

Liza M. Walsh, Esq.  
CONNELL FOLEY LLP  
85 Livingston Avenue  
Roseland, New Jersey 07068-1765  
(973) 535-0500

Of Counsel:

William E. Solander, Esq.  
Jason A. Leonard, Esq.  
FITZPATRICK, CELLA, HARPER & SCINTO  
1290 Avenue of the Americas  
New York, NY 10104-3800  
(212) 218-2100

*Attorneys for Plaintiffs*  
*SANOFI-AVENTIS U.S. LLC,*  
*AVENTIS PHARMA S.A. and SANOFI*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S. LLC,  
AVENTIS PHARMA S.A. and  
SANOFI

Plaintiffs,

v.

ONCO THERAPIES LIMITED,

Defendant.

C.A. No.: \_\_\_\_\_

**(Filed Electronically)**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Sanofi-Aventis U.S. LLC (hereinafter “Sanofi U.S.”), Aventis Pharma S.A. (hereinafter “Aventis”) and Sanofi (collectively, “Plaintiffs”) for their Complaint against defendant Onco Therapies Limited (hereinafter “Onco” or “Defendant”), hereby allege as follows:

## THE PARTIES

1. Plaintiff Sanofi U.S. is an indirectly wholly owned U.S. subsidiary of Sanofi and 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.

2. Plaintiff Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

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

4. Plaintiff Sanofi is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

5. On information and belief, Onco is a corporation organized and existing under the laws of India, having its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.

6. On information and belief, Onco is a wholly-owned subsidiary of Strides Arcolab Limited (hereinafter "Arcolab"). On information and belief, Arcolab is a corporation organized and existing under the laws of India, having its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.

7. On information and belief, Onco conducts business through and with Agila Specialties Inc. (hereinafter "Agila"), formerly known as Strides, Inc. On information and belief, Agila is a corporation organized and existing under the laws of New Jersey, having its

principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Agila is an agent or affiliate of Onco.

8. On information and belief, Onco conducts business through and with Strides Pharma Inc. (hereinafter “Strides Pharma”). On information and belief, Strides Pharma is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Pharma is a wholly-owned subsidiary of Arcolab. On information and belief, Strides Pharma is an agent or affiliate of Onco.

9. On information and belief, Onco assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application (“ANDA”) No. 207381 (hereinafter “the Onco ANDA”) concerning a proposed drug product, cabazitaxel injection [60 mg/1.5 mL] [40 mg/mL] (“Onco’s Proposed ANDA Product”).

### **JURISDICTION AND VENUE**

10. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Onco. On information and belief, Onco conducts business through and with Agila. On information and belief, Agila is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Agila is registered with the New Jersey Department of Treasury under entity identification number 0100791546. On information and belief, Agila maintains a registered

corporate agent at 37 Veronica Avenue, Somerset, New Jersey 08873. On information and belief, Agila is an agent or affiliate of Onco. On information and belief, Onco conducts business through and with Strides Pharma. On information and belief, Strides Pharma is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Pharma is registered with the New Jersey Department of Treasury under entity identification number 0400580219. On information and belief, Strides Pharma maintains a registered corporate agent at 201 South Main Street, Suite 3, Lambertville, New Jersey 08530. On information and belief, Strides Pharma holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5004572.

12. On information and belief, Onco directly or through its affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District.

13. On information and belief, Onco has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Onco engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey.

14. On information and belief, Onco regularly conducts and/or solicits business, directly, or through its parent company, Arcolab, and/or affiliate or subsidiary companies, Agila, and Strides Pharma, in the State of New Jersey. On information and belief, Onco engages in other persistent courses of conduct, directly, or through its parent company,

Arcolab, and/or affiliate or subsidiary companies, Agila, and Strides Pharma, in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

15. Onco is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Onco has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiff Sanofi U.S., having commercial headquarters in the State of New Jersey. In its May 5, 2015 Paragraph IV Notice Letter, Onco states that it intends to engage in the commercial manufacture, use, and/or sale of Onco's Proposed ANDA Product before the expiration of U.S Patent No. 8,927,592 (the "592 patent," copy attached as Exhibit A) throughout the United States, including in this Judicial District.

16. In the alternative, Onco is subject to jurisdiction in the United States under the principles of general jurisdiction, and specially in the State of New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Onco has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

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

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

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