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Paper 10
Date: October 23, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, LLC,
Petitioner,

v.

BIOGEN, INC. AND GENENTECH, INC.,
Patent Owner.

Case IPR2017-01227
Patent 7,682,612 B1

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and JACQUELINE T. HARLOW, Administrative *Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Celltrion, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 23–35 and 37–57 (Paper 2; "Pet.") of U.S. Patent No. 7,682,612 B1 (Ex. 1101; "the '612 patent"). Biogen, Inc. and Genentech, Inc. ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 8.

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 23–35 and 37–57. Accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. Related Proceedings

The parties inform us of no related pending litigations. Pet. 4; Paper 6.

The '612 patent is currently the subject of IPR2017-01230, filed concurrently with this proceeding by Petitioner. Petitioner also filed a petition for *inter partes* review of U.S. Patent No. 8,206,711 (IPR2017-01229), which is related to the '612 patent.

B. The '612 Patent (Ex. 1101)

The '612 patent discloses therapeutic regimens involving the administration of anti-CD20 antibodies for the treatment of chronic lymphocytic leukemia (CLL). Ex. 1101, Abst., 2:16–21. "[A] particularly preferred chimeric anti-CD20 antibody is RITUXAN® (rituximab), which is a chimeric gamma 1 anti-human CD20 antibody." *Id.* at 3:18–20.

With regard to dosing, the '612 patent discloses that "[t]ypically

effective dosages will range from about 0.001 to about 30 mg/kg body weight, more preferably from about 0.01 to 25 mg/kg body weight, and most preferably from about 0.1 to about 20 mg/kg body weight." *Id.* at 3:50–54. "Such administration may be effected by various protocols, e.g., weekly, bi-weekly, or monthly, dependent on the dosage administered and patient response." *Id.* at 3:55–57. "A particularly preferred dosage regimen will comprise administration of about 375 mg/m^2 weekly for a total of four infusions." *Id.* at 3:64–66.

C. Illustrative Claims

Petitioner challenges claims 23–35 and 37–57 of the '612 patent. Independent claims 23 and 28 are illustrative of the challenged claims and are reproduced below:

> 23. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the anti-CD20 antibody therapy is combined with chemotherapy, wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.
>
> 28. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the anti-CD20 antibody is administered to the patient at a dosage of about 500 to about 1500 mg/m2, wherein the anti-CD20 antibody therapy is combined with chemotherapy, and wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.

D. The Asserted Grounds

Petitioner challenges claims 23–35 and 37–57 of the '612 patent on the following grounds. Pet. 33–66.

Ground	Reference[s]	Basis	Challenged Claims
1	Czuczman,[1] FDA Transcript,[2] Batata,[3] and Maloney[4]	§ 103	23–35, 37–57
2	Byrd[5] and MD Anderson Newsletter[6]	§ 103	23–35, 37–57

[1] Ex. 1111, Czuczman, M.S. et al., Chemoimmunotherapy of Low-Grade Lymphoma with the anti-CD20 Antibody IDEC-C2B8 in Combination with CHOP Chemotherapy, Cancer Invest. 14:59-61 (Abstract 53) (1996) ("Czuczman").

[2] Ex. 1107, Public Hearing Transcript, Biological Response Modifiers Advisory Committee, Center for Biological Evaluation and Research, Food and Drug Administration, nineteenth meeting (July 25, 1997) ("FDA Transcript").

[3] Ex. 1108, Batata, A. & Shen, B., *Relationship between Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma: A Comparative Study of Membrane Phenotypes in 270 Cases*, 70(3) CANCER 625-632 (1992) ("Batata").

[4] Ex. 1109, Maloney, D.G. et al., *Phase I Clinical Trial Using Escalating Single-Dose Infusion of Chimeric Anti-CD20 Monoclonal Antibody (IDEC-C2B8) in Patients with Recurrent B-Cell Lymphoma*, 84(8) BLOOD 2457-2466 (Oct. 15, 1994) ("Maloney 1994").

[5] Ex. 1110, Byrd, J.C. et al., *Old and New Therapies in Chronic Lymphocytic Leukemia: Now Is the Time for a Reassessment of Therapeutic Goals*, 25(1) Semin. Oncol. 65–74 (Feb. 1998) ("Byrd").

[6] Ex. 1103, Archived website for Leukemia Insights Newsletter, 3(2) (Archived on February 2, 1999) ("MD Anderson Newsletter"); Petitioner contends that MD Anderson Newsletter was also available as a print version

Ground	Reference[s]	Basis	Challenged Claims
3	Byrd, MD Anderson Newsletter and Kipps[7]	§ 103	41–42

Petitioner supports its challenge with the Declaration of Michael Andreeff, M.D (Ex. 1105).

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given their "ordinary and customary meaning," 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) (quoting *Phillips v. AWH Corp*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)).

Petitioner and Patent Owner propose constructions for certain claim terms. Pet. 21–25; Prelim. Resp. 14–24. We determine that no explicit construction of any claim term is necessary to determine whether to institute a trial in this case. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (Only terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

(Ex. 1163).

[7] Ex. 1155, Kipps, T.J. *Chapter 106: Chronic lymphocytic leukemia and related diseases*, in Williams Hematology Fifth Edition, 1017–1039 (Beutler, E. et al., eds., 1995) ("Kipps").

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