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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

BIOGEN, INC.,
Patent Owner.

Case IPR2017-01094
Patent 8,557,244 B1

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

FRANKLIN, *Administrative Patent Judge.*

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

I. INTRODUCTION

Celltrion, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1 and 2 of U.S. Patent No. 8,557,244 B1 (Ex. 1001, "the '244 patent"). Paper 2 ("Pet."). Biogen, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); *see also* 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 1 and 2. Accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. Related Proceedings

Petitioner and Patent Owner explain that they are not aware of any other pending proceedings involving the '244 patent. Pet. 4; Paper 7, 2. Petitioner has filed also petitions for *inter parties* review involving related U.S. Patent Nos. 8,329,172 B2 (IPR2017-01093) and 9,296,821 B2 (IPR2017-01095). *Id*.

B. The '244 Patent

The '244 patent relates to a method of treating a patient who is greater than 60 years old and has diffuse large cell lymphoma ("DLCL"), along with bulky disease (tumor > 19 cm in diameter). Ex. 1001, 8:41–47. The treatment comprises administering an unlabeled chimeric anti-CD20 antibody and CHOP (cyclophosphamide, hydroxydaunorubicin/doxorubicin, vincristine, and prednisone/prednisolone) chemotherapy. *Id*. In particular, a preferred antibody is rituximab. *Id*. at 8:48–49. DLCL refers to an

aggressive, intermediate-grade non-Hodgkin's lymphoma ("NHL"). *Id*. at 2:42–45, 65–67.

C. Challenged Claims

Claims 1 and 2 of the '244 patent are reproduced below:

> 1. A method of treating a patient with diffuse large cell lymphoma, comprising administering an unlabeled chimeric anti-CD20 antibody and CHOP (cyclophosphamide, hydroxydaunorubicin/doxorubicin, vincristine, and prednisone/prednisolone) chemotherapy to the patient, wherein the patient is > 60 years old and has bulky disease (tumor >10 cm in diameter).
>
> 2. The method of claim 1, wherein the chimeric antibody is rituximab.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1 and 2 of the '244 patent on the following grounds:

Claims	**Basis**	**References**
1 and 2	Pre-AIA § 103	Link,[1] McNeil,[2] and the FDA Transcript[3]

[1] Link et al., *Phase II Pilot Study of the Safety and Efficacy of Rituximab in Combination with CHOP Chemotherapy in Patients with Previously Untreated Intermediate- or High-Grade NHL, Program/Proceedings*, 17 AM. SOC. CLIN. ONCOL. 3a (Abstract 7) (1998) (Ex. 1005).
[2] McNeil, *Non-Hodgkin's Lymphoma Trials In Elderly Look Beyond CHOP*, 90 J. NAT. CANCER INST. 266–67 (1998) (Ex. 1006).
[3] Transcript of Proceedings, Nineteenth Meeting, Biological Response Modifiers Advisory Committee, Department of Health and Human Services, Food and Drug Administration (July 25, 1997) (Ex. 1010).

Claims	Basis	References
1 and 2	Pre-AIA § 103	Link, McNeil, and the Rituxan Label[4]
1 and 2	Pre-AIA § 103	The E4494 Patient Consent Form[5] and the FDA Transcript
1 and 2	Pre-AIA § 103	Sonneveld[6] and Link

Petitioner also relies upon the Declarations of Izidore Lossos, M.D. (Ex. 1003) and Walter Longo, M.D. (Ex. 1004).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to 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, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the

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[4] IDEC Pharmaceuticals Corporation and Genentech, Inc., Product label for Rituxan (1997) (Ex. 1008).

[5] Eastern Cooperative Oncology Group E4494/Cancer and Leukemia Group B CALGB 9793, *Phase III Trial of CHOP versus CHOP and Chimeric Anti-CD20 Monoclonal Antibody (IDEC-C288) in Patients 60 Years or Older with Diffuse Mixed, Diffuse Large Cell and lmmunoblastic Large Cell Histology Non-Hodgkin's Lymphoma*, Appendix I: Suggested Patient Consent Form (undated) (Ex. 1007).

