Stephen M. Orlofsky
David C. Kistler
New Jersey Resident Partners
BLANK ROME LLP
301 Carnegie Center, 3d Floor
Princeton, NJ 08540
Telephone: (609) 750-7700

OF COUNSEL:
Douglas Carsten
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
Suite 200
San Diego, CA 92130

William C. Jackson
BOIES, SCHILLER & FLEXNER LLP
5301 Wisconsin Ave, NW
Washington, DC 20015

Attorneys for Plaintiff
United Therapeutics Corporation

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

UNITED THERAPEUTICS CORPORATION	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.:
	)	
SANDOZ, INC.,	)	
	)	
Defendant.	)	

COMPLAINT AND JURY DEMAND

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Defendant Sandoz, Inc. ("Sandoz"), alleges 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, Sections 100 *et seq.*, involving United States Patent 8,497,393 ("the '393 patent") (attached as Exhibit A hereto).

2. This action arises out of Sandoz's submission of Abbreviated New Drug Application ("ANDA") No. 203649 to the United States Food and Drug Administration (the "FDA") seeking approval, prior to the expiration of the '393 patent, to manufacture, market, and sell a generic copy of UTC's REMODULIN® (Treprostinil Sodium) Injection product which is approved by the FDA for treatment of pulmonary arterial hypertension.

THE PARTIES

3. UTC is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotech company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions.

4. Upon information and belief, Sandoz is a corporation organized and existing under the laws of the State of Colorado and has its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

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

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

7. Upon information and belief, this Court has personal jurisdiction over Sandoz with respect to this Complaint because, *inter alia*, of its continuous and systematic contacts with

this judicial district where it maintains its principal place of business. Upon information and belief, Sandoz derives substantial revenue from articles used and consumed in this judicial district and, consistent with its practice with respect to other generic products, following any FDA approval of Sandoz's ANDA, Sandoz will sell its generic product throughout the United States, including in New Jersey. In addition, Sandoz has previously availed itself of this Court as a forum in which to bring patent litigation against others. *See, e.g., Sandoz v. Eli Lilly and Co.*, Civil Action No. 2:07-cv-04100-DMC-MF (D.N.J.).

8. In addition, the acts giving rise to this action are centered in New Jersey and Sandoz has consented to the jurisdiction and venue of New Jersey. By letter dated July 23, 2014, Sandoz "of 506 Carnegie Center, Suite 400, Princeton, NJ 08540," gave notice of the acts giving rise to this action. The letter identified the relevant contact for "any inquiries concerning or for any service of process or legal information" as the Head of U.S. Patent Litigation of Sandoz Inc. located in Sandoz's Princeton, NJ offices. Sandoz's accompanying Offer of Confidential Access Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) requested that UTC agree that any claims for breach of that agreement granting confidential access "may be brought in courts located in the State of New Jersey and consent to the jurisdiction and venue of such courts for any such claims." Thus, Sandoz is availing itself of New Jersey in connection with its ANDA, making jurisdiction and venue proper in New Jersey.

9. Additionally, another matter involving Sandoz's ANDA No. 203649 and certain patents assigned to UTC (specifically, United States Patent Nos. 5,153,222 ("the '222 patent"), 6,765,117 ("the '117 patent"), and 7,999,007 ("the '007 patent")) is being litigated in this Court. Trial in that matter concluded in June of this year. On August 29, 2014, the Court entered an

opinion holding that Sandoz had not proved invalidity of either the '117 or '007 patent and that Sandoz infringed the '117 patent, but not the '007 patent.

BACKGROUND

10. UTC holds an approved New Drug Application (No. 21-272) for Treprostinil Sodium Injection, which UTC markets and sells under the registered trademark REMODULIN®.

11. REMODULIN® is a pharmaceutical product initially approved in the United States in May 2002, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and resulting in high pressure in the pulmonary arteries and decreased blood flow from the heart to the lungs, thereby depriving the body of oxygen.

12. REMODULIN® is an injectable product approved for sale in 1 mg/mL, 2.5 mg/mL, 5 mg/mL, and 10 mg/mL concentrations.

13. The '393 patent, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®," was duly and legally issued by the United States Patent and Trademark Office on July 30, 2014, and is scheduled to expire December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

14. UTC is the lawful owner of the '393 patent by assignment of all right, title, and interest in and to the '393 patent, including the right to bring infringement suits thereon.

15. REMODULIN® and its manufacture are covered by one or more claims of the '393 patent, which has been listed in connection with REMODULIN® in the FDA's *Approved Drug Products with Therapeutic Equivalents* publication (also known as the "Orange Book").

ACTS GIVING RISE TO THIS ACTION

16. Sandoz notified UTC in a letter dated February 2, 2012 ("Sandoz's First Notice Letter"), that it had filed ANDA No. 203649 with the FDA, seeking approval to commercially manufacture, market, use and sell a generic copy of REMODULIN® (Treprostinil Sodium) Injection, 200 mg/20 mL (10 mg/mL), prior to the expiration of the '222 patent, the '117 patent, and the '007 patent.

17. Sandoz notified UTC in a letter dated December 7, 2012 ("Sandoz's Second Notice Letter"), that it had amended it previously-filed ANDA No. 203649 to seek FDA approval to commercially manufacture, market, use and sell generic copies of REMODULIN® (Treprostinil Sodium) Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), and 100 mg/20 mL (5 mg/mL) (collectively, together with the 200 mg/20 mL (10 mg/mL) dosage strength covered by Sandoz's First Notice Letter, "Sandoz's ANDA Products"), prior to the expiration of the '222 patent, the '117 patent, and the '007 patent.

18. Sandoz notified UTC in a letter dated July 23, 2014 ("Sandoz's Third Notice Letter") that it had again amended ANDA No. 203649, now seeking approval to commercially manufacture, market, use and sell generic copies of REMODULIN® (Treprostinil Sodium) Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200mg/20mL (10mg/mL) ("Sandoz's ANDA Products") prior to the expiration of the '393 patent.

19. Upon information and belief, Sandoz amended ANDA No. 203649 with the FDA seeking approval to commercially manufacture, market, use and sell generic copies of REMODULIN® (Treprostinil Sodium) Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200mg/20mL (10mg/mL) prior to the expiration of the '393 patent.

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.