

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED LTD.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner.

Case IPR2016-00006
Patent 8,497,393

Patent Owner Response to Petition

TABLE OF CONTENTS

I. INTRODUCTION1

II. SUMMARY OF THE ARGUMENT1

III. STRUCTURAL/FUNCTIONAL DIFFERENCES OF THE CLAIMED PRODUCTS OVER THE CITED ART.....6

A. The Importance of Purity in Pharmaceuticals.....7

B. The '393 Product Has A Different Impurity Profile and a Higher Purity Than Moriarty.....9

C. The Differences In Impurity Profile And Average Purity Between The '393 Product And Moriarty Are Functionally Important.....12

IV. CLAIM CONSTRUCTION.....13

A. Intrinsic Evidence Can Override The Presumption That “Comprising” Creates An “Open” Claim Construction.....13

B. The Distinct Impurity Profile And Higher Purity Of the '393 Patent Product Were Clearly Considered Part of the Claimed Product During Prosecution16

V. GROUND 1: PHARES FAILS TO EXPLICITLY OR INHERENTLY DISCLOSE EACH AND EVERY LIMITATION OF CLAIMS 1-5, 7-9, 11-14 OR 16-2018

A. SteadyMed Cannot Pick and Choose From Unrelated Portions of Phares to Establish Anticipation19

B. The Proper Construction of a “product comprising a compound [of/having] formula [I/IV] or a pharmaceutically acceptable salt thereof” Precludes A Finding That Phares Anticipates the Present Claims.....20

C. The Higher Melting Point of Phares’ Diethanolamine Salt Does Not Necessarily Mean That it is of Higher Purity Than the Diethanolamine Salts of the '393 Patent.....22

D. Phares Fails To Disclose the Claimed Process for Making Treprostinil or Any Purity or Impurity Profile for Treprostinil Diethanolamine24

VI. GROUND 2: MORIARTY AND PHARES FAIL TO RENDER OBVIOUS CLAIMS 1-5, 7-9, 11-14, OR 16-2027

VII. <u>GROUND 3: MORIARTY, PHARES, KAWAKAMI, AND EĞE</u>	
FAIL TO RENDER OBVIOUS CLAIMS 6, 10, 15, 21, AND 22.....	33
A. The Product of Claims 6, 15, and 21 Are Different Than the Prior	
Art Treprostnil Products.....	33
1. The '393 Patent Product is Structurally and Functionally	
Distinct from Moriarty's Product	34
B. There Is No Motivation For A POSA To Combine Moriarty and	
Phares with Ege and Kawakami.....	34
1. There Is No Motivation to Follow the Carboxylate Salt	
Formation With Regeneration of the Carboxylic Acid.....	35
2. Kawakami Would Have Motivated One of Ordinary Skill	
In The Art To Select A Dicyclohexyl Amine Salt, Teaching	
Away From The Diethanolamine Salt of Claims 14 and 18.....	41
3. Kawakami Does Not Provide A Reasonable Expectation Of	
Success That Treprostnil Products Could Be Further	
Purified Because Different Impurities Are Targeted.....	42
4. Any "Close" Structural Similarity of the Moriarty Free	
Acid Does Not Render the Claims Obvious	45
5. Additional Claim Limitations Are Not Disclosed by the	
Cited Prior Art.....	45
VIII. SECONDARY CONSIDERATIONS REBUT ANY POSSIBLE	
CASE OF OBVIOUSNESS.....	47
A. Long-Felt Unmet Need	47
B. Unexpected Results.....	49
IX. CONCLUSION	49

TABLE OF AUTHORITIES

	Page(s)
Federal Cases	
<i>Atofina v. Great Lakes Chem. Corp.</i> , 441 F.3d 991 (Fed. Cir. 2006).....	17
<i>In re Buszard</i> , 504 F.3d 1364 (Fed. Cir. 2007).....	15
<i>Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.</i> , 246 F.3d 1336 (Fed. Cir. 2001).....	13
<i>Day Intern., Inc. v. Reeves Brothers, Inc.</i> , 260 F.3d 1343 (Fed. Cir. 2001).....	14
<i>In re Fisher</i> , 427 F.2d 833 (C.C.P.A., 1970)	39
<i>In re Hoeksema</i> , 399 F.2d 269 (C.C.P.A. 1968)	45
<i>Knoll Pharm. Co., Inc. v. Teva. Pharm. USA, Inc.</i> , 367 F.3d 1381, (Fed.Cir. 2004).....	48
<i>In re Omeprazole Patent Litigation</i> , 536 F.3d 1361 (Fed. Cir. 2008).....	44
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008).....	39
<i>Purdue Pharma L.P. v. Endo Pharms. Ins.</i> , 438 F.3d 1123 (Fed. Cir. 2006).....	17
<i>SafeTCare Mfg., Inc. v. Tele-Made, Inc.</i> , 497 F.3d 1262 (Fed. Cir. 2007).....	14
<i>Standard Oil Co. v. American Cyanamid Co.</i> , 774 F.2d 448 (Fed. Cir. 1985).....	14
<i>Toro Co. v. White Consol. Indus., Inc.</i> , 199 F.3d 1295 (Fed. Cir. 1999).....	14
<i>United States v. Adams</i> , 383 U.S. 39 (1966).....	38

United Therapeutics Corp. v. Sandoz, Inc.,
2014 WL 4259153 (D.N.J. Aug 29, 2014)17

In re Zletz,
893 F.2d 319 (Fed. Cir. 1989).....15

Federal Statutes

35 U.S.C. § 316(a)(8).....1

35 U.S.C. § 316(e)1, 6

Regulations

21 C.F.R. § 600.3 (r) (2015)7

37 C.F.R. § 42.120.....1

Other Authorities

Marti, E., *Purity determination by differential scanning calorimetry*22

R. Adhiyaman, et.al., *Crystal modification of dipyridamole using different solvents and crystallization conditions*23

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.