[6] Sonneveld et al., *Comparison of Doxorubicin and Mitoxantrone in the Treatment of Elderly Patients With Advanced Diffuse Non-Hodgkin's Lymphoma Using CHOP Versus CNOP Chemotherapy*, 90 J. Clin. Oncol. 2530–2539 (1995) (Ex. 1009).

invention. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner and Patent Owner propose constructions for certain claim terms. Pet. 20–23; Prelim. Resp. 13–19. In view of our analysis, we determine that construction of claim terms is not necessary for purpose of this Decision. *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).

B. Obviousness over Link, McNeil, and the FDA Transcript

Petitioner asserts that claims 1 and 2 would have been obvious over Link, McNeil, and the FDA Transcript. Pet. 34–46.

1. Link

Link describes a phase II pilot study of the safety and efficacy of administering Rituxan in combination with CHOP chemotherapy to 31 patients with previously untreated intermediate- or high-grade NHL. Ex. 1005, 3a (Abstract 7). Patients had a median age of 49 and included those with a pathology of IWF G (DLCL). *Id*. Link describes Rituxan as "rituximab, IDEC-C2B8," a chimeric monoclonal antibody that targets the CD20 antigen expressed on normal and malignant B-cells. *Id*. Link reports that the study resulted in 19 patients having a complete response, 10 patients having a partial response, and one patient with progression. *Id*. According to Link, the study regimen "represents a tolerable therapy . . . and may offer higher response rates" than seen with conventional CHOP therapy alone. *Id*.

2. McNeil

McNeil describes a randomized trial for elderly patients with intermediate-grade NHL involving a combination treatment of CHOP and Rituxan (IDEC-C2B8). Ex. 1006, 266. McNeil explains that the trial, organized by the Eastern Cooperative Oncology Group ("ECOG"), "will recruit 630 patients age 60 and over" to receive the combination therapy. *Id*.

3. The FDA Transcript

The FDA Transcript covers a July 25, 1997 public hearing of the FDA Biological Response Modifiers Advisory Committee discussion of rituximab (IDEC-C2B8) between the FDA and representatives of IDEC Pharmaceuticals, including Dr. Antonio Grillo-Lopez, a named inventor of the '244 patent. Ex. 1010, 4. During the hearing, Dr. Grillo-Lopez described a study involving treating patients having low-grade or follicular NHL with rituximab. *Id*. at 36. Dr. Grillo-Lopez explains that, in the Phase II pivotal trial, 21 of the 166 patients had bulky disease and treatment resulted in a response rate of 38%. *Id*. at 45–46, 128–130.

4. Analysis

Petitioner asserts that Link and McNeil each disclose treating DLCL patients by administering an unlabeled chimeric anti-CD20 antibody (rituximab) and CHOP chemotherapy. Pet. 38–39. Petitioner asserts that McNeil is specifically directed to treating patients over age 60 and that Link's teaching that the "average patient age of 49 suggests that some patients may have been over 60." *Id*. at 40. Petitioner asserts that Link and McNeil do not "indicate any exclusion of patients with bulky disease" from their studies, so a person of skill in the art would "consider it highly likely that numerous patients in the studies disclosed in Link and McNeil had

bulky disease" because the artisan would have understood that about 30% of DLCL patients have bulky disease. *Id*. at 41. Further, Petitioner relies on the disclosure of the FDA Transcript as supplying the "bulky disease" claim requirement. *Id*. at 40. According to Petitioner, the FDA Transcript "repeatedly discloses positive results of administering rituximab to treat patients with bulky disease." *Id*.

Patent Owner argues, among other things, that neither Link nor McNeil teaches or suggests treating DLCL patients having *bulky disease* with the combination of rituximab and CHOP. Prelim. Resp. 31. Further, Patent Owner asserts that Petitioner has not established that the FDA Transcript is a printed publication and that, even if it were, the reference provides no teaching or suggestion regarding treating DLCL patients having *bulky disease* with rituximab, much less a combination of rituximab and CHOP. *Id*. at 20–23, 33.

We agree with those assertions by Patent Owner. In particular, we note that Petitioner does not assert that Link and McNeil each disclose treating DLCL patients having bulky disease. Rather, Petitioner asserts only that a person of skill in the art would "consider it highly likely that numerous patients in the studies disclosed in Link and McNeil had bulky disease because both Link and McNeil studied patients with DLCL." Pet. 41. Insofar as that argument is an assertion that each of those references inherently discloses treating DLCL patients having bulky disease, that argument is insufficient, as it is based upon probabilities. It is well established that "inherency does not follow even from a very high likelihood that a prior art method will result in the claimed invention." *In re Montgomery*, 677 F.3d 1375, 1384 (Fed. Cir. 2012).

