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Paper 7
Entered: February 11, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,
Petitioner,

v.

CELGENE CORP.,
Patent Owner.

Case IPR2018-01504
Patent 9,056,120 B2

Before GRACE KARAFFA OBERMANN, TINA E. HULSE, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Dr. Reddy's Laboratories, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet."), requesting institution of an *inter partes* review of claims 1–8, 12–34, and 38–53 of U.S. Patent No. 9,056,120 B2 (Ex. 1001, "the '120 patent"). Celgene Corp. ("Patent Owner") timely filed a Preliminary Response (Paper 6, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has not demonstrated sufficiently that certain press releases relied upon in its patentability challenges qualify as printed publications. We thus decline to institute an *inter partes* review of claims 1–8, 12–34, and 38–53 of the '120 patent.

A. *Related Proceedings*

"Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '120 patent" and "is not aware of any prior petitions for *inter partes* review related to the '120 patent." Pet. 55–56. Petitioner is a defendant in the following litigation involving the '120 patent: *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Case No. 2:17-cv-05314-SDW-LDW (D.N.J.). *Id.*

Additionally, Case IPR2018-01507 (IPR507) and Case IPR2018-01509 (IPR509) involve the same parties but different challenged patents. Concurrently with this decision, the Board issues decisions denying

institution in IPR507 and IPR509 based on substantially the same analysis set forth in this decision.

B. *The '120 Patent (Ex. 1001)*

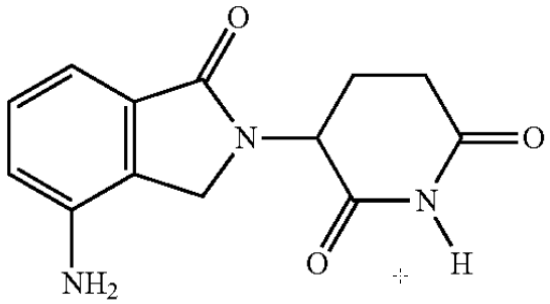
The '120 patent issued on June 16, 2015, and claims priority to Provisional application No. 60/418,468 filed on October 15, 2002. *See* Ex. 1001, Title Page. It names Jerome B. Zeldis as the sole inventor. *Id.*

The '120 patent discusses methods of treating, preventing and/or managing myelodysplastic syndromes ("MDS") with a combination therapy using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidin-2,6-dione (lenalidomide) and azacitidine. *Id.*, Title, Abstract. The '120 patent identifies lenalidomide, also known by its commercial name as Revimid, as an immunomodulatory compound to be used in such treatment methods. *Id.* at 1:24–30.

C. *Illustrative Claim*

Claims 1 and 28 are the only independent claims. Claim 1 is illustrative and reproduced below:

1. A method of treating myelodysplastic syndrome, which comprises administering to a patient in need thereof about 1 mg to about 25 mg per day of a compound having the formula:



or a pharmaceutically acceptable salt, solvate or stereoisomer thereof. Ex. 1001, 27:26–42.

D. *Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of the claims of the '120 patent on the following grounds:

Reference(s)	Basis	Claims Challenged
List 2001,[1] '230 patent,[2] Celgene Press Release 5/8/2001,[3] and Celgene Press Release 8/28/2001[4]	§ 103(a)	1–8, 12–34, and 38–53
Thomas 2000a,[5] '230 patent, Celgene Press Release 5/8/2001, and Celgene Press Release 8/28/2001	§ 103(a)	1–8, 12–34, and 38–53

[1] Richard J. Klasa, Alan F. List, and Bruce D. Cheson, *Rational Approaches to Design of Therapeutics Targeting Molecular Markers*, HEMATOLOGY 443 (2001) (Ex. 1004).

[2] U.S. Patent No. 6,281,230 B1 (Ex. 1006).

[3] Press Release, Celgene Corp., *Positive Interim Results Presented at the VIIIth International Myeloma Workshop on Celgene Corporation's Lead IMiD(TM) (REVIMID(TM))* (May 8, 2001) (on file with PR Newswire) (Ex. 1008).

[4] Press Release, Celgene Corp., *Celgene Corporation Awarded Additional Patent Protection For Lead IMiD(TM), REVIMID(TM): Comprehensive Patent Protection for REVIMID Includes Coverage of the Active Ingredient, Pharmaceutical Compositions, and Therapeutic Uses* (Aug. 28, 2001) (on file with PR Newswire) (Ex. 1010).

[5] Deborah A. Thomas, MD and Hagop M. Kantarjian, MD, *Current Role of Thalidomide in Cancer Treatment*, 12 CURRENT OP. IN ONCOLOGY 564 (2000) (Ex. 1005).

II. ANALYSIS

A. *Claim Construction*

We interpret 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) (2016)[6]. Under that standard, claim terms are given their ordinary and customary meaning in view of the specification, as understood by a person 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). We resolve disputed claim terms only to the extent necessary to our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

The Petition does not assert that any claim term requires express construction and states that "one of ordinary skill in the art would understand the claim terms to have their plain and ordinary meanings." Pet. 4. Patent Owner agrees with Petitioner. Prelim. Resp. 32. We determine that no explicit construction of any claim term is necessary to determine whether to institute trial in this case.

B. *Public Accessibility of Prior Art Relied Upon in Petition*

Patent Owner contends that Petitioner has failed to establish Celgene

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[6] A recent amendment to this rule does not apply here, because the Petition was filed before November 13, 2018. *See* "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board," 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42).

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