

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR2016-01582

U.S. Patent No. 8,822,438

PETITIONER'S REPLY TO PATENT OWNER RESPONSE

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U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Wockhardt's Reply to Patent Owner Response to the Petition

TABLE OF CONTENTS

I. INTRODUCTION 1

II. ARGUMENT..... 2

 A. The'438 patent claims would have been *prima facie* obvious2

 1. Obviousness does not require "safety and effectiveness" or "FDA approval," as Patent Owner suggests 2

 (a) Gerber taught the combination of ketoconazole and prednisone as treating prostate cancer 3

 (b) O'Donnell teaches abiraterone as a potent, more specific CYP17 inhibitor than ketoconazole, and provides a motivation for maintaining prednisone..... 5

 (c) Sartor provides further, independent evidence that prednisone "treats" under the Board's construction..... 10

 2. Wockhardt's Petition is materially different than the Amerigen and Mylan Petitions 12

 3. Gerber, O'Donnell, and Sartor provide more than a reasonable expectation that abiraterone with prednisone "treats" prostate cancer..... 13

 4. Janssen's experts' testimony should be entitled to little or no weight..... 15

 5. The prior art's use of docetaxel does not "teach away" 15

 6. Alleged concerns over prednisone's side-effects do not "teach away." 17

 B. Secondary considerations do not weigh in favor of patentability.....19

 1. The alleged unexpected results are illusory and have no nexus to the challenged claims 20

Wockhardt's Reply to Patent Owner Response to the Petition

2. There is no relevant skepticism, failure of others, or long-felt need..... 23

3. Janssen has not demonstrated commercial success 24

III. CONCLUSION..... 26

*Wockhardt's Reply to Patent Owner Response to the Petition***I. INTRODUCTION**

Wockhardt's Petition presented irrefutable evidence that the '438 patent claims are obvious. Before August 2006, the prior art taught that abiraterone¹ and prednisone independently had "treatment" activity against prostate cancer, as construed by this Board. The '438 patent claims merely recite the co-administration of two well-known drugs—abiraterone (a CYP17 enzyme inhibitor) with prednisone (a steroid)—for a known and established use (prostate cancer). The '438 patent, thus, is nothing more than the "predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Patent Owner's ("Janssen") Response ("POR") has not credibly rebutted this obviousness showing. Wockhardt's Petition established that the '438 patent claims are obvious over the following prior art:

- **Gerber**, which teaches the combination of ketoconazole (another CYP17 enzyme inhibitor) and prednisone for the treatment of prostate cancer;
- **O'Donnell**, which expressly teaches that abiraterone is a potent and

¹ Unless otherwise specified, "abiraterone" is used throughout the Reply to mean "abiraterone acetate" and "abiraterone" *in vivo*.

Wockhardt's Reply to Patent Owner Response to the Petition

more selective CYP17 enzyme inhibitor than ketoconazole; and

- **Sartor**, which teaches prednisone as an independent, stand-alone treatment for prostate cancer.

This Board has found obviousness under nearly identical circumstances. *See Accord Healthcare Inc., USA v. Daiichi Sankyo Co., Ltd.*, IPR2015-00865, Paper 12 (PTAB Sept. 12, 2016) (holding obvious claims to prasugrel (ADP antagonist) and aspirin over prior art disclosing clopidogrel (ADP antagonist) and aspirin). In *Daiichi*, the Board found a POSA would have had a reason to substitute clopidogrel with the claimed prasugrel, because it had greater ADP antagonist activity. The '438 patent claims here are no different, and the same reasoning from *Daiichi* applies.

II. ARGUMENT

A. The '438 patent claims would have been *prima facie* obvious

1. Obviousness does not require "safety and effectiveness" or "FDA approval," as Patent Owner suggests

Wockhardt's petition demonstrated that the '438 patent claims would have been obvious over Gerber, O'Donnell, and Sartor. Janssen's POR tries to undermine the prior art teachings based on legally irrelevant arguments. For example, Janssen argues that the references do not show a "survival benefit," or that their teachings were not confirmed by "placebo-controlled randomized trials," or that they do not show an "extension of life" in patients, or that regimens in the

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