

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

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.

Defendant.

C.A. No.: _____

Electronically Filed

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 Accord Healthcare, Inc. (hereinafter “Accord” or “Defendant”), hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi U.S. is a 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, defendant Accord is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

6. On information and belief, Accord is a wholly-owned subsidiary of Intas Pharmaceuticals Ltd. (hereinafter “Intas”). On information and belief, Intas is a corporation organized under the laws of India, with its principal place of business at 2nd Floor, Chinubai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

ACCORD ANDA

7. On information and belief, Accord assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), Abbreviated New Drug Application (“ANDA”) No. 207693 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the Federal Food, Drug and

Cosmetic Act) (hereinafter “the Accord ANDA”) concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter “Accord’s Proposed ANDA Product”).

ACCORD B2 NDA

8. On information and belief, Accord assembled and caused to be filed with the FDA, New Drug Application (“NDA”) No. 207949 pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the Federal Food, Drug and Cosmetic Act) (hereinafter “the Accord B2 NDA”) concerning a proposed drug product, Cabazitaxel Injection, 20 mg/mL, 3 mL (hereinafter “Accord’s Proposed B2 Product”).

JURISDICTION AND VENUE

9. 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).

10. This Court has personal jurisdiction over Accord. On information and belief, Accord directly or through its alter ego, 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. On information and belief, Intas as parent company and Accord as trade name are the holders of Registration No. 5003815 active wholesale drug and medical device license with the New Jersey Department of Health, available at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (last visited December 11, 2014).

11. On information and belief, “Accord has been servicing the needs of the US healthcare industry since 2009,” and its “business in the USA . . . currently accounts for more

that [sic] USD 100 million in revenue.” Accord Healthcare, Global Presence – USA site available at <http://www.accord-healthcare.com/global-presence-usa.html> (last visited December 11, 2014). On information and belief, Accord is “the preferred supplier for leading distributors and retail pharma chains” in the United States. Intas, International Operations, USA site available at http://www.intaspharma.com/index.php?option=com_content&view=article&id=56&Itemid=63 (last visited December 11, 2014).

12. On information and belief, Accord has previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Otsuka Pharmaceutical Co., Ltd. v. Intas Pharmaceuticals Ltd. et al.*, Civil Action No. 1:14-cv-06158 (JBS)(KMW), D.I. 38, 3, 7-11 (D.N.J. Dec. 8, 2014); *Otsuka Pharmaceutical Co., Ltd. v. Intas Pharmaceuticals Ltd. et al.*, Civil Action No. 1:14-cv-03996 (JBS)(KMW), D.I. 45, 3, 10-14 (D.N.J. Dec. 8, 2014); *Novartis Pharmaceuticals Corp. et al. v. Wockhardt USA LLC et al.*, Civil Action No: 2:12-cv-03967 (SDW)(SCM), D. I. 89, 5, 9-13 (D.N.J. Jun. 6, 2013); *Merck Sharp & Dohme Corp. v. Accord Healthcare, Inc. et al.*, Civil Action No: 3:12-cv-03324 (PGS)(LHG), D. I. 27, 5, 14-17 (D.N.J. Sep. 24, 2012); *Hoffman-LaRoche Inc. v. Accord Healthcare, Inc. et al.*, Civil Action No: 2:11-cv-03663 (ES)(CLW), D. I. 7, 4, 11-15 (D.N.J. Nov. 28, 2011); *Hoffman-LaRoche Inc. v. Accord Healthcare, Inc. et al.*, Civil Action No: 2:11-cv-01192 (ES)(CLW), D. I. 11, 4-5, 11-14 (D.N.J. May 31, 2011); *AstraZeneca Pharmaceuticals LP et al. v. Accord Healthcare, Inc. et al.*, Civil Action No: 3:09-cv-00619 (JAP)(TJB), D. I. 9, 2, 8-11 (D.N.J. Mar. 20, 2009); and *AstraZeneca Pharmaceuticals LP et al. v. Accord Healthcare, Inc. et al.*, Civil Action No: 3:08-cv-04804 (JAP)(TJB), D. I. 15, 3, 7-11 (D.N.J. Oct. 28, 2008).

13. On information and belief, Accord has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Accord 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, and maintenance of corporate agents in the State of New Jersey.

14. On information and belief, Accord regularly conducts and solicits business in the State of New Jersey, engages in other persistent courses of conduct 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. Accord is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, Accord 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. By letter dated November 24, 2014 (“November 24 ANDA Notice Letter”), Accord notified Plaintiffs that it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“ANDA Paragraph IV Certification”) with respect to U.S Patent No. 5,847,170 (“’170 patent”). By letter dated November 25, 2014 (“November 25 B2 Notice Letter”), Accord notified Plaintiffs that it had filed a certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) (“B2 Paragraph IV Certification”) with respect to the ’170 patent. Accord sent its November 24 ANDA Notice Letter and its November 25 B2 Notice Letter to Sanofi U.S.’s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiffs’s cause of action arose from Accord’s contacts with Sanofi U.S. in Bridgewater, New Jersey. In its November 24 ANDA Notice Letter, Accord states that it intends

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.