2 NDA Product.

95. Plaintiffs filed suit against Sandoz for infringement of the '170 patent and the '592 patent within 45 days of receiving this Notice Letter. *See Sanofi-Aventis US LLC et al. v. Sandoz Inc.*, C.A. No. 16-cv-5678-MAS-LHG (D.N.J.).

96. On information and belief, the FDA has granted tentative approval to the Sandoz B2 NDA.

97. Sandoz committed acts of infringement of the '110 and '777 patents by submitting and maintaining NDA No. 208715 with the intent to make, use, offer to sell, and/or sell the drug product that is the subject of NDA No. 208715 in this Judicial District, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Plaintiffs.

98. This Court has personal jurisdiction over Sandoz. On information and belief, Sandoz 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, Sandoz 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, Sandoz 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.

99. On information and belief, Sandoz has consented to jurisdiction and venue in this Judicial District by participating in one or more prior cases arising out of the filing of its ANDAs or B2 NDAs and has filed counterclaims in such cases. *See, e.g.*, *Merck Sharp & Dohme Corp v. Sandoz, Inc.*, C.A. No. 19-312-RGA (D. Del. Apr. 10, 2019), D.I. 10; *Genentech, Inc. et al v. Sandoz, Inc.*, C.A. No. 19-202-RGA (D. Del. May 3, 2019), D.I. 15; *Astellas US LLC et al. v. Sandoz Inc.*, No. 18-1676-CFC (D. Del. Nov. 30, 2018), D.I. 13; *H. Lundbeck A/S et al. v. Sandoz Inc. et al.*, No. 18-177-LPS (D. Del. Apr. 13, 2018), D.I. 9; and *Biogen International GmbH et al. v. Sandoz, Inc.*, C.A. No. 17-874-MN (D. Del. Oct. 16, 2017), D.I. 9.

100. Sandoz is also subject to personal jurisdiction in the State of Delaware because Sandoz 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.

101. On information and belief, upon approval of the Sandoz B2 NDA, Sandoz and/or its subsidiaries, affiliates or agents will market, sell and/or distribute Sandoz's Proposed B2 NDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

102. On information and belief, upon approval of the Sandoz B2 NDA, Sandoz and/or its subsidiaries, affiliates or agents will place Sandoz's Proposed B2 NDA 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.

PRESENT JEVTANA® LITIGATION

103. Plaintiffs filed this suit against Defendants for infringement of the '110 patent on June 12, 2020.

104. Each Defendant has answered Plaintiffs' Complaint.

105. The '777 patent issued on July 21, 2020.

106. Pursuant to 21 C.F.R. § 314.53(d)(3), Plaintiffs timely submitted to the FDA the patent number and expiration date of the '777 patent and identified it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '777 is listed in the Orange Book for JEVTANA®.

PRIOR JEVTANA® LITIGATION WITH DEFENDANTS

107. Plaintiffs filed lawsuits for infringement of one or both of the '170 and the '592 patents against each Defendant within 45 days of receiving their respective Notice Letters.

108. On September 15, 2017, the court consolidated for trial the actions pending against, among other defendants, Fresenius, Apotex, and Actavis in *Sanofi-Aventis US LLC et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 14-cv-7869-MAS-LHG (D.N.J.) ("Consolidated Lead Case").

109. On or before September 15, 2017, the court entered stipulations between Plaintiffs and each of DRL, Breckenridge, and Sandoz, under which the parties to each of these actions agreed, among other things, to be bound by particular aspects of any final judgment in the Consolidated Lead Case. DRL, Breckenridge, and Sandoz agreed to be bound by any judgment as to the infringement and validity of the '170 and '592 patents entered in the Consolidated Lead Case.

110. The court conducted an eight-day bench trial on September 18-20 and September 25-29, 2017 in the Consolidated Lead Case.

111. After trial, the court concluded that: 1) the Defendants infringed claims 1 and 2 of the '170 patent; 2) the Defendants failed to demonstrate the invalidity of those claims of the '170 patent by clear and convincing evidence; 3) the Defendants demonstrated invalidity of the asserted claims of the '592 patent by clear and convincing evidence.

112. The court entered final judgment in favor of Plaintiffs and against each of Actavis, Apotex, Breckenridge, DRL, Fresenius, and Sandoz that the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the cabazitaxel injection products that are the subjects of each such Defendant's ANDA and/or B2 NDA would infringe claims 1 and 2 of the '170 patent. The court ordered that pursuant to

35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Actavis's, Apotex's, Breckenridge's, DRL's, Fresenius's, and Sandoz's ANDA and/or B2 NDA shall be a date not earlier than the expiration of the '170 patent together with the period of Pediatric Exclusivity awarded to Plaintiffs, which is currently September 26, 2021. The court also enjoined those Defendants pursuant to 35 U.S.C. § 271(e)(4)(B) from commercial manufacture, use, sale, offer for sale within the United States or importation into the United States of its respective Proposed ANDA Product and/or Proposed B2 NDA Product until the expiration of the '170 patent, which is currently March 26, 2021.

