

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

IPR2016-00286
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

Amerigen Pharmaceuticals Limited (“Petitioner”) 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 12, “Prelim. Resp.”). 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. 1–2; Paper 6, 2–3. Patent Owner represents that the following proceedings have not been terminated: *BTG Int’l Ltd., et al. v. Actavis Labs. FL, Inc., et al.*, C.A. No. 2:15-cv-05909-KM-JBC (D. N.J.); and *Janssen Biotech, Inc., et al. v. Mylan Pharm. Inc., et al.*, C.A. No. 1:15-cv-00130-IMK (N.D. W. Va.). Paper 13, 2–3. Patent Owner also states that the ’438 patent is “the subject of *ex parte* reexamination request No. 90/020,096, which has been assigned to an Office examiner for determination.” *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 used, 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. O’Donnell, A. et al., *Hormonal impact of the 17 α -hydroxylase/C_{17,20}-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer*, British Journal of Cancer 90:2317–2325 (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 cancer*, J. Urol. 144:1177–79 (1990) (“Gerber”) (Ex. 1004); and
3. U.S. Patent No. 5,604,213 to Barrie, issued February 18, 1997 (“Barrie”) (Ex. 1005).

Petitioner also relies on the declarations of Scott R. Serels, M.D. (Ex. 1002, the “Serels Declaration”) and DeForest McDuff, Ph.D. (Ex. 1017, the “McDuff Declaration”) in support of its arguments.

E. The Asserted Grounds

Petitioner challenges 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

III. ANALYSIS

We turn now to Petitioner’s asserted grounds of unpatentability, Patent Owner’s arguments in the Preliminary Response, 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 In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 890 (mem.) (2016). Under the broadest reasonable interpretation standard, claim terms are 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,” “anti-cancer agent,” and “refractory cancer.” Pet. 17–19. Patent Owner accepts Petitioner’s definitions of those terms. Prelim. Resp. 18. These claim terms are discussed and defined explicitly in the specification of the ’438 patent, as noted by Petitioner. Pet. 18. Accordingly, we construe those terms as set forth in the specification and below:

Claim term(s)	Construction
“treat,” “treating,” and “treatment	include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer Ex. 1001, 3:46–50
“anti-cancer agent”	any therapeutic agent that directly or indirectly kills cancer cells or directly or

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