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Paper No. 9
Entered: November 13, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

BIOGEN, INC.,
Patent Owner.

Case IPR2017-01166
Patent 8,329,172 B2

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

Opinion of the Board filed by *Administrative Patent Judge* HARLOW.

Opinion Dissenting filed by *Administrative Patent Judge* SNEDDEN.

HARLOW, *Administrative Patent Judge.*

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

I. INTRODUCTION

Pfizer, Inc. ("Petitioner"), filed a Petition requesting an *inter partes* review of claim 1 of U.S. Patent No. 8,329,172 B2 (Ex. 1001, "the '172 patent"). Paper 2 ("Pet."). Biogen, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See also* 37 C.F.R. § 42.4 (a).

For the reasons set forth below, we deny the Petition.

A. Related Matters

The '172 patent has previously been challenged by each of Celltrion, Inc. and Boehringer Ingelheim International GmbH; however, the Board declined to institute *inter partes* review in those proceedings. Pet. 5; Paper 6, 2; *Celltrion, Inc. v. Biogen, Inc.*, IPR2017-01093 (PTAB Oct. 6, 2017) (Paper 12); *Boehringer Ingelheim Int'l GmbH v. Biogen, Inc.*, IPR2015-00418 (PTAB July 13, 2015) (Paper 14). The parties do not identify any additional proceedings involving the '172 patent.

Concurrent with this proceeding, Petitioner has also filed petitions for *inter partes* review involving U.S. Patent Nos. 8,557,244 B1 (IPR2017-01167) and 8,821,873 B2 (IPR2017-01168). Pet. 5; Paper 6, 2.

B. The ’172 Patent

The ’172 patent is titled “Combination Therapies for B-Cell Lymphomas Comprising Administration of Anti-CD20 Antibody.” Ex. 1001, [54]. The ’172 patent describes treating B-cell lymphomas with anti-CD20 antibodies combined with other therapeutic regimens, such as chemotherapy. Ex. 1001, 2:7–38. The ’172 patent explains that CD20 is a B-cell-restricted differentiation antigen that is usually expressed at very high levels on cancerous B-cells, and is “appealing for targeted therapy, because it does not shed, modulate, or internalize.” *Id*. at 1:33–41. The ’172 patent explains that a preferred anti-CD20 antibody “is C2B8 (IDEC Pharmaceuticals, Rituximab).” *Id*. at 2:59–60.

The ’172 patent discloses that rituximab, also known as “RITUXAN®” has been approved for use in relapsed and previously treated low-grade non-Hodgkin’s lymphoma (“LG-NHL”), but that such patients may nonetheless still be subject to disease relapse. *Id*. at 1:47–58. Therefore, the ’172 patent advises, “it would be advantageous if anti-CD20 antibodies had a beneficial effect in combination with other lymphoma treatments, and if new combined therapeutic regimens could be developed to lessen the likelihood or frequency of relapse.” *Id*. at 1:60–64.

In this regard, the ’172 patent describes a Phase III study conducted by the Eastern Cooperative Oncology Group (“ECOG”) of patients with LG-NHL in which a subset of patients responsive to cyclophosphamide, vincristine, and prednisone (“CVP”) chemotherapy “will undergo a second

randomization to Rituximab maintenance therapy (375 mg/m^2 weekly times 4 every 6 months for 2 years (Arm C)[)]." Ex. 1001, 13:8–16.

C. Illustrative Claim

Claim 1, reproduced below, is the sole claim of the '172 patent.

> 1. A method of treating low grade B-cell non-Hodgkin's lymphoma in a human patient comprising administering to the patient chemotherapy consisting of CVP therapy to which the patient responds, followed by rituximab maintenance therapy, wherein the maintenance therapy comprises four weekly administrations of rituximab at a dose of 375 mg/m^2 every 6 months, and wherein the maintenance therapy is provided for 2 years.

Ex. 1001, 22:56–63.

D. Evidence Relied Upon

Petitioner relies upon the following prior art references (Pet. 21–27):

Hochster et al., *Prolonged Time to Progression (TTP) In Patients with Low Grade Lymphoma (LGL) Treated with Cyclophosphamide (C) and Fludarabine (F) [ECOG1491]*, American Society of Clinical Oncology, Program/Proceedings, Thirty-Fourth Annual Meeting (May 1998) (Ex. 1005) ("Hochster I").