113. On appeal, the United States Court of Appeals for the Federal Circuit affirmed the district court's judgment of nonobviousness concerning claims 1 and 2 of the '170 patent.

114. On information and belief, each Defendant has made, and continues to make, substantial preparation to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product and/or Proposed B2 NDA Product, upon the expiration of the '170 patent and imminently upon final approval of its ANDA and/or B2 NDA.

JURISDICTION AND VENUE

115. 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). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

116. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, aided, abetted, contributed to, or participated in the commission of a tortious act of patent infringement in submitting and maintaining each ANDA and/or B2 NDA that has led to foreseeable harm and injury to Plaintiffs, one of which is a

Delaware company, and will imminently commit, aid, abet, contribute to, or participate in the commission of a tortious act of patent infringement by selling its Proposed ANDA Product and/or Proposed B2 NDA Product in the United States, including Delaware, which will lead to foreseeable harm and injury to Plaintiffs.

117. This Court also has personal jurisdiction over each Defendant because the affiliations of each with the State of Delaware, including in many instances organization or organization of subsidiaries in Delaware, are so continuous and systematic as to render each Defendant essentially at home in this forum. Those Defendants that are foreign corporations not residing in the United States are subject to jurisdiction throughout the United States, and specifically in the State of Delaware pursuant to Fed. R. Civ. P. 4(k)(2).

118. This Court also has personal jurisdiction over each Defendant because each has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of organization for itself and/or subsidiaries and consenting to jurisdiction by participating in lawsuits and/or asserting counterclaims or filing complaints in lawsuits filed in this Court.

119. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

120. Venue is proper in this Court for each Defendants under 28 U.S.C. §§ 1391 and 1400(b).

JEVTANA® AND THE PATENTS-IN-SUIT

121. 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.

122. 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 related to the '592 patent by a chain of continuation applications and relies on the same provisional patent applications. 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.

123. The claims of the '110 patent are materially different from and patentably distinct from all issued claims of the '592 patent, because, among other things, the claims of the '110 patent require administration of cabazitaxel with the intentional purpose of prolonging survival and administration of a premedication regimen, neither of which was a limitation in any issued claim of the '592 patent.

124. 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.

125. The claims of the '777 patent are materially different and patentably distinct from all issued claims of the '592 patent, because, among other things, the claims of the

'777 patent require administration of cabazitaxel with the intentional purpose of prolonging survival and administration of an H_2 antagonist, neither of which was a limitation in any issued claim of the '592 patent.

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

126. Plaintiffs incorporate each of the preceding paragraphs 1 – 125 as if fully set forth herein.

127. Each Defendant, via its Notice Letter(s) and prior litigation conduct, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product and/or Proposed B2 NDA Product prior to the expiration of the '592 patent, and therefore prior to the expiration of the '110 patent.

128. By submitting and maintaining its ANDA and/or B2 NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product and/or Proposed B2 NDA Product prior to the expiration of the '110 patent, each Defendant committed an act of infringement of one or more of the claims of the '110 patent under 35 U.S.C. § 271(e)(2)(A).

129. On information and belief, each Defendant intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product and/or Proposed B2 NDA Product with proposed labeling immediately and imminently upon final approval of its ANDA and/or B2 NDA.

130. On information and belief, the proposed labeling for each Defendant's Proposed ANDA Product's and/or Proposed B2 NDA Product will be substantially identical to

the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '110 patent.

131. 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).

132. 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.

133. 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.

134. Thus, on information and belief, the use of each Defendant's Proposed ANDA Product and/or Proposed B2 NDA 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).

135. On information and belief, each Defendant will have 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 its ANDA and/or B2 NDA is approved and its Proposed ANDA Product and/or Proposed B2 NDA Product is marketed, sold, distributed, and/or imported.

136. The foregoing acts by each Defendant 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).

137. If each Defendant'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)

138. Plaintiffs incorporate each of the preceding paragraphs 1 – 137 as if fully set forth herein.

139. On information and belief, each Defendant intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product and/or Proposed B2 NDA Product with proposed labeling immediately and imminently upon final approval of its ANDA and/or B2 NDA and prior to the

expiration of the '110 patent. Therefore, a case or controversy exists between each Defendant and Plaintiffs as to infringement of the '110 patent.

140. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of each Defendant's Proposed ANDA Product and/or Proposed B2 NDA Product would infringe one or more claims of the '110 patent.

141. On information and belief, the proposed labeling for each Defendant's Proposed ANDA Product's and/or Proposed B2 NDA Product's will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '110 patent.

142. 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).

143. 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.

144. 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.

145. Thus, on information and belief, the use of each Defendant's Proposed ANDA Product and/or Proposed B2 NDA 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).

146. On information and belief, each Defendant will have 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 its ANDA and/or B2 NDA is approved and its Proposed ANDA Product and/or Proposed B2 NDA Product is marketed, sold, distributed, and/or imported.

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

148. If each Defendant'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 UNDER 35 U.S.C. § 271(e)

149. Plaintiffs incorporate each of the preceding paragraphs 1 – 148 as if fully set forth herein.

150. Each Defendant, via its Notice Letter(s) and prior litigation conduct, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product and/or Proposed B2 NDA Product prior to the expiration of the '592 patent, and therefore prior to the expiration of the '777 patent.

151. By submitting and maintaining its ANDA and/or B2 NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product and/or Proposed B2 NDA Product prior to expiration of the '777 patent, each Defendant has committed an act of infringement of one or more claims of the '777 patent under 35 U.S.C. § 271(e)(2).

152. On information and belief, each Defendant intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product and/or Proposed B2 NDA Product with proposed labeling immediately and imminently upon final approval of its ANDA and/or B2 NDA.

153. On information and belief, the proposed labeling for each Defendant's Proposed ANDA Product and/or Proposed B2 NDA Product will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '777 patent.

154. 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).

155. 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.

156. 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.

157. Thus, on information and belief, the use of each Defendant's Proposed ANDA Product and/or Proposed B2 NDA 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).

158. On information and belief, each Defendant will have 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 its ANDA and/or B2 NDA is approved and its Proposed ANDA Product and/or Proposed B2 NDA Product is marketed, sold, distributed, and/or imported.

159. The foregoing acts by each Defendant 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).

160. If each Defendant'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 UNDER 35 U.S.C. § 271(B)

161. Plaintiffs incorporate each of the preceding paragraphs 1 –160 as if fully set forth herein.

162. On information and belief, each Defendant intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product and/or Proposed B2 NDA Product with proposed labeling immediately and imminently upon final approval of its ANDA and/or B2 NDA and prior to the expiration of the '777 patent. Therefore, a case or controversy exists between each Defendant and Plaintiffs as to infringement of the '777 patent.

163. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of each Defendant's Proposed ANDA Product and/or Proposed B2 NDA Product would infringe one or more claims of the '777 patent.

164. On information and belief, the proposed labeling for each Defendant's Proposed ANDA Product and/or Proposed B2 NDA Product will be substantially identical to the JEVTANA® label, and instructs and encourages physicians to practice the claimed methods of the '777 patent.

165. 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).

166. 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.

167. 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.

168. Thus, on information and belief, the use of each Defendant's Proposed ANDA Product and/or Proposed B2 NDA 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).

169. On information and belief, each Defendants will have 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 its ANDA and/or B2 NDA is approved and its Proposed ANDA Product and/or Proposed B2 NDA Product is marketed, sold, distributed, and/or imported.

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

171. If each Defendant'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 each Defendant's submission and maintenance of its ANDA and/or B2 NDA constituted an act of infringement of the '110 patent;

B. A judgment (or a declaration) that each Defendant's making, using, offering to sell, or selling in the United States or importing into the United States of its respective Proposed ANDA Product and/or Proposed B2 NDA Product will infringe the '110 patent;

C. A permanent injunction restraining and enjoining each Defendant, 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 its respective Proposed ANDA Product and/or Proposed B2 NDA 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 each Defendant's ANDA and/or B2 NDA 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 each Defendant's submission and maintenance of its ANDA and/or B2 NDA constituted an act of infringement of the '777 patent;

F. A judgment (or a declaration) that each Defendant's making, using, offering to sell, or selling in the United States or importing into the United States of its respective Proposed ANDA Product and/or Proposed B2 NDA Product will infringe the '777 patent;

G. A permanent injunction restraining and enjoining each Defendant, 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 its respective Proposed ANDA Product and/or Proposed B2 NDA 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 each Defendant's ANDA and/or B2 NDA 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 any Defendant engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed ANDA Product and/or Proposed B2 NDA 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.

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July 31, 2020

CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 31, 2020, upon the following in the manner indicated:

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