Liza M. Walsh
Tricia B. O'Reilly
Joseph L. Linares
CONNELL FOLEY LLP
One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, NJ 07102
(973) 757-1100

Of Counsel:
Michael K. Nutter (*pro hac vice* pending)
Kurt A. Mathas (*pro hac vice* pending)
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601-9703
(312) 558-5600

Attorneys for Defendant Watson Laboratories, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. WATSON LABORATORIES, INC., Defendant.	Honorable Peter G. Sheridan Civil Action No: 15-cv-5723 **WATSON LABORATORIES, INC.'S ANSWER AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Watson Laboratories, Inc. ("Watson"), by and through the undersigned attorneys, answers the Complaint of United Therapeutics Corporation ("UTC" or "Plaintiff") as

follows.[1] This pleading is based upon Watson's knowledge as to its own activities, and upon information and belief as to the activities of others.

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 Nos. 6,521,212 ("the '212 patent") (attached as Exhibit A hereto), 6,756,033 ("the '033 patent") (attached as Exhibit B hereto), and 8,497,393 (the '393 patent") (attached as Exhibit C hereto).

ANSWER: Watson admits that the Complaint purports to bring an action for infringement of the '212, '033 and '393 patents and that the action purports to arise under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*. Watson denies that the '212, '033 and '393 patents were legally or properly issued. Watson otherwise denies the remaining allegations of paragraph 1.

2. This action arises out of Watson's submission of Abbreviated New Drug Application ("ANDA") No. 208172 to the United States Food and Drug Administration (the "FDA") seeking approval, prior to the expiration of the '212, '393, and '033 patents, to manufacture, market, and sell a generic copy of UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml that is approved by the FDA for treatment of pulmonary arterial hypertension.

ANSWER: Watson admits that this action purports to relate to Watson's ANDA No. 208172, which seeks to obtain approval for the commercial manufacture, use or sale of a treprostinil inhalation solution, 0.6 mg/ml before the dates of expiration of the '212, '033 and '393 patents. Watson further admits that TYVASO® is indicated for treatment of pulmonary arterial hypertension. Watson otherwise denies the remaining allegations of paragraph 2.

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.

[1] Contemporaneously herewith Watson is filing a motion to dismiss as to Counts 2, 4 and 6. Pursuant to Local Civ. R. 12.2, Watson is not required to respond to Counts 2, 4 and 6, if at all, until 14 days after the Court's ruling on its motion to dismiss.

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.

ANSWER: Watson admits, on information and belief, that 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. Watson otherwise denies the remaining allegations of paragraph 3.

4. Upon information and belief, Watson is a corporation organized and existing under the laws of the State of California and has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

ANSWER: Watson admits that it is a corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 06054. Watson denies that it is a corporation organized under the laws of the State of California.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Watson does not contest subject matter jurisdiction over Plaintiff's infringement claims against Watson under 35 U.S.C. § 271(e)(2)(A) (Counts 1, 3 and 5) for purposes of this action only. Watson denies that the Court has subject matter jurisdiction over Plaintiff's infringement claims against Watson under 35 U.S.C. § 271(a), (b), (c), or (g) (Counts 2, 4 and 6). Watson further admits that the action purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Watson otherwise denies the remaining allegations of paragraph 5.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Watson does not contest that venue is proper in this judicial district for the purposes of this case.

7. Upon information and belief, this Court has personal jurisdiction over Watson with respect to this Complaint because of, inter alia, its continuous and systematic contacts with this judicial district. The notice letter was sent from Watson at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, NJ 07054. Upon information and belief, Watson 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 Watson's ANDA, Watson will sell its generic product throughout the United States, including in New Jersey. Upon information and belief, Watson is registered to conduct business in the State of New Jersey and employs people throughout New Jersey, including at least the following locations: Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054; 100 Enterprise Drive, Rockaway, New Jersey 07866; and 350 Mt. Kemble Avenue, Morristown, New Jersey 07960. In addition, Watson has previously availed itself of this Court as a forum in which to bring patent litigation against others.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Watson states that it will not contest personal jurisdiction for purposes of this case. Watson further admits that it has a place of business in Parsippany, New Jersey. Watson otherwise denies the remaining allegations of paragraph 7.

BACKGROUND

8. UTC holds an approved New Drug Application (No. 22-387) for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml, which UTC markets and sells under the registered trademark TYVASO®.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Watson admits, on information and belief, that UTC is the holder of approved New Drug Application No. 22-387 directed to TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml, which is sold under the trade name TYVASO®. Watson otherwise denies the remaining allegations of paragraph 8.

9. TYVASO® is a pharmaceutical product initially approved by FDA in the United States in July 2009, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and results

in high pressure in the pulmonary arteries, which increases strain on the right ventricle of the heart, thereby leading to heart failure and death.

ANSWER: Watson admits that TYVASO® was approved by the FDA in the United States in July 2009 and is indicated for the treatment of pulmonary arterial hypertension. Watson otherwise denies the remaining allegations of paragraph 9.

10. TYVASO® is an inhalable product approved for sale in a 0.6 mg/mL concentration.

ANSWER: Watson admits TYVASO® is indicated for oral inhalation only and is approved for sale in a 0.6 mg/mL concentration. Watson otherwise denies the remaining allegations of paragraph 10.

11. The ’212 patent, entitled “Method for treating peripheral vascular disease by administering benzindene prostaglandins by inhalation” was duly and legally issued by the United States Patent and Trademark Office on February 18, 2003, and is scheduled to expire on November 13, 2018. The named inventors are Gilles Cloutier, James Crow, Michael Wade, Richard E. Parker, and James E. Loyd.

ANSWER: Watson admits that, on its face, the ’212 patent is entitled “Method for treating peripheral vascular disease by administering benzindene prostaglandins by inhalation,” bears a issuance date of February 18, 2003, and is scheduled to expire on November 13, 2018. Watson further admits that, on its face, the named inventors of the ’212 patent are listed as Gilles Cloutier, James Crow, Michael Wade, Richard E. Parker, and James E. Loyd. Watson denies that the ’212 patent was legally or properly issued.

12. UTC is the lawful owner of the ’212 patent by assignment of all right, title and interest in and to the ’212 patent, including the right to bring infringement suits thereon.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Watson admits that, per the face of the patent, UTC is identified as the assignee of the ’212 patent. Watson otherwise denies the remaining allegations of paragraph 12.

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.