

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

LIQUIDIA TECHNOLOGIES, INC.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner.

---

Case IPR2020-00770

Patent 9,604,901

---

Patent Owner Preliminary Response Under  
35 U.S.C. § 313 and 37 C.F.R. § 42.107

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	THE '901 PATENT .....	2
III.	CLAIM CONSTRUCTION .....	6
	A. Pharmaceutical Batch .....	8
	B. “Pharmaceutical Product” .....	9
	C. Storing, Storage .....	10
	D. A salt treprostinil .....	11
IV.	THE BOARD SHOULD DENY INSTITUTION UNDER § 325(D) .....	12
	A. The Advanced Bionics Two-Part Framework.....	13
	B. Liquidia Relies on the Same Art (Becton Factors (a) & (b)) .....	14
	C. Liquidia Relies on the Same Arguments (Becton Factor (d)).....	21
	D. Liquidia Fails to Prove the Examiner Erred in A Manner Material to The Patentability of Challenged Claims.....	23
	1. Factor (c) – the examiner thoroughly evaluated the same art and substantially the same arguments in a variety of permutations.....	24
	2. Factors (e) & (f) – Liquidia has failed to show an error warranting reconsideration.....	25
V.	LIQUIDIA’S ARGUMENTS ARE NOT SUPPORTED BY RELIABLE EVIDENCE .....	29
VI.	LIQUIDIA’S “THREE STRONG BASES FOR INVALIDATION” ARE FACTUALLY IRRELEVANT OR INCOMPLETE .....	30
	A. A Known Synthesis of Treprostinil Is Not the Issue .....	31
	B. Liquidia Assumes the Inherency It Must Prove.....	31
	C. The Board’s Findings In the '393 IPR Do Not Render the '901 Claims Obvious .....	33
VII.	THE GROUNDS SHOULD BE DENIED ON THE MERITS .....	34
	A. Scope and Content of the Prior Art .....	34

1.	Liquidia Focuses on the Wrong Problem .....	34
2.	Liquidia’s Positions Lack Basis.....	37
3.	The ’393 Patent and the ’901 Patent Are Not Directed to the Same Invention .....	43
4.	Phares and Moriarty are Directed to Different Problems .....	50
5.	The Prior Art Does Not Teach Stability .....	51
B.	Liquidia Misidentifies the Person of Ordinary Skill.....	55
C.	Liquidia Ignores the Differences Between the Claimed Invention and Phares .....	57
1.	Ground 1: Phares Alone Did Not Render Claims 1-9 Obvious .....	57
2.	Ground 2: Moriarty and Phares Did Not Render Claims 1-9 Obvious .....	61
VIII.	LIQUIDIA IGNORES OBJECTIVE INDICIA OF OBVIOUSNESS .....	69
IX.	CONCLUSION.....	72

## TABLE OF AUTHORITIES

### Cases

<i>American Hoist &amp; Derrick Co. v. Sowa &amp; Sons</i> , 725 F.2d 1350, 1359 (Fed. Cir. 1984) .....	17, 30
<i>Biotec Biologische Naturverpackungen v. Biocorp., Inc.</i> , 249 F.3d 1341, 1353 (Fed. Cir. 2001).....	67
<i>Graham v. John Deere Co.</i> , 383 U.S. 1, 17 (1966) .....	45, 59
<i>In re Cyclobenzaprine Hydrochloride</i> , 676 F.3d 1063 (Fed. Cir. 2012).....	72
<i>In re Huston</i> , 308 F.3d 1267, 1279 (Fed. Cir. 2002) .....	23
<i>In re Soni</i> , 54 F.3d 746, 750 (Fed. Cir. 1995).....	72, 73, 74
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398, 406 (2007).....	68
<i>Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.</i> , 558 F.3d 1341, 1350 (Fed. Cir. 2009) .....	28
<i>Motionless Keyboard Co. v. Microsoft Corp.</i> , 486 F.3d 1376, 1385 (Fed. Cir. 2007) .....	36
<i>Panduit Corp. v. Dennison Mfg. Co.</i> , 810 F.2d 1561, 1577-78 (Fed. Cir. 1987)....	69
<i>Par Pharm., Inc. v. Twi Pharms., Inc.</i> , 773 F.3d 1186, 1195 (Fed. Cir. 2014).....	34, 40, 70
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) .....	7

<i>Shire Dev., LLC v. Watson Pharm., Inc.</i> , 848 F.3d 981, 984 (Fed. Cir. 2017) .....	70
<i>Süd-Chemie Inc. v. Multisorb Technologies</i> , 554 F.3d 1001 (Fed. Cir. 2009).....	74
<i>Sundance, Inc. v. DeMonte Fabricating Ltd.</i> , 550 F.3d 1356, 1363–64 (Fed. Cir. 2008) .....	32
<i>United States v. Adams</i> , 383 U.S. 39 (1966).....	7, 37
Statutes	
35 U.S.C. § 103 .....	44, 59
35 U.S.C. § 312(a)(3).....	28
35 U.S.C. § 314(a) .....	6
35 U.S.C. § 325(d) .....	13
35 U.S.C. §316.....	72
35 U.S.C. §316(e) .....	8
Other Authorities	
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> .....	passim
<i>Becton, Dickinson &amp; Co. v. Baxter Int’l</i> , IPR2018-01741, Paper 8, 13-14 (2019)...	8
<i>Dexcowin Global, Inc. v. Aribex, Inc.</i> , IPR2016-00436, Paper 12, 5-6 (2016).....	5
<i>Hunting Titan, Inc. v. DynaEnergetics Europe GmbH</i> , IPR2018-00600, Paper 67 (2020) (precedential).....	24

# 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.