William J. O'Shaughnessy
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

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 Avenue, 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.: 3:15-cv-05723
	)	(PGS-LHG)
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	
	)	

PLAINTIFF UNITED THERAPEUTICS' MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR LEAVE TO AMEND ITS COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **Page(s)**

OTHER AUTHORITIES

INTRODUCTION

Plaintiff United Therapeutics Corporation ("UTC") respectfully submits this Memorandum of Law in Support of Its Motion for Leave to Amend Its Complaint pursuant to Paragraph 19 of the Scheduling Order and Federal Rule of Civil Procedure 15(a). Paragraph 19 of the Court's Scheduling Order provides that "[a]ny party may file a motion to amend pleadings or add parties by August 26, 2016." [D.E. 35]. UTC's proposed First Amended Complaint is annexed to the Declaration of William J. O'Shaughnessy as Exhibit A. Defendant Watson Laboratories, Inc. ("Watson") does not oppose this motion.

STATEMENT OF FACTS

UTC commenced this action for patent infringement against Watson on July 22, 2015. [D.E. 1]. In its Complaint, UTC claimed that Watson's submission of Abbreviated New Drug Application ("ANDA") No. 208172 infringed United States Patent Nos. 6,521,212 ("the '212 patent"), 6,756,033 ("the '033 patent"), and 8,497,393 ("the '393 patent") (collectively, the "original patents-in-suit"). The claims in the original patents-in-suit cover UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml and delivery system, an FDA-approved treatment for pulmonary arterial hypertension. Watson's ANDA seeks approval to market a generic copy of the TYVASO® product (the "ANDA Product") before the expiration of the original patents-in-suit. Watson filed its Answer on September 1, 2015, denying that its manufacturing, marketing, and sales of its ANDA Product would infringe UTC's patents and asserting a counterclaim for a declaratory judgment of invalidity and/or noninfringement of the original patents in-suit. [D.E. 10].

After the litigation commenced, UTC learned that the United States Patent and Trademark Office ("USPTO") granted two additional patents that cover UTC's TYVASO®

product and thereby implicate Watson's ANDA Product. Specifically, UTC learned on May 17, 2016 that the USPTO issued U.S. Patent No. 9,339,507 ("the '507 patent") and that subsequently the FDA listed the '507 patent in the FDA's Approved Drug Products with Therapeutic Equivalents publication (also known as the "Orange Book"). Thereafter, UTC learned on June 7, 2016 that the USPTO had issued an additional patent, U.S. Patent No. 9,358,240 ("the '240 patent"), and that subsequently the FDA listed the '240 patent in the Orange Book.[1] Similar to the original patents-in-suit, Watson's submission of ANDA No. 208172 is an act of infringement with respect to UTC's '507 patent and '240 patent.

LEGAL ARGUMENT

When reviewing a motion to amend a party's pleading, "[t]he Court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a); *see also* Fed. R. Civ. P. 7(a) (defining "pleading" to include a complaint). Leave to amend is granted liberally. *Heyl & Patterson Int'l, Inc. v. F. D. Rich Hous. of V. I., Inc.*, 663 F.2d 419, 425 (3d Cir. 1981); *see also Muha v. Rutgers*, No. 08-2142 (FLW), 2009 WL 689738, at *2 (D.N.J. Mar. 11, 2009) ("Courts have a liberal tendency in granting leave to amend . . .") (citing *United States v. Hougham*, 364 U.S. 310, 317 (1960)). A court's discretion to deny leave to amend is limited. *See Heyl & Patterson*, 663 F.2d at 425; *see also Adams v. Gould Inc.*, 739 F.2d 858, 864 (3d Cir. 1984) ("This liberal amendment philosophy [of the federal rules] limits the district court's discretion to deny leave to amend."). Undue prejudice to the non-moving party is "the touchstone for the denial of leave to amend." *Heyl & Patterson,* 663 F.2d at 425 (quoting *Cornell & Co. v. Occupational Safety & Health Review Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978)). "To establish prejudice, the non-moving party must make a showing that allowing the amended pleading would (1) require the

[1]http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022387&Product_No=001&table1=OB_Rx.

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.