McNeil, *Non-Hodgkin's Lymphoma Trials In Elderly Look Beyond CHOP*, 90 J. NAT. CANCER INST. 266–67 (1998) (Ex. 1003) ("McNeil").

IDEC Pharmaceuticals Corporation and Genentech, Inc., Product label for Rituxan® (1997) (Ex. 1004) ("Rituxan Label").

Petitioner also relies upon the Declarations of Howard Ozer, M.D., Ph.D. (Ex. 1002) and Scott Bennett, Ph.D. (Ex. 1016) to support its contentions.

E. Asserted Ground of Unpatentability

Petitioner asserts the following ground of unpatentability (Pet. 6):

Claim	Basis	Reference(s)
1	§ 103(a)	Hochster I, Rituxan Label, and McNeil

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 invention, in the context of the entire disclosure. *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. 25–26; Prelim. Resp. 12–14. 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. Priority Date of the '172 Patent

The '172 patent issued from U.S. Patent Application No. 11/840,956, filed on August 18, 2007. Ex. 1001, [21], [22]. The '172 patent is a continuation of U.S. Patent Application No. 10/196,732, filed on July 17, 2002, now abandoned, which is a continuation of U.S. Patent Application No. 09/372,202, filed on August 11, 1999, now U.S. Patent No. 6,455,043. *Id*. at [63]. The '172 patent claims priority to U.S .Provisional Patent Application No. 60/096,180, filed on August 11, 1998. *Id*. at [60].

Petitioner contends that the subject matter of claim 1 does not find support in the provisional application to which the '172 patent claims priority. Pet. 6–9. Rather, Petitioner argues, the effective filing date of the claimed subject matter at issue here is August 11, 1999. *Id*. at 9. Patent Owner does not dispute Petitioner's contention. *See*, *e.g.*, Prelim. Resp. 12–15 (disputing status of Rituxan Label as prior art, but not challenging Petitioner's assertions regarding priority date). Therefore, for purposes of this decision, we accord the subject matter of claim 1 of the '172 patent an effective filing date of August 11, 1999. Furthermore, because Petitioner relies 35 U.S.C. § 102(b) as the basis for establishing each of the asserted references as prior art (Pet. 23, 26, and 27), we highlight that the '172 patent has a critical date of August 11, 1998.

C. Level of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

According to Petitioner, a person of ordinary skill in the art at the time of the invention would have been "a practicing oncologist with at least an M.D. degree and several years of experience treating patients with NHL and/or researching treatments for NHL, including with chemotherapeutic drugs." Pet. 10 (citing Ex. 1002 ¶ 15). Patent Owner does not address Petitioner's position on this matter and does not propose its own description for a person of ordinary skill in the art at the time of the invention.

At this stage in the proceeding, we determine that Petitioner's description of the level of ordinary skill in the art is supported by the current record. Moreover, we have reviewed the credentials of Dr. Ozer (Ex. 1002, Attachment A), and, at this stage in the proceeding, we consider him to be qualified to opine on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention. We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Obviousness over Hochster I, Rituxan Label, and McNeil

Petitioner asserts that claim 1 is unpatentable under § 103 as obvious in view of the combination of Hochster I, the Rituxan Label, and McNeil. Pet. 21–52. Patent Owner disagrees. Prelim. Resp. 12–53.

1. Hochster I

Hochster I describes the results of a phase I/II study examining the combination of fludarabine ("F") and cyclophosphamide ("C") as a first-line chemotherapy to treat LG-NHL patients. Ex. 1005, *66. Hochster I states that based on the "promising" results of that study, "we are conducting phase III study of CF vs. CVP ± anti-CD20 maintenance with PCP & H-Z prophylaxis (E1496)."[1] *Id*.

2. 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. 1004, 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 various clinical trials in which 375 mg/m^2 of Rituxan was administered intravenously weekly for four doses to patients

[1] As Dr. Ozer explains, "the phrase 'PCP & H-Z prophylaxis' referred to standard treatments to prevent infections associated with chemotherapy and drugs that affect the immune system (e.g., rituximab)." Ex. 1002 ¶ 56.

having relapsed or refractory NHL, including relapsed or refractory LG-NHL. *Id*.

