UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.
Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.
Patent Owner

U.S. Patent No. 9,555,027

Title: Pharmaceutical Composition

Inter Partes Review Case No. Unassigned

DECLARATION OF PROFESSOR GRAHAM BUCKTON

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. Introduction....1

II. Background and Qualifications....2

III. List Of Documents Considered In Forming My Opinions....6

IV. My Understanding of the Relevant Law....9

A. Claim Construction....9
B. Obviousness....9

V. Level of Ordinary Skill in the Art....12

VI. Summary of the '027 Patent Disclosure and Alleged Invention....13

A. The Specification....13
B. The Claims of the '027 Patent....17

VII. Claim construction....20

A. "Pregelatinized starch"....21
B. "Equivalent dissolution profile across the range of lurasidone"....23

VIII. The State of the Art in 2005....25

A. Formulation of oral preparations with good disintegration and rapid dissolution was well known in the art....25
B. Lurasidone (and formulations thereof) were known in the art....28
C. Lurasidone was known to be effective at doses from 5 to 120 mg....31
D. It was known to select excipients to improve the dissolution rate....33
E. It was known that different dosage amounts of a given formulation should be proportionally scaled, should have acceptable tablet size, and should share equivalent dissolution characteristics....36
F. Pregelatinized starch was a commonly used disintegrant (and multifunctional excipient) in oral dosage forms....40
G. Pregelatinized starch was known to impart rapid dissolution and disintegration behavior in immediate release oral dosage forms....44

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

H. Pregelatinized starch was used in formulations of poorly soluble APIs to impart rapid dissolution and disintegration 46
I. The beneficial dissolution and disintegration behavior of pregelatinized starch was known to apply to formulations with a wide range of API loading 48
J. Pregelatinized starch was typically used in amounts ranging from 1-75% of total weight of the oral dosage form.....49

IX. Summary of Prior Art 50

A. EP 1 327 440 A1 (Ex. 1008, "Fujihara") 50
B. PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN (Michael E. Aulton ed., 1988) (Ex. 1009, "Aulton").....58
C. U.S. Patent No. 4,911,921 (Ex. 1010, "Denton") 62
D. Chowdary, K.P.R. and Rama Rao, N., "Formulation and Evaluation of Dispersible Tablets with Pregelatinized Starch," *Indian Drugs*, 35(6):368-371 (1998) (Ex. 1011, "Chowdary") 64

X. Sumitomo did not fairly Characterize the prior art during prosecution 67

A. The prior art does not support Sumitomo's argument that pregelatinized starch has unpredictable effects on dissolution 67
B. Salpekar does not teach away from the claimed range of pregelatinized starch.....72
C. One of ordinary skill would consider formulations of other poorly soluble APIs relevant to formulations of lurasidone 77

XI. Overview of my conclusions 79

XII. The Challenged Claims would have been Obvious to One of Ordinary Skill in 2005.....81

A. The Challenged Claims were obvious over Fujihara in view of Aulton 81
1. Fujihara discloses ranges of lurasidone content and excipients that overlap with the Challenged Claims.....82
2. One of ordinary skill would have been motivated to increase the dose of lurasidone in Fujihara while maintaining equivalent dissolution between doses.....84
3. One of ordinary skill would have used the higher content of lurasidone disclosed in Fujihara 86

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

4. One of ordinary skill was motivated to select a known disintegrant in Fujihara 87
5. It would have been obvious to combine Fujihara with Aulton to select pregelatinized starch as a disintegrant because pregelatinized starch was in a small group of commonly used disintegrants.....88
6. There is no evidence of unexpected results of the claimed ranges 93
7. Combining Fujihara with Aulton yields every limitation of the challenged claims.....100
B. The Challenged Claims would have been obvious over Fujihara in view of Denton and Chowdary 118
1. One of ordinary skill would have been motivated to improve the oral preparations of Fujihara to increase the dose of lurasidone while maintaining equivalent dissolution between doses.....118
2. One of ordinary skill would have used the higher content of lurasidone disclosed in Fujihara 119
3. To limit tablet size and maintain equivalent dissolution profiles between doses across a broad range, one of ordinary skill would have looked to Denton's use of pregelatinized starch 119
4. One of ordinary skill further would have looked to Chowdary to use 10%-20% pregelatinized starch 123
5. There is no evidence of unexpected results for the claimed ranges.....126
6. Combining Fujihara with Denton and Chowdary yields every limitation of the Challenged Claims 127
C. Reasonable Expectation of Success 133

XIII. There Are No Secondary Considerations of Non-Obviousness.....136

XIV. Conclusion 137

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

I, Professor Graham Buckton, hereby declare as follows.

I. INTRODUCTION

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

2. I have been retained as an expert witness on behalf of Par Pharmaceutical, Inc. ("Par") for the above captioned *inter partes* review ("IPR"). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is £375 per hour for my work on this matter. I also am reimbursed for travel and other direct expenses. I have no personal or financial interest in the outcome of this proceeding.

3. I understand that this declaration is being submitted in support of a petition for IPR of U.S. Patent No. 9,555,027 (Ex. 1001, "the '027 Patent"), which issued from U.S. Application No. 14/512,189 ("the '189 application") on January 31, 2017. The '027 Patent names Kazuyuki Fujihara as inventor. I further understand that, according to USPTO records, the '027 Patent is currently assigned to Sumitomo Dainippon Pharma Co., Ltd. ("Patent Owner").

4. The cover page of the '027 Patent indicates that it was filed as the '189 application on October 10, 2014. The cover page of the '027 Patent also claims priority to two related U.S. patent applications, U.S. Non-provisional Application No. 14/183,283 ("the '283 application," filed on February 18, 2014),

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

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.