

Petition for *Inter Partes* Review of  
U.S. Patent No. 9,593,066 B2

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

LIQUIDIA TECHNOLOGIES, INC.,

Petitioner

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner

U.S. Patent No. 9,593,066

Issue Date: March 14, 2017

Title: Process to Prepare Treprostinil, the Active Ingredient in Remodulin®

---

**DECLARATION OF JEFFREY D. WINKLER, PH.D.  
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW  
OF U.S. Patent No. 9,593,066**

## Table of Contents

I.	INTRODUCTION .....	1
II.	QUALIFICATIONS .....	2
III.	MATERIALS CONSIDERED .....	3
IV.	PERSONS OF ORDINARY SKILL IN THE ART .....	4
V.	UNDERSTANDING OF LEGAL CONCEPTS.....	5
	A. Anticipation .....	5
	B. Obviousness.....	6
	C. Product-By-Process Claims.....	6
VI.	OVERVIEW OF THE '066 PATENT.....	7
VII.	CLAIM INTERPRETATION.....	13
VIII.	THE '066 PATENT IS INVALID.....	13
	A. Summary.....	13
	B. The Synthesis of Treprostinil Was Well-Known .....	14
	C. Formation of a Carboxylate Salt from a Carboxylic Acid and the Addition of an Acid to a Carboxylate Salt to Regenerate the Carboxylic Acid is Standard Chemical Purification Known in the Art .....	17
	D. The Claimed Treprostinil and Treprostinil Diethanolamine Salt Disclosed in the '066 Patent is Not Distinct from the Prior Art.....	20
IX.	PHARES RENDERS OBVIOUS CLAIMS 1-7 OF THE '066 PATENT .....	21
	A. Overview of Phares .....	21
	B. Independent Claim 1.....	25
	1. Phares discloses claim element 1[a].....	25

## Table of Contents

2. Phares discloses claim element 1[b].....	28
3. Phares discloses claim element 1[c].....	31
4. Phares discloses claim element 1[d].....	31
5. Phares renders obvious claim element 1[e].....	32
6. Phares discloses claim element 1[f].....	33
7. Phares discloses claim element 1[g].....	35
C. Dependent Claim 2.....	37
D. Dependent Claims 3 and 4.....	37
E. Dependent Claim 5.....	38
F. Dependent Claim 6.....	39
G. Dependent Claim 7.....	40
X. PHARES ANTICIPATES CLAIMS 8-10 OF THE '066 PATENT.....	41
A. Independent Claim 8.....	41
1. Phares discloses claim elements 8[a] and 8[b].....	41
2. Phares discloses claim element 8[c].....	42
3. Phares discloses claim elements 8[d] and 8[e].....	43
4. Phares discloses claim element 8[f].....	45
5. Phares discloses claim element 8[g].....	45
B. Dependent Claim 9.....	46
C. Dependent Claim 10.....	46
XI. MORIARTY IN COMBINATION WITH PHARES RENDERS OBVIOUS CLAIMS 1-10 OF THE '066 PATENT.....	47
A. Overview of Moriarty.....	47
B. Motivation to Combine Moriarty with Phares.....	49
C. Independent Claim 1.....	50

## Table of Contents

1. Moriarty in combination with Phares teaches claim element 1[a].....	50
2. Moriarty in combination with Phares teaches claim element 1[b].....	54
3. Moriarty in combination with Phares teaches claim element 1[c].....	55
4. Phares teaches claim element 1[d] .....	56
5. Phares teaches claim element 1[e].....	57
6. Moriarty in combination with Phares teaches claim element 1[f].....	58
7. Moriarty in combination with Phares teach claim element 1[g].....	60
D. Dependent Claim 2 .....	62
E. Dependent Claims 3, 4 and 5.....	63
F. Dependent Claim 6 .....	64
G. Dependent Claim 7 .....	65
H. Independent Claim 8.....	67
1. Moriarty in combination with Phares teach claim elements 8[a]-8[c] .....	67
2. Phares teach claim elements 8[d]-[f].....	70
3. Moriarty in combination with Phares teaches claim element 8[g].....	70
I. Dependent Claim 9 .....	71
J. Dependent Claim 10 .....	71
XII. NO SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS .....	72
XIII. CONCLUSION.....	72

I, Jeffrey D. Winkler, hereby declare and state as follows:

## **I. INTRODUCTION**

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained by counsel for the Petitioner to offer technical opinions with respect to U.S. Patent No. 9,593,066 (“the ’066 patent”) and prior art references cited in *inter partes* review proceedings for the ’066 patent.

3. I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$850 per hour. My compensation is not dependent on the outcome of, or the content of my testimony in, the present IPR.

4. I have reviewed the ’066 patent and, in assessing it, I have considered the teachings of the scientific literature before December 17, 2007, in light of general knowledge in the art before that date.

5. This declaration presents my opinion that Claims 1-10 of the ’066 patent would have been anticipated and/or obvious to a person of ordinary skill in the art before December 17, 2007. The technology of the ’066 patent involves nothing more than basic organic chemistry techniques – in my view, “organic chemistry 101” – all of which were well-known in the art prior to December 17, 2007.

# 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.