3. McNeil

McNeil describes a randomized trial for elderly patients with intermediate-grade NHL involving a combination treatment of CHOP and Rituxan (IDEC-C2B8). Ex. 1003, 266. McNeil explains that the trial, organized by the ECOG, "will recruit 630 patients age 60 and over" to receive the combination therapy. *Id*. McNeil additionally discloses that the trial will test the efficacy of CHOP plus rituxan maintenance therapy. *Id*. McNeil states that "[a]fter initial therapy, patients who responded will be again randomly assigned to receive the maintenance regimen — Rituxan every 6 months for 2 years — or observation." *Id*. McNeil further observes that "[t]his is the first randomized trial to address maintenance therapy in any kind of NHL." *Id*.

4. Discussion

Petitioner contends that claim 1 of the '172 patent is rendered obvious by the combination of Hochster I, the Rituxan Label, and McNeil because Hochster I discloses treating LG-NHL patients with CVP therapy, followed by rituximab maintenance therapy (Pet. 28–33), the Rituxan Label teaches the administration of four weekly doses of 375 mg/m^2 of Rituxan (*id*. at 33–38), and McNeil describes a study evaluating the administration of Rituxan maintenance therapy every six months for two years (*id*. at 39–45). Petitioner further asserts that the method of claim 1 produces no unexpected

results, and thus, the evidence of secondary indicia of nonobviousness presented during prosecution of the ’172 patent is insufficient to establish the nonobviousness of claim 1. *Id*. at 45–52.

Patent Owner responds first that the Rituxan Label does not qualify as prior art because Petitioner has not presented evidence that the label “is a copy of a document publicly disseminated before the priority date” of the ’172 patent. Prelim. Resp. 13. Patent Owner additionally contends that Petitioner fails to establish a rational for combining the cited references to arrive at the claimed invention (*id*. at 16–45), and that Petitioner fails to establish a reasonable expectation of success in using the rituximab maintenance protocol recited in claim 1 of the ’172 patent. *Id.* at 45–53.

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” for purposes of this decision. Accordingly, we determine that, for purposes of this Decision, the Rituxan Label is unavailable as prior art against the ’172 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 bears the ultimate burden of persuasion to prove unpatentability by a preponderance of the evidence, as well as the initial burden of production to establish the existence of prior art that renders the claims unpatentable. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015). In this regard, we have often required a petitioner to make a threshold showing that the reference relied upon was publicly accessible as a printed publication prior to the effective filing date of a challenged patent. *See, e.g.*, *Mylan Pharms. v. Boehringer Ingelheim Int'l GmbH*, Case IPR2016-01566, slip op. at 10–12 (PTAB Feb. 3, 2017) (Paper 15) (finding that purported "printed package insert" was not a printed publication); *Frontier Therapeutics, LLC v. Medac Gesellschaft Fur Klinische Spezialpraparate MBH*, Case IPR2016-00649, slip op. at 22 (PTAB Sept. 1, 2016) (Paper 10) (same).

To establish that the Rituxan Label was publicly accessible before August 11, 1998, Petitioner relies on the testimony of its document authentication and public accessibility declarant, Dr. Bennett (Ex. 1002), who supports his testimony with: (1) a copy of the Rituxan Label obtained from the FDA website on an unspecified, but relatively recent date (Ex. 1016, Attachment 2a); (2) a printout of the Rituxan page from the Genentech website as it existed on January 23, 1998 (*id*. at Attachment 2b); and (3) a paper by Leget and Czuczman published in November 1998 (*id*. at

Attachment 2d).[2] Petitioner also relies on the entry for Rituxan in the 1999 edition of the Physician's Desk Reference ("PDR") (Ex. 1039) and a disclosure by Maloney of a Rituxan dosage regimen of "4 weekly doses of 375 mg/m^2".[3] As explained below, however, because none of the evidence proffered by Petitioner, either alone or in combination, suggests that the Rituxan Label was disseminated or otherwise made available to ordinarily skilled artisans exercising reasonable diligence prior to the critical date for the '172 patent, this evidence is insufficient to establish, for purposes of this decision, the public accessibility of that reference.