Thus, the combined teachings of Link and McNeil result in at least one deficiency, i.e., the failure to teach treating DLCL patients having bulky disease. Petitioner relies upon the FDA Transcript to cure that deficiency. Pet. 36–38. However, as Patent Owner has correctly asserted, Prelim. Resp. 20, Petitioner has not established adequately that the FDA Transcript is a prior art printed publication. *See* 35 U.S.C. § 311(b) (patentability of a claim may be challenged "only on the basis of prior art consisting of patents or printed publications"); *see also* 35 U.S.C. § 102(b) ("A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent . . . .").

The Federal Circuit has held that "public accessibility" is "the touchstone" in determining whether a reference is a printed publication. *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986). "A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (quoting *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).

Petitioner has not shown that the FDA Transcript was publicly accessible to the extent required to establish it as a "printed publication." Petitioner asserts that the FDA Transcript was made available to the public on August 8, 1997. Pet. 26. In support of that assertion, Petitioner relies upon a letter from Dynna Bigby from the Division of Dockets Management ("DDM") (Ex. 1039) at the FDA. *Id*. According to Petitioner, the letter

establishes that (a) the FDA Transcript would have been received on August 8, 1997, the date stamped on the FDA Transcript; (b) the DDM would have made the document publicly available via the DDM Public Reading Room; and (c) access to the FDA Transcript would have required filling out a reading room request form for the document. *Id*. Even if each of those assertions were taken as true, what is missing is some supported explanation that such availability of the FDA Transcript was in a manner and to an extent that "persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence" would have been able to locate it. *Id*. at 28–29. In other words, Petitioner has not explained how such persons may have known that the FDA transcript existed and was available, upon request, in the DDM Public Reading Room. Without that information, Petitioner has not shown that the FDA Transcript is a prior art printed publication. Consequently, the transcript cannot be relied upon to cure the deficiencies of Link and McNeil, or otherwise assist in challenging the patentability of claims 1 and 2.

Thus, based on the information presented, we determine that Petitioner has not shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claims 1 and 2 over Link, McNeil, and the FDA transcript.

C. Obviousness over Link, McNeil, and the Rituxan Label

Petitioner asserts that claims 1 and 2 would have been obvious over Link, McNeil, and the Rituxan Label. Pet. 47–49.

1. The Rituxan Label

The Rituxan Label describes Rituxan (rituximab) as a genetically engineered chimeric murine/human monoclonal antibody directed against

the CD20 antigen found on the surface of normal and malignant B lymphocytes. Ex. 1008, 1. The product is formulated for intravenous administration and is indicated for the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell NHL. *Id*. The reference reports results from a clinical trial of patients with relapsed or refractory, bulky, low-grade NHL, wherein ten of the 21 patients obtained a complete or partial remission. *Id*.

2. Analysis

Petitioner relies on Link and McNeil in the same manner discussed above in section II. B. Petitioner relies on the Rituxan Label as teaching the efficacy of treating bulky disease with rituximab. Pet. 48. Petitioner asserts that the Rituxan Label reports the same study data as the FDA Transcript, such that it would have been obvious to a person of ordinary skill in the art to combine the Rituxan Label with Link and McNeil in the same manner and for the same reasons discussed above regarding the combination of Link, McNeil and the FDA Transcript in section II. B. *Id.*

For the same reasons set forth in section II. B., we find that the combined teachings of Link and McNeil result in at least one deficiency, i.e., the failure to teach treating DLCL patients having bulky disease. Further, Petitioner's reliance upon the Rituxan Label to cure that deficiency is unavailing, as we agree with Patent Owner that Petitioner has not shown that the Rituxan Label was publicly accessible to the extent required to establish it as a "printed publication." Prelim. Resp. 24–26.

