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Paper 29
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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
Patent 8,822,438 B2

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

KALAN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Wockhardt Bio AG ("Petitioner") filed a Petition (Paper 4, "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 13, "Prelim. Resp."). Pursuant to Board authorization (Paper 17), Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 22, "Reply") and Patent Owner filed a Surreply to Petitioner's Reply (Paper 27, "Surreply"). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute an *inter partes* review as to claims 1–20 as discussed below.

Our findings of fact and conclusions of law, including those relating to the broadest reasonable construction of the patent claim terms, are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. Our final decision will be based on the full record developed during trial.

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. 66; Paper 8, 2–4. Of those, 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.); *Janssen Biotech, Inc. v. Mylan Pharm. Inc.*, C.A. No. 1:15-cv-00130-IMK (N.D. W. Va.); *BTG Int'l Ltd. v. Amerigen Pharm., Inc.*, C.A. No. 2:16-cv-02449-KM-JBC (D. N.J.)

and *BTG Int'l Ltd. v. Glenmark Pharm. Inc.,* C.A. No. 2:16-cv-05909 (D. N.J.). Paper 8, 3–4. The '438 patent is the subject of *inter partes* review numbers IPR2016-00286 (instituted May 31, 2016), IPR2016-01337 (instituted and joined with IPR2016-00286 on September 19, 2016) and IPR2016-01332. *Id.* at 2–3. 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)." *Id.* at 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, Title, Abstract. 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 an effective amount of a CYP17 inhibitor, such as abiraterone acetate, with a steroid such as prednisone or dexamethasone. *Id.* at 2:9–3:20.

C. 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 administered, and the type of prostate cancer being treated. *Id.* at 16:21–17:14.

D. The Prior Art

Petitioner relies on the following prior art:

1. Gerber, G.S. & Chodak, G.W., *Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer*, 144 J. Urol. 1177–79 (1990) ("Gerber") (Ex. 1004);
2. 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 2317–2325 (2004) ("O'Donnell") (Ex. 1005); and
3. Sartor, O. et al., *Effect of prednisone on prostate-specific antigen in patients with hormone-refractory prostate cancer*, 52 Urology 252–256 (1998) ("Sartor") (Ex. 1006).

Petitioner also relies on the Declarations of Dr. Paul A. Godley (Ex. 1002, the "Godley Declaration") and Dr. Robert Stoner (Ex. 1077, the "Stoner Declaration") in support of its arguments.

E. The Asserted Ground

Petitioner challenges claims 1–20 of the '438 patent on the following ground:

References	Basis	Claims Challenged
Gerber, O'Donnell, and Sartor	§ 103(a)	1–20

III. ANALYSIS

We turn now to Petitioner's asserted ground of unpatentability, Patent Owner's arguments in the Preliminary Response, the Reply, the Surreply, and the supporting evidence to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a).

A. Claim Interpretation

The Board interprets claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under the broadest reasonable interpretation standard, claim terms are generally given their ordinary and customary meaning in view of the specification, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner proposes that we construe the claim terms "treat," "treating," "treatment," and "therapeutically effective amount of prednisone." Pet. 20–21. Petitioner notes that these claim terms have already been construed in IPR2016-00286, Paper 14, and states that it analyzes the claims under those constructions for the purpose of this proceeding. *Id.* Patent Owner does not

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