Turning first to the copy of the Rituxan Label obtained from the FDA website, the fact that said label "is available *today* from the FDA's website, which represents that it is the original approved label for Rituxan™ as of November 26, 1997" (Pet. 24 (emphasis added)) is not pertinent to the question of whether the Rituxan Label was publicly accessible before August 11, 1998. In this regard, we note that the record is devoid of evidence concerning the availability of the Rituxan Label from the FDA website (or elsewhere) prior to the critical date of the '172 patent. Indeed, Petitioner does not affirmatively assert that the Rituxan Label embodied in Exhibit 1004—the only version of that label relied upon as prior art in this

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[2] Leget and Czuczman, *Use of rituximab, the new FDA-approved antibody*, 10(6) CURR. OPIN. ONCOL., 548–551 (1998) (Ex. 1016, Attachment 2d).
[3] 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 (1994) (Ex. 1008).

proceeding—was itself disseminated or otherwise made available to interested relevant artisans before the priority date of the '172 patent. *See* Pet. 24–25 (arguing that the appearance of the same or substantially the same *information* as set forth in the Rituxan Label of Exhibit 1004, on the Genentech website, in a different form, establishes the public accessibility of Exhibit 1004).

Furthermore, the FDA website's present identification of the Rituxan Label as the originally approved label, without more, is insufficient to establish that such label was publicly accessible prior to August 11, 1998. For example, Petitioner neither asserts, nor offers evidence to suggest that the version of the Rituxan Label on the FDA website was in fact included as a package insert with Rituxan, or indicating when any Rituxan package insert was made available to interested artisans. Nor does Petitioner contend that Rituxan was on sale, or otherwise available to the public prior to the critical date for the '172 patent. Absent additional context, we do not find the fact that the FDA website currently identifies the partially handwritten Rituxan Label as the first approved version of that label persuasive evidence, for purposes of this Decision, that the Rituxan Label was disseminated or otherwise available to reasonably diligent interested artisans before the critical date of the '172 patent.

As to the printout of the January 23, 1998 version of the Rituxan webpage on the Genentech website obtained from the Internet Archive ("Rituxan Webpage," Ex. 1016, Attachment 2b), even accepting Petitioner's contention that the webpage includes the same information as the Rituxan

Label, the fact remains that the Rituxan Webpage and Rituxan Label are not the same document. Rather, "Rituximab" is partially written by hand on the Rituxan Label but not the Rituxan Webpage, and the two documents bear different layouts. Because the Rituxan Webpage and Rituxan Labels are materially different documents, and Petitioner offers no explanation as to why the purported public accessibility of the Rituxan Webpage establishes that the Rituxan Label was likewise accessible, we find Petitioner's reliance on the Rituxan Webpage unpersuasive. *See SRI Int'l*, 511 F.3d at 1194 ("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." (quoting *Bruckelmyer*, 445 F.3d at 1378) (emphasis added)); *see also* 35 U.S.C. § 311(b) ("A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims . . . on the basis of prior art consisting of patents or printed publications.").

Moreover, Petitioner does not present evidence sufficient to show, for purposes of this Decision, that the Rituxan Webpage was in fact publicly accessible. "[E]vidence that a query of a search engine before the critical date, using any combination of search words, would have led to the [reference] appearing in the search results" is probative of public accessibility. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016). Absent such evidence of indexing, various additional factors, including testimony indicating that the particular online publication

in question was well-known to the community interested in the subject matter of the reference, and the existence of numerous related articles located within the same publication can support a determination of public accessibility. *See Voter Verified*, 698 F.3d at 1380–81.

For example, Petitioner does not endeavor to establish that the Rituxan Webpage, or the Genentech website of which it was a part, was well-known to the community interested in the subject matter of the reference, indexed, or that it included numerous related articles. Petitioner relies instead on Dr. Bennett's testimony that

> [i]t is *self-evident* that Genentech *would have wished* to make Document 2 readily available to physicians and others. Therefore, the reasonable conclusion is that (1) internet search engines in 1997 would have been able to find and index Document 2, and (2) that a person of ordinary skill in the art in 1997 using typical internet search tools would have readily found a copy of Document 2.

