

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,

Petitioner

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner

Inter Partes Review No. IPR2020-00770

U.S. Patent No. 9,604,901

**JOINT PAPER CONCERNING PETITIONER'S REQUEST TO STRIKE
PORTIONS OF PATENT OWNER'S PAPER NOS. 12 AND 25 AND
EXHIBITS 2002 AND 2025**

TABLE OF CONTENTS

	Page
I. INTRODUCTION AND REQUESTED RELIEF	1
A. Issue #1: Whether Claim 1 Requires No Isolation Between Method Steps (B) and (C)	1
B. Issue #2: Whether Claims 6 and 7 Require Actual Storage.....	2
1. Petitioner’s Narrative: UTC’s Inconsistent Positions Concerning “Storage” of the Treprostinil Salt Prior to Use.....	2
2. Patent Owner’s Narrative Regarding the “Storage” Limitation of Claims 6 and 7	5
3. Chart of Portions of Patent Owner’s Submissions Regarding “Storage” that Should be Struck	8

I. INTRODUCTION AND REQUESTED RELIEF

Pursuant to the Board's Order of May 3, 2021, the parties file this joint paper addressing the portions of Patent Owner's Response (Paper No. 12), Sur-Reply (Paper No. 25), and Declarations of Dr. Pinal (EX2002, EX2025) that Petitioner believes should be struck.

A. Issue #1: Whether Claim 1 Requires No Isolation Between Method Steps (B) and (C)

Attached as Exhibits 1043 to 1046 are highlighted copies of the Patent Owner's Response, Sur-Reply, Exhibit 2002, and Exhibit 2025, identifying in yellow the portions by page and line number or paragraph number that Petitioner believes should be stricken. Portions identified with strikethrough and in black indicate statements the parties jointly agree should be stricken.

Paper/Exhibit	Petitioner Identification of Passages to be Stricken	Patent Owner Identification of Passages to be Stricken
Patent Owner Response (Paper No. 12)	<ul style="list-style-type: none">• 5:13-15• 5:17-6:8• 11:5-14• 15:12-16:5• Footnote 1• 19:8-20:18• 25:1-3• 29:3-6• 29:16-34:18• 51:10-14• 53:9-12• 56:14-60:16• 61:16-64:17• 66:19-67:13	<ul style="list-style-type: none">• 11:10-14• 15:12-13• 25:7-8• 29:5-6, 16-17• 34:11-17• 53:9-12• 56:15-16, 18• 58:14• 59:7• 62:12-13

Ex. 2002	<ul style="list-style-type: none"> • ¶¶ 135-140 • ¶ 170 • ¶¶ 274-277 • ¶¶ 294-295 • ¶ 304 • ¶ 305 	None
Ex. 2025	<ul style="list-style-type: none"> • ¶ 90 • ¶ 91 • ¶ 95 • ¶¶ 156-160 • ¶ 256 • ¶ 258 • ¶ 291 	None
Patent Owner's Sur-Reply (Paper No. 25)	<ul style="list-style-type: none"> • 4:8-9 • 17:18-18:5 • 19:12 • 22:10-16 • 22:14-16 • 23:1-24:2 • Footnote 3 	None

B. Issue #2: Whether Claims 6 and 7 Require Actual Storage

1. Petitioner's Narrative: UTC's Inconsistent Positions Concerning "Storage" of the Treprostinil Salt Prior to Use

Claim 6, and its dependent claim 7, recite: "storing a pharmaceutical batch of a salt of treprostinil as claimed in claim 1 at ambient temperature, and preparing a pharmaceutical product from the pharmaceutical batch after storage." EX1001, 18:12-20. UTC argued that the claims require actual storage of the "salt of treprostinil" (evidenced by storage stability data) prior to using the salt to make the claimed pharmaceutical product and that Phares (EX1008) did not "teach or suggest the 'storing'/'storage' limitation in these claims," because it "provides no stability

data.” POR, 11-12, 37-38, 50-52, 65; EX2002, ¶¶222, 229-230, 235-236, 251; EX2025, ¶¶91, 204, 211-212, 217-218, 230, 283-285. UTC also included storage-specific objective indicia of nonobviousness, arguing that “neither Phares nor Moriarty provides any indication of . . . whether refrigerating or other measures would be necessary to provide stability in a batch form.” POR, 68-69. UTC continued to make this argument in its Sur-Reply, specifically stating “Phares offers no guidance about treprostinil or a salt thereof as a pharmaceutical batch to be stored and *used for later* making finished dosage forms. . . . Phares similarly provides *no storage stability data* for treprostinil diethanolamine[.]” Sur-Reply, 18¹; *see also id.*, 11-13 (“storage/storing” limitation requiring actual storage); 24-25 (relying on storage as objective indicia). UTC, thus, interprets claims 6 and 7 to require actual storage of the “salt of treprostinil” prior to use.²

UTC’s expert in the parallel district court proceeding, Dr. Ruffolo, opined that in the ’901 patent, actual storage was not required. Specifically, Dr. Ruffolo equated the “storage” limitation in claim 6 of the ’901 patent with the “storage” limitation in claims 6 and 8 of UTC’s U.S. Patent No. 9,593,066 and provided an identical claim

¹ All emphasis is added unless otherwise noted.

² Whether actual storage is required or not, claims 6 and 7 are invalid for the reasons presented in the Petitioner’s Petition and Reply. *See* Paper No. 1, 43-45, 67-70; Paper No. 15, 6-8, 18-21, 26.

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.