In particular, Petitioner asserts that the Rituxan Label is dated "November 1997" was "published and publicly available more than one year before August 11, 1999, the earliest filing to which the '244 patent claims

priority." Pet. 27. Central to Petitioner's position is its assertion that the Rituxan Label "was included in the packaging of Rituxan, which was approved by the FDA on November 26, 1997." *Id*. at 26. In support of that assertion, Petitioner refers to the SEC Form 10-K/A filed by IDEC. *Id*. (citing Ex. 1029, 2).[7] However, Petitioner does not explain how that document, or its disclosure that Rituxan "received regulatory approval in the United States" on a particular date establishes when the Rituxan Label set forth in Exhibit 1008 was made publicly available. Indeed, Petitioner does not explicitly assert on what specific date it alleges that the Rituxan Label was publicly available. Nor does Petitioner provide any documentary or testimonial evidence to support its contention that the Rituxan Label was included in the packaging of a disseminated drug product, or otherwise made available in a manner such that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence would have been able to locate it. For at least those reasons, we agree with Patent Owner that Petitioner has not met its burden of establishing that the Rituxan Label is a "printed publication." Prelim. Resp. 26.

Thus, based on the information presented, we determine that Petitioner has not shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claims 1 and 2 over Link, McNeil, and the Rituxan Label.

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[7] IDEC Pharmaceuticals Corp., Form 10-K/A Annual Report for the Fiscal Year Ended Dec. 31, 1997, filed with the U.S. Securities and Exchange Comm. ("SEC Form 10-K/A filed by IDEC") (Ex. 1029).

D. Obviousness over the E4494 Patient Consent Form and the FDA Transcript

Petitioner asserts that claims 1 and 2 would have been obvious over the E4494 Patient Consent Form and the FDA Transcript. Pet. 49–53.

1. The E4494 Patient Consent Form

The E4494 Patient Consent Form invites patients with NHL to participate in a research study to compare treatment using CHOP with or without anti-CD20 antibody (IDEC-C2B8). Ex. 1007, 1.

2. Analysis

Petitioner asserts that the E4494 Patient Consent Form discloses details of the same clinical trial discussed in McNeil. Pet. 50. Petitioner relies on the E4494 Patient Consent Form in the same manner as it relied on McNeil, as discussed above in section II. B. *Id*. Additionally, Petitioner relies on the FDA Transcript in the same manner discussed above in that same section. *Id*.

For the same reasons discussed in section II. B., Petitioner has not shown that the FDA Transcript was publicly accessible to the extent required to establish it as a "printed publication."

Further, we agree with Patent Owner that Petitioner has not shown that the E4494 study was publicly accessible to the extent required to establish it as a "printed publication." Prelim. Resp. 26–29. Petitioner relies upon the Declaration of Dr. Longo, a sub-investigator in the E4494 clinical trial, as verifying that the E4494 Patient Consent Form was "freely available to potential patients and interested clinicians without any confidentiality restrictions as of December 1997." Pet. 28 (citing Ex. 1004 ¶¶ 3, 4). In particular, Petitioner directs us to Dr. Longo's explanation that he received

copies of the E4494 Patient Consent Form and that he distributed the form to approximately ten prospective patients who inquired about the E4494 trial. *Id*. at 29 (Ex. 1004 ¶¶ 32, 40). However, as Patent Owner correctly asserts, Dr. Longo does not state when he first received copies of such form or when he distributed them to patients. *See* Prelim. Resp. 26–27. Thus, Petitioner and Dr. Longo have not shown satisfactorily that such document was "publicly accessible" as a result of it being "disseminated."

As for showing that the E4494 Patient Consent Form was otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence can locate it, Petitioner and Dr. Longo explain that "any interested physician could have learned about the E4494 trial by, for example, visiting the list of active protocols on the ECOG website." Pet. 30 (citing Ex. 1004 ¶ 47; Ex. 1049, 4).[8] According to Petitioner and Dr. Longo, the website contains a list of active protocols indexed by subject matter under the heading "Lymphoma Committee" and provides the protocol number, such that an interested party could then access the protocol and patient consent form for that listed number. *Id*. at 30–31 (citing Ex. 1004 ¶¶ 47–48). Petitioner and Dr. Longo, however, fail to support that assertion with evidence that "any interested party" would know to visit the ECOG website to look for the E4494 Patient Consent Form, or that doing so would result in obtaining a copy of that document. The ECOG protocol listing on the website, Ex. 1049, does not provide direct access to the E4494 Patient Consent Form, e.g., in terms of a

[8] ECOG Active Protocols List, https://web.archive.org/web/19980519084342/http:/ecog.dfci.harvard.edu/~ecogdba/active_reports/Lymphoma.html (archived May 19, 1998) (Ex. 1049, App'x A).

hyperlink, nor does the website provide information as to what E4494 documents are available or how a website visitor may access them. For at least those reasons, Petitioner has not established that the E4494 Patient Consent Form was "otherwise made available" in a manner required for that document to be recognized as a "printed publication"

Thus, based on the information presented, we determine that Petitioner has not shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claims 1 and 2 over the E4494 Patient Consent Form and the FDA Transcript.

