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Paper 84
Entered: January 17, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332[1]
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU, and KRISTINA M. KALAN, *Administrative Patent Judges*.

KALAN, *Administrative Patent Judge.*

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

[1] Case IPR2017-00853 has been joined with this proceeding.

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Mylan") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 8,822,438 B2 (Ex. 1001, "the '438 patent") pursuant to 35 U.S.C. §§ 311–319. Janssen Oncology, Inc. ("Patent Owner") filed a Preliminary Response (Paper 14, "Prelim. Resp."). We instituted an *inter partes* review of claims 1–20 on certain grounds of unpatentability alleged in the Petition (Paper 21, "Dec.").

Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., and Hikma Pharmaceuticals, LLC (collectively, the "Actavis Petitioners") filed a Petition for *inter partes* review of claims 1–20 of the '438 patent. Case IPR2017-00853, Paper 8. Together with its Petition, the Actavis Petitioners filed a Motion for Joinder to join the case with the previously instituted proceeding in IPR2016-01332. *Id.*, Paper 9. We instituted trial in IPR2017-00853 and joined the Actavis Petitioners as a Petitioner in IPR2016-01332. *Id.,* Paper 19.

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 35, "PO Resp."). Mylan and the Actavis Petitioners (collectively, "Petitioner") filed a Reply (Paper 55, "Reply"). Pursuant to a Board Order (Paper 64), Patent Owner filed an Identification of New Arguments and Evidence in Petitioner's Reply (Paper 65), to which Petitioner filed a Reply

(Paper 74). An oral hearing was held on May 24, 2017. A transcript of the hearing has been entered into the record. Paper 82 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6. In this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we determine that Petitioner has shown by a preponderance of the evidence that all claims of the '438 patent for which trial was instituted, namely, claims 1–20, are unpatentable.

II. BACKGROUND

A. Related Matters

The parties indicate that the '438 patent is being asserted in a number of district court proceedings, some of which have been terminated. Pet. 1–2; Paper 7, 3. Patent Owner represents that the following proceedings have not been terminated: *BTG Int'l Ltd. v. Actavis Labs. FL, Inc.,* C.A. No. 2:15-cv-05909-KM-JBC (D.N.J.); and *Janssen Biotech, Inc. v. Mylan Pharms. Inc.,* C.A. No. 1:15-cv-00130-IMK (N.D. W. Va.), *BTG Int'l Ltd. v. Amerigen Pharms., Inc.,* C.A. No. 2:16-cv-02449-KM-JBC (D.N.J.); and *BTG Int'l Ltd. v. Glenmark Pharms. Inc., USA*, C.A. No. 2:16-cv-5909 (D.N.J). Paper 27, 3.

Patent Owner also states that the '438 patent was the subject of *ex parte* reexamination request No. 90/020,096, but "will not be granted a filing date for failure to comply with the requirements of 37 C.F.R. § 1.501(a)." Paper 7, 2.

B. The '438 Patent

The '438 patent, titled "Methods and Compositions for Treating Cancer," describes methods that comprise "administering a 17α-hydroxylase/$C_{17, 20}$-lyase inhibitor, such as abiraterone acetate (i.e., 3β-

acetoxy-17-(3-pyridyl)androsta-5,16-diene), in combination with at least one additional therapeutic agent such as an anti-cancer agent or a steroid." Ex. 1001, at [54], [57]. As described in the '438 patent, it is believed that testosterone and dihydrotestosterone promote the growth of prostate cancer. *Id.* at 1:49–51. Hormone therapy can be used to suppress the production or block the effects of hormones such as testosterone. *Id.* at 1:43–51.

The enzyme 17α-hydroxylase/$C_{17, 20}$-lyase ("CYP17") is involved in testosterone synthesis. *Id.* at 3:66–4:1. CYP17 inhibitors have been shown to be useful in the treatment of cancer, specifically, androgen-dependent disorders like prostate cancer. *Id.* at 5:23–27. Abiraterone acetate, a prodrug of abiraterone, is a CYP17 inhibitor. *Id.* at 2:10–12.

The '438 patent describes administration of a therapeutically effective amount of a CYP17 inhibitor, such as abiraterone acetate, with a therapeutically effective amount of at least one additional therapeutic agent including, but not limited to, an anti-cancer agent, such as mitoxantrone, paclitaxel, docetaxel, leuprolide, goserelin, triptorelin, seocalcitol, bicalutamide, or flutamide, or a steroid, such as hydrocortisone, prednisone, or dexamethasone. *Id.* at 2:9–3:20.

C. Challenged Claims

Claim 1 of the '438 patent is reproduced below:

> 1. A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.

Ex. 1001, 16:16–20. Dependent claims 2–20 of the '438 patent describe additional limitations of the method, including the amount of abiraterone

acetate and the amount of prednisone used and the type of prostate cancer being treated. *Id.* at 16:21–17:14.

D. Prior Art References Relied Upon by Petitioner

Petitioner relies on the following prior art:

1. O'Donnell, A. et al., *Hormonal impact of the 17α-hydroxylase/ $C_{17,20}$-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer*, 90 British Journal of Cancer 2317–25 (2004) ("O'Donnell") (Ex. 1003);
2. Gerber, G.S. & Chodak, G.W., *Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic prostate cancer*, 144 J. Urol. 1177–79 (1990) ("Gerber") (Ex. 1004); and
3. U.S. Patent No. 5,604,213 to Barrie, issued February 18, 1997 ("Barrie") (Ex. 1005).

E. Instituted Grounds of Unpatentability

We instituted *inter partes* review of claims 1–20 of the '438 patent on the following grounds:

References	Basis	Claims Challenged
O'Donnell and Gerber	§ 103	1–20
Barrie and Gerber	§ 103	1–4 and 6–11

In support of its challenges, Petitioner relies on the declarations of Marc B. Garnick, M.D. (Ex. 1002; Ex. 1104, 1153), Ivan T. Hoffman (Ex. 1017; Ex. 1134, 1146, 1151, 1154), Ian McKeague, Ph.D. (Ex. 1091), John Bantle, M.D. (Ex. 1097) and Bryan D. Beel (Ex. 1152). Patent Owner relies on the declarations of Ian Judson, M.D. (Ex. 2028), Matthew Rettig, M.D. (Ex. 2038), Richard Auchus, M.D., Ph.D. (Ex. 2040), Christopher A. Vellturo, Ph.D. (Ex. 2044), and Johann S. De Bono (Ex. 2118).

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