Ex. 1016 ¶ 51 (emphasis added). We give such unsupported and conclusory testimony little weight. 37 C.F.R. § 42.65(a).

With regard to Leget and Czuczman, Petitioner has not adequately shown that the citation to "Rituximab [package insert]" in fact refers to the version of the Rituxan Label in Exhibit 1004, handwriting and all. Indeed, Dr. Bennett simply concludes, without evidence or explanation, that Leget and Czuczman identifies the Rituxan Label "as the 13th item in its list of references." Ex. 1016 ¶ 52. We give such testimony little weight. 37 C.F.R. § 42.65(a). We are similarly unpersuaded by Dr. Bennett's

unsupported and conclusory testimony that even though Leget and Czuczman was published months after the critical date for the '172 patent,

> [g]iven the time required to research and write a paper, to submit the paper and have it reviewed, and to have it published, it is reasonable to assume the Leget and Czuczman paper was in preparation prior to August 1998. That Document 2 was therefore in actual public use prior to August 1998 is a reasonable inference.

Ex. 1016 ¶ 52; *see* 37 C.F.R. § 42.65(a). We, therefore, determine, for purposes of this Decision, that reference in Leget and Czuczman, which was published after the critical date of the '172 patent to an unspecified "Rituximab [package insert]" does not support Petitioner's contention that the Rituxan Label was publicly available before August 11, 1998.

Concerning the Rituxan entry in the 1999 PDR, first, as explained above, even crediting Petitioner's assertion that the 1999 PDR includes the same information as the Rituxan Label (Pet. 25), the fact remains that the Rituxan entry in the 1999 PDR and the Rituxan Label are not the same document. *Compare* Ex. 1039 *with* Ex. 1004. Second, even accepting Petitioner's assertion that the PDR was received by the National Library of Medicine on December 30, 1998 (Pet. 25), the record does not include evidence to support the conclusion that the 1999 PDR was publicly accessible prior to the August 11, 1998 critical date for the '172 patent.

As to Petitioner's contention that "the relevant information cited below from the Rituxan™ label (*e.g.*, the dosage regimen of '4 weekly doses of 375 mg/m^2') was also publicly available in the Maloney paper, which was published in September 1997" (Pet. 25 (quoting Ex. 1008, 1)), we again

observe that evidence that two distinct documents disclose the same information, without more, is insufficient to establish one document as persuasive support for the public accessibility of the other. Moreover, we note that Petitioner did not rely on Maloney in its asserted ground of unpatentability as a basis for selecting the recited dose of rituximab, and, thus, Petitioner cannot belatedly rely on Maloney as disclosing the steps of claim 1 for which it relies on the Rituxan Label in its Petition. *See* Pet. 34 ("it would have been obvious to select the already-approved and clinically proven dosing regimen that was explicitly 'recommended' by the Rituxan[] label for LG-NHL.").

Accordingly, in view of the above, we determine that Petitioner has failed to establish sufficiently in the Petition that the Rituxan Label was publically accessible as of the critical date of August 11, 1998. Thus, on this record, the Rituxan Label fails to qualify as prior art under 35 U.S.C. § 102, and Petitioner has not established a reasonable likelihood of prevailing in demonstrating the obviousness of claim 1 without the Rituxan Label.

The Dissenting Opinion ("Dissent") raises several points which we deem important to address. To begin, the Dissent contemplates whether the record "convincingly" establishes the public accessibility of the Rituxan Label. Dissent 3, 7. We note, however, that this is not the standard applied in the instant Decision, or at any stage of an *inter partes* review proceeding. Rather, as set forth above, pursuant to the requirement that an *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood

that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition" (35 U.S.C. § 314(a)), we assess in this Decision whether Petitioner has made a threshold showing that the Rituxan Label is a "printed publication" within the meaning of 35 U.S.C. §§ 102 and 311(b), and, for the reasons discussed, determine that it has not.