E. Obviousness over Sonneveld and Link

Petitioner asserts that claims 1 and 2 would have been obvious over Sonneveld and Link. Pet. 53–60.

1. Sonneveld

Sonneveld is a journal article describing a randomized, multicenter phase III trial performed to investigate the feasibility of CHOP chemotherapy in elderly patients (≥ 60) with advanced NHL of intermediate- and high-grade malignancy. Ex. 1009, 3. Along with the age requirement, eligible patients included those having a confirmed diagnosis of diffuse mixed or large-cell NHL, including groups D through H, and those having bulky disease. *Id*. at 4. Of 149 patients, 72 were randomly assigned to receive CHOP, and 79 received CNOP (replacing doxorubicin for mitoxantrone). *Id*. The characteristics of the analyzed patients are listed in Table 1 and the Response Rates are set forth in Table 2. *Id*. at 6. Sonneveld explains that "the response rate with CHOP is superior to that with CNOP, and the overall survival rate is also significantly better." *Id*. at 11. Based upon the study results, Sonneveld concludes that "CHOP is tolerated by the

majority of elderly patients and that toxicity is not an important cause of treatment failure." *Id*.

2. Analysis

Petitioner asserts that "Sonneveld teaches CHOP as a recommended therapy for patients over age 60 with DLCL, including patients with bulky disease." Pet 54. Petitioner asserts also that Link teaches administering a combination of CHOP and rituximab in DLCL patients. *Id*. According to Petitioner, it would have been obvious to combine the teachings of Sonneveld and Link to arrive at the inventions of claims 1 and 2. *Id*.

Patent Owner acknowledges that Sonneveld teaches treating 72 patients with CHOP, some of whom had DLCL (grade G NHL). Prelim. Resp. 56–57. Patent Owner, however, asserts that Petitioner has not shown that Sonneveld teaches that any of that specific population of patients also had bulky disease. *Id*. at 56. Rather, according to Patent Owner, Sonneveld describes some patients as having bulky disease without further characterizing those patients as having a grade of NHL corresponding to DLCL. *Id*.

We agree with Patent Owner. Indeed, Petitioner acknowledges that Sonneveld's patients represent a diverse NHL population, including diffuse mixed cell NHL, diffuse large cell NHL, and more particularly, IWF groups D through H. Pet. 53 (citing Ex. 1009, 4 and 5 (Table 1)). Petitioner asserts that the claim term "diffuse large cell lymphoma" does not require construction. *Id*. at 23. If construed, Petitioner contends that term should "refer to any diffuse large cell lymphoma, as recognized by those skilled in the art at the time," i.e., including DLCL grades F, G, and H under the IWF.

Id. Further, Petitioner explains that its "invalidity grounds remain viable under a construction of 'diffuse large cell lymphoma' as being equivalent to IWF grade G NHL," and not including IWF grades F or H. *Id*. at 23. However, even if we apply Petitioner's proposed construction that DLCL includes IWF grades F, G, and H, Petitioner has not shown that Sonneveld discloses treating such patients, wherein those patients also have bulky disease. Neither Petitioner nor Dr. Lossos has explained how a person of skill in the art would understand whether Sonneveld's IWF grade F, G, and/or H NHL patients have bulky disease. Nor do we see that Sonneveld discloses whether any patient having bulky disease also exhibits IWF grade F, G, or H NHL. *See* Ex. 1009, Table 1 (listing characteristics of trial patients separately). Link does not cure that deficiency as the reference does not teach treating DLCL patients having bulky disease, as discussed above in section II. B.

Thus, based on the information presented, we determine that Petitioner has not shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of claims 1 and 2 over Sonneveld and Link.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claims 1 and 2 of the '244 patent are unpatentable.

ORDER

Accordingly, it is hereby:

ORDERED that Petitioner's request for an *inter partes* review of claims 1 and 2 of the '244 patent is *denied*.

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