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United Therapeutics Corporation

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

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

COMPLAINT AND JURY DEMAND

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Watson Laboratories, Inc. ("Watson"), 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 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).

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.

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, 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.

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 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.

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®.

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.

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

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.

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.

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. The '033 patent, entitled "Method for delivering benzindene prostaglandins by inhalation," was duly and legally issued by the United States Patent and Trademark Office on June 29, 2004, 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.

16. UTC is the lawful owner of the '033 patent by assignment of all right, title and interest in and to the '033 patent, including the right to bring infringement suits thereon.

17. TYVASO® and its FDA approved manufacture and uses are covered by one or more claims of the '212 patent, the '033 patent, and the '393 patent, which have been listed in

connection with TYVASO® in the FDA's *Approved Drug Products with Therapeutic Equivalents* publication (also known as the "Orange Book").

ACTS GIVING RISE TO THIS ACTION

18. Watson notified UTC by letter dated June 12, 2015, which was delivered to UTC on or about, Saturday, June 13, 2015 ("Watson's Notice Letter"), that it had filed ANDA No. 208172 with the FDA seeking approval to commercially manufacture, market, use, and sell generic copies of TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/mL ("Watson's ANDA Product") prior to the expiration of the '212,'033, and '393 patents.

19. Watson's Notice Letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to recite Watson's "factual and legal basis" for its opinion that the '212, '033, and '393 patents are not valid, are unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Product. Yet that statement did not include any explanation as to why claims 1-5 and 9-12 of the '212 patent, claims 4 and 6-10 of the '033 patent, and any claim of the '393 patent were invalid. The statement also did not include anything beyond conclusory statements as to why claims 6-8 of the '212 patent and claims 1-3 and 5 of the '033 patent were invalid. The statement also did not include anything beyond conclusory statements regarding alleged non-infringement. Watson provided no explanation as to the alleged unenforceability.

20. Upon information and belief, Watson submitted ANDA No. 208172 with the FDA seeking approval to commercially manufacture, market, use, and sell generic copies of TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/mL ("Watson's ANDA Product") prior to the expiration of the '212, '033, and '393 patents.

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