We also observe that the Dissent appears to place upon Patent Owner a burden to assist Petitioner in demonstrating that a cited reference is a prior art printed publication. Dissent 3 ("Patent Owner is uniquely positioned to know whether or not those references were publicly disseminated prior to the critical date of August 11, 1998."). Such a requirement would contravene our statutory mandate, as we are required under 35 U.S.C. § 314(a) to decide whether to institute a trial based on "the information presented in the petition," not the information that a Petitioner might obtain, with the cooperation of the Patent Owner.

Moreover, insofar as the Dissent proposes that Petitioner may be able to cure the above-described deficiencies relating to the public accessibility of the Rituxan Label through resort to 37 C.F.R. §§42.123(a) and/or 42.64(b)(2), it does not explain how such discovery could cure the defects of that Exhibit. Dissent 3–6. For example, the Dissent does not address the fact that the Petition does not allege or endeavor to establish that the Rituxan Label, i.e., Exhibit 1004, was publicly accessible before the critical date of the '172 patent.[4]

[4] In this respect, we note that although the Dissent appears to acknowledge

Further, the cases to which the Dissent refers that permitted the submission of supplemental information to support public accessibility are, significantly, addressed to situations where that information "does not change the grounds of unpatentability authorized in [the] proceeding, nor does it change the evidence initially presented in the Petition to support those grounds of unpatentability." *Biomarin Pharm. Inc. v. Genzyme Therapeutic Prods. Ltd. P'shp*, Case IPR2013-00534, slip op. at 5–6 (PTAB Jan. 7, 2015) (Paper 80); *see also Valeo North America, Inc. v. Magna Elecs., Inc.*, Case IPR2014-01204, slip op. at 2–3, 5 (PTAB Apr. 10, 2015) (Paper 26) ("[W]e agree with Petitioner that the proffered information (Exhibits 1026–1031) does not change the grounds of unpatentability or the evidence presented initially in the Petition."); *Ford Motor Co. v. Paice LLC*, Case IPR2014-01415, slip op. at 2 (PTAB Apr. 27, 2015) (Paper 15) (unopposed motion to submit supplemental information); *VOXX International Corp. v. Johnson Safety, Inc.*, Case IPR2017-00554, slip op. at 7–12 (PTAB June 14, 2017) (Paper 9) (not addressed to the submission of supplemental information or supplemental evidence).

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that the Rituxan Label (Ex. 1004) and the Rituxan Website (Ex. 1016, Attachment 2b) are distinct documents, the Dissent nevertheless appears occasionally to conflate them. *Compare* Dissent 5 ("Rituxan Webpage is a printout of a Genentech webpage . . . containing the same or substantially the same material content found in Rituxan Label.") *with id.* at 7 ("Rituxan Label, a label for a drug approved by the FDA in November 1997 and posted to the manufacturer/distributor's website in January 1998"). As set forth above, we determine that the Rituxan Label and Rituxan Website are materially different documents.

In this regard, we note that the suggestion that Petitioner might, during trial, adduce evidence that either the Rituxan Website (Dissent 4) or "the commercially approved drug label for Rituxan" (*id*. at 5) was publicly accessible before the critical date of the '172 patent would do little to establish that the Rituxan Label relied upon as prior art in the Petition was itself publicly accessible. We likewise observe that reliance on either the Rituxan Website or the commercially approved drug label for Rituxan, rather than the Rituxan Label of Exhibit 1004, would change the grounds of unpatentability set forth in the Petition, a scenario not contemplated by the aforementioned cases.

We similarly clarify, contrary to the Dissent's implication (Dissent 4–7), that the Petition relies solely upon the Rituxan Label as disclosing the administration of four weekly doses of 375 mg/m^2 of Rituxan (Pet. 33–38). Neither Maloney, the Rituxan Website, nor an alternate, commercially approved drug label for Rituxan is relied upon as prior art in a ground of unpatentability asserted in this proceeding. Indeed, because the '172 patent includes only a single claim, if any such reference were relied upon as prior art in the Petition, it necessarily would be asserted against claim 1. Consequently, while the Dissent identifies several instances where the Board has applied prior art relied upon as to one ground of unpatentability to a claim not expressly challenged under that ground, *see e.g.*, *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, slip op. at 22 (PTAB Jan. 9, 2013) (Paper 15), those cases are inapposite to the course of action the Dissent advocates here. Namely, none of the cited cases stands for the

proposition that a document not relied upon in the Petition as prior art for any asserted ground of unpatentability should, sua sponte, be added or substituted into an asserted ground of unpatentability by the Board.

Lastly, we observe that while the Dissent disagrees with our determination that Petitioner has not adequately established, for purposes of institution, that the Rituxan Label was publicly accessible prior to the critical date for the '172 patent, it does not otherwise undertake to squarely address the merits of the Petition so as to make a determination as to whether trial should be instituted.

III. ORDER

In consideration of the foregoing, it is

ORDERED that the Petition is DENIED and no trial is instituted.

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Case IPR2017-01166
Patent 8,329,172 B2

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

SNEDDEN, *Administrative Patent Judge*, dissenting.

I agree with the majority's recitation of the facts, established by the present record. I also agree with the majority's evaluation that the evidence submitted by Patent Owner casts doubt on Petitioner's assertion that either Rituxan Label (Ex. 1004) or Rituxan Website (Ex. 1016, Attachment 2b) are

prior art to the ’172 patent. Where the majority and I part ways, however, is whether this record meets the “reasonable likelihood” standard for institution of an *inter partes* review. Because I find that the information presented in the Petition and the Preliminary Response shows that there is a reasonable likelihood Petitioner would prevail on the merits of Petitioner’s contention that claim 1 of the ’172 patent would have been obvious over the asserted art, I respectfully dissent.

In an *inter partes* review trial, the petitioner bears the burden of establishing unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden only applies at the conclusion of the trial and the close of the evidence; we do not require a petitioner to meet its ultimate burden based on the information in its petition alone. Rather, the statute speaks in general terms of whether *the record* as it stands at that time of the decision on institution – “the information presented in the petition . . . and any response” – shows that there is a reasonable likelihood of the petitioner prevailing. 35 U.S.C. § 314(a).

The reasonable likelihood standard for instituting *inter partes* review is, therefore, not a *lower* standard of proof than a preponderance of the evidence, but instead asks whether the same preponderance standard is reasonably likely to be met *at a later time*. We must assess the persuasiveness of the petitioner’s evidence while “recognizing that [we are] doing so without all evidence that may come out at trial.” *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 883 (Fed. Cir. 1992); *See also, Genzyme Therapeutic Prods. Ltd. P’ship v. Biomarin Pharma. Inc.*,

825 F.3d 1360, 1367 (Fed. Cir. 2016) ("The purpose of the trial in an *inter partes* review proceeding is to give the parties an opportunity to build a record by introducing evidence—not simply to weigh evidence of which the Board is already aware.").

The majority faults Petitioner for not establishing sufficiently that either Rituxan Label or Rituxan Website were publicly available more than one year prior to the filing date of the '172 patent. *See* Majority Opinion, Section II.D.4. I agree that the record, as it currently stands, does not convincingly establish this fundamental aspect of Petitioner's case. But the record does not convincingly establish the converse, either. Rituxan Label and Rituxan Website disclose the commercially approved drug label for Patent Owner's own drug product. Thus, Patent Owner is uniquely positioned to know whether or not those references were publicly disseminated prior to the critical date of August 11, 1998. Notably missing from the record is Patent Owner's affirmative statement that the commercially approved drug label for Rituxan was not publicly disseminated prior to the critical date of August 11, 1998.

In any event, for the purposes of determining whether to institute *inter partes* review, we need not resolve the parties' dispute over whether Rituxan Label is a printed publication. We need only determine whether Petitioner has shown a reasonable likelihood of proving by a preponderance of evidence that Rituxan Label is a printed publication. In doing so, we must be aware of the mechanisms available to Petitioner at trial for responding to evidentiary challenges. Specifically, Petitioner would have the opportunity

at trial to respond to Patent Owner's contentions with regard to sufficiency of evidence with supplemental information under § 42.123(a) and/or evidentiary objections with supplemental evidence under 37 C.F.R. § 42.64(b)(2). *See generally Groupon Inc. v. Blue Calypso, LLC*, Case CBM2013-00033, slip op. at 25 (PTAB May 12, 2013) (Paper 29) (distinguishing admissibility of evidence from sufficiency of evidence). The Board has granted other petitioners' motions to submit supplemental information under 37 C.F.R. § 42.123, in order to confirm the public availability of references upon which trial had been instituted. *Biomarin Pharm. Inc. v. Genzyme Therapeutic Prods. Ltd. P'shp*, Case IPR2013-00534, slip op. at 5–6 (PTAB Jan. 7, 2015) (Paper 80); *Valeo North America, Inc. v. Magna Elecs., Inc.*, Case IPR2014-01204, slip op. at 2–3, 5 (PTAB Apr. 10, 2015) (Paper 26); *Ford Motor Co. v. Paice LLC*, Case IPR2014-01415, slip op. at 2 (PTAB Apr. 27, 2015) (Paper 15); *VOXX International Corp. v. Johnson Safety, Inc.*, Case IPR2017-00554, slip op. at 7–12 (PTAB June 14, 2017) (Paper 9). I see no reason why, in this case, Petitioner should not be afforded a similar opportunity, given that it has made a threshold showing in its Petition.

Considering the evidence proffered by Petitioner, I would conclude that there is a reasonable likelihood that Petitioner may yet, during the course of an *inter partes* review trial, adduce evidence sufficient to prove that either Rituxan Label or Rituxan Website were publicly available as of the critical date. There is no dispute that, in November 1997, the U.S. Food and Drug Administration ("FDA") approved the biologic rituximab under

the brand name Rituxan. Ex. 1002 ¶ 49; *see also*, Ex. 1036, 1. Furthermore, Rituxan Label contains a "November 1997" copyright notice identifying IDEC Pharmaceuticals Corporation[5] and Genentech, Inc. as author. Ex. 1004, 2. The Rituxan Label appears to be the type of literature that would be disseminated to physicians and provided with the drug upon purchase. Ex. 1004. While Rituxan Label is modified in the top margin to include a handwritten "Rit" to complete the spelling of "Rituximab" on the document provided by Petitioner, there is no allegation or any information that the document is a forgery, or that it has been altered materially. Indeed, this "handwritten" version of the Rituxan drug label is the exact version obtainable from the FDA website. Ex. 1016 ¶¶ 50 (Attachment 2a).

Rituxan Website further corroborates Petitioner's positon that the commercially approved drug label for Rituxan was publicly available prior to August 11, 1998. Rituxan Webpage is a printout of a Genentech webpage archived by the Internet Archive ("Wayback Machine") on January 23, 1998, containing the same or substantially the same material content found in Rituxan Label. Ex. 1016 ¶¶ 51 (Attachment 2b). Rituxan Website also contains the identical copyright notice and document number "G48097-R0 (544) November 1997" that appears on Rituxan Label. *Id*.; *compare*, Ex. 1039, 8 (a copy of the Rituxan label appearing in the 1999 edition of the *Physician's Desk Reference* having a 1998 copyright notice and document number "4809702 Revised July1998.").

[5] IDEC Pharmaceuticals Corporation merged with Biogen, Inc.

The majority further faults Petitioner for failing to indicate that Rituxan was available for sale prior to August 11, 1998. This information is precisely the type of specific facts that may be established at trial under additional discovery. *See Garmin Int'l Inc. et al. v. Cuozzo Speed Techs*. LLC, IPR2012-00001, Paper 26, 3–4 (discussing the five factors the Board typically weighs when considering whether additional discovery in an IPR is "necessary in the interest of justice.").

Moreover, I note that Petitioner also relies on Maloney for the relevant information disclosed in Rituxan Label, which further supports a conclusion that the information presented in the Petition demonstrates a reasonable likelihood that Petitioner would prevail with respect to its challenge to claim 1. *See* Pet. 25 ("[T]he relevant information cited below from the Rituxan™ label (e.g., the dosage regimen of '4 weekly doses of 375 mg/m^2') was also publicly available in the Maloney paper, which was published in September 1997."). Accordingly, the Petition provides an alternative reference for the relevant information that may be relied upon in our institution determination. Although the statutes and rules require the petition to set forth its bases for challenging the elements of the claims by identifying specific evidence, the