UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, *Plaintiff*, v. B. BRAUN MEDICAL INC. *Defendant*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius") brings this action for patent infringement against Defendant B. Braun Medical Inc. (B. Braun").

1. This is an action by Fresenius against B. Braun for infringement of United States Patent No. 8,476,010 ("the '010 patent"). This action arises out of B. Braun's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Diprivan®, an innovative intravenously administered sedative and anesthetic, prior to the expiration of the '010 patent.

THE PARTIES

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi USA, LLC was formerly known as APP Pharmaceuticals, LLC.

3. Upon information and belief, Defendant B. Braun is a Pennsylvania corporation with its principal place of business at 824 Twelfth Avenue, Bethlehem, PA 18018-3524.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

4. This action for patent infringement arises under 35 U.S.C. § 271.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction Over B. Braun

6. Upon information and belief, this Court has personal jurisdiction over B. Braun because B. Braun through its affiliates and/or agents (1) has sought approval from the FDA to market and sell its proposed generic Diprivan® product throughout the United States, including in Delaware; (2) conducts business in this Judicial District; and (3) has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, B. Braun products in this Judicial District, and deriving substantial revenue from such activities. Upon information and belief, B. Braun utilizes the services of its registered agent, Corporation Service Company located at 2711 Centerville Rd., Suite 400, Wilmington, DE 19808, for its sales and marketing in Delaware. Upon information and belief, Corporation Service Company is a corporation organized and existing under the laws of Delaware.

7. Additionally, B. Braun has been sued for patent infringement in this district and did not contest personal jurisdiction. *See Hospira, Inc. v. B. Braun Medical, Inc.*, C.A. No. 13-819; *see also Rydex Techs. LLC v. B. Braun Medical Inc. et al.*, C.A. No. 13-663. B. Braun has also purposefully availed itself of the rights and benefits of this Court by asserting counterclaims

in lawsuits filed in this Court, and proactively filing suit for patent infringement in this district. *See B. Braun Medical Inc. et al. v. Termuro Medical Corp. et al.*, CA No. 09-347.

8. Upon information and belief, B. Braun has agreements with retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware.

9. Upon information and belief, B. Braun has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Diprivan®, for sale and use throughout the United States, including the State of Delaware.

10. Upon information and belief, B. Braun has applied for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including in Delaware.

11. On February 24, 2016, B. Braun sent a letter to Fresenius, a Delaware Limited Liability Company, stating that it had filed ANDA No. 207929 seeking FDA approval to market a generic Diprivan® product prior to the expiration of the '010 patent.

12. Upon information and belief, B. Braun will market, sell, and offer for sale its proposed generic version of Diprivan® in the State of Delaware following FDA approval of that product.

13. Upon information and belief, as a result of B. Braun's marketing, selling, or offering for sale of its generic version of Diprivan® in the State of Delaware, Fresenius will lose sales of Diprivan® and be injured in the State of Delaware.

14. Upon information and belief, B. Braun's systematic and continuous business contacts within Delaware render it at home in Delaware.

15. Upon information and belief, this Court has personal jurisdiction over B. Braun for the reasons stated herein, including, *inter alia,* B. Braun's activities in the forum, activities

directed at the forum, significant contacts with the forum, and consent, all of which render B. Braun at home in the forum. Personal jurisdiction is proper at least under *Acorda Therapeutics Inc. v. Mylan Pharms Inc.*, No. 2015-1456, 2016 WL 1077048 (Fed. Cir. 2016).

Venue

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

BACKGROUND

The Patent-in-Suit: United States Patent No. 8,476,010

17. The '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures," was duly and lawfully issued on July 2, 2013 to inventors Neil P. Desai, Andrew Yang, and Sherry Xiaopei Ci. The named inventors assigned the '010 patent to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC. Accordingly, Fresenius is the owner of all rights, title, and interest in the '010 patent. The '010 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book" ("Orange Book") with respect to Diprivan®. The '010 patent will expire on June 1, 2025. A true and accurate copy of the '010 patent is attached hereto as Exhibit A.

The Diprivan® Drug Product

18. Fresenius currently sells, promotes, distributes, and markets Diprivan® (propofol) injectable emulsion in the United States.

19. Diprivan® is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

20. Fresenius holds an approved New Drug Application ("NDA") No. 19627 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection

with the Diprivan® 1% (propofol) injectable emulsion product containing 10 mg propofol per 1 ml of emulsion.

The B. Braun ANDA

21. B. Braun filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, in 20 mL, 50 mL and 100 mL vials, that B. Braun asserts is a generic copy of Diprivan® ("B. Braun's generic Diprivan® products") prior to the expiration of the '010 patent.

22. The FDA assigned the B. Braun ANDA the number 207929.

23. B. Braun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(II), a certification that U.S. Patent Nos. 5,714,520; 5,731,355; 5,731,356 and 5,908,869 ("the '520, '355, '356, and '869 patents") have expired.

24. B. Braun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '010 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of B. Braun's generic Diprivan® products ("B. Braun's Paragraph IV Certification"). B. Braun notified Fresenius of this certification, in a letter dated February 24, 2016 sent by U.S. Mail ("B. Braun Notice Letter").

25. In the B. Braun Notice Letter, B. Braun offered Fresenius confidential access to ANDA No. 207929 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The initial OCA provided by B. Braun contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order. Fresenius and B. Braun proceeded to negotiate the provisions of the OCA, and

DOCKET ALARM

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.