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Paper No. 79
Entered: August 18, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
WOCKHARDT BIO AG, TEVA PHARMACEUTICALS USA, INC.,
AUROBINDO PHARMA U.S.A. INC., and SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE
and AMNEAL PHARMACEUTICALS LLC,
Petitioners,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2015-01340
Patent RE44,186 E[1]

Before MICHAEL P. TIERNEY, *Vice Chief Administrative Patent Judge*, RAMA G. ELLURU and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

Opinion for the Board filed by Administrative Patent Judge ELLURU.

Opinion Concurring filed by Vice Chief Administrative Patent Judge TIERNEY.

ELLURU, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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[1] Wockhardt from IPR2016-01029, Teva from IPR2016-01122, Aurobindo from IPR2016-01117, and Sun/Amneal from IPR2016-01104 have each been joined as a Petitioner to this proceeding.

I. INTRODUCTION

A. Background

Mylan Pharmaceuticals Inc. ("Mylan") filed a Petition to institute an *inter partes* review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of U.S. Patent No. RE44,186 E (Ex. 1001, "the '186 patent"). Paper 3, 17 ("Pet."). Astrazeneca AB ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We subsequently ordered Mylan to respond to certain arguments raised in the Preliminary Response. Paper 10. Mylan filed an authorized Reply to Patent Owner's Preliminary Response. Paper 11.

We initially denied institution of an *inter partes* review of all the challenged claims. Paper 12, 14. Mylan subsequently filed a Request for Rehearing. Paper 13. On May 2, 2016, we granted the Request for Rehearing in an Order (Paper 15) and concurrently instituted an *inter partes* review of all the challenged claims (Paper 16, 34–35 ("Dec.")). Patent Owner timely filed a Response to the Petition. Paper 28 ("PO Resp."). Mylan subsequently timely filed a Reply to Patent Owner's Response. Paper 41 ("Pet. Reply").

Subsequent to our Institution Decision, Wockhardt Bio AG ("Wockhardt"), Teva Pharmaceuticals USA, Inc. ("Teva"), Aurobindo Pharma U.S.A., Inc. ("Aurobindo"), and Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Amneal Pharmaceuticals LLC ("Sun/Amneal") (collectively, "follow-on Petitioners") each filed separate follow-on Petitions for *inter partes* review challenging claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the '186 patent based on the same grounds of unpatentability presented by Mylan. *See* IPR2016-01029, Paper 1 (Wockhardt Petition); IPR2016-01122, Paper 1 (Teva Petition); IPR2016-

01117, Paper 1 (Aurobindo Petition); IPR2016-01104, Paper 3 (Sun/Amneal Petition). Each of the follow-on Petitioners also requested joinder with the *inter partes* review initiated based on Mylan's Petition. Pursuant to 35 U.S.C. § 315(c), we determined that the follow-on Petitions warranted institution and joined the follow-on Petitioners as parties to this proceeding, subject to the requirement that all Petitioners would present consolidated filings, evidence, and arguments, and not seek any additional discovery from Patent Owner.[2] *See* Papers 34, 38, 39, and 53.

Petitioners rely on the Declarations of Dr. David P. Rotella (Exs. 1003 (in support of Pet.), 1074 (in support of Pet. Reply)), Dr. Robert J. Tanenberg (Ex. 1041), and Dr. Deforest McDuff (Ex. 1060). Patent Owner relies on the Declarations of Dr. Ann E. Weber (Ex. 2056), Dr. M. James Lenhard (Ex. 2057), Dr. Christine S. Meyer (Ex. 2059), and Dr. Jeffrey Robl (Ex. 2173).

An oral hearing for this proceeding was held on January 25, 2017, a transcript of which has been entered in the record. Paper 77 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine Petitioners have not established, by a preponderance of the evidence, that claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the '186 patent are unpatentable.

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[2] Mylan, Wockhardt, Teva, Aurobindo, and Sun/Amneal will be collectively referred to as "Petitioners" in this Decision.

B. Related Proceedings

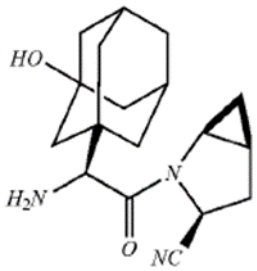
Petitioners and Patent Owner identify the following district court proceedings involving the '186 patent: *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, 14-cv-00696 (D. Del. 2014); *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, 14-cv-00094 (D.W. Va. 2014); *AstraZeneca AB v. Aurobindo Pharma Ltd. et al.*, 14-cv-01469 and 14-cv-00664 (D. Del 2014); *AstraZeneca AB v. Actavis Laboratories FL, Inc.*, 14-cv-01356 (D. Del. 2014); *AstraZeneca AB v. Sun Pharma Global FZE et al.*, 14-cv-00694 (D. Del. 2014); *AstraZeneca AB v. Amneal Pharmaceuticals LLC.*, 14-cv-00697 (D. Del. 2014); and *AstraZeneca AB v. Wockhardt Bio AG et al.*, 14-cv-00696 (D. Del. 2014). Pet. 16; Paper 2; Paper 5, 1. Patent Owner additionally identifies *AstraZeneca AB v. Watson Laboratories, Inc.*, 14-cv-00666 (D. Del. 2014) as involving the '186 patent. Paper 5, 1.

C. The '186 Patent (Ex. 1001)

The '186 patent is directed to "cyclopropyl-fused pyrrolidine-based inhibitors of dipeptidyl peptidase IV (DP-4) ["DP 4"], and to a method for treating diabetes." Ex. 1001, 1:19–21. DP 4 is responsible for the metabolic cleavage of certain endogenous peptides including glucagon. *Id.* at 1:34–42. Glucagon is a peptide with multiple physiologic roles, including the stimulation of insulin secretion, the promotion of satiety, and the slowing of gastric emptying. *Id.* at 1:44–48. Glucagon is rapidly degraded in the body, primarily by DP 4-mediated enzymatic cleavage. *Id.* at 1:55–64. Inhibitors of DP 4 *in vivo* may, therefore, increase endogenous levels of glucagon, and serve to ameliorate the diabetic condition. *Id.* at 1:64–67.

D. Illustrative Claim

We instituted a review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42. Claims 1, 8, 10, 25, 32, and 39 are independent claims. For purposes of this Decision, claim 25 is illustrative of the challenged claims and is drawn to the compound shown below, or a pharmaceutically acceptable salt thereof.



Id. at 91:18–33. The illustrated compound is known as (1S,3S,5S)-2-[(2S)-2-amino-2-(3-hydroxy-1-adamantyl) acetyl]-2-azabicyclo[3.1.0]hexane-3-carbonitrile or "saxagliptin."[3] *See* Pet. 3; Ex. 1003 ¶ 15; Ex. 2047, 9[4]. Petitioners state that each claim challenged under "Ground 1," claims 1, 2, 4, 6–11, 25–28, 32–35, 39, and 40, either defines the saxagliptin compound or includes saxagliptin within its scope. Pet. 22–23. Petitioners further contend that the species of claim 25 is obvious over the prior art, and thus, broader claims which also encompass the species are also obvious. Pet. 3–4 (citation omitted). All the challenged claims are directed to compounds, compositions, and methods relating to the specific compound recited in claim 25. *See* Pet. 4–5, 22–23; PO Resp. 68–69; Tr. 7:12–8:5. Thus, our

[3] Saxagliptin is the active pharmaceutical ingredient in two FDA-approved drugs, Onglyza and Kombiglyze XR, for the treatment of diabetes. PO Resp. 1.

[4] Cites to exhibits refer to a document's original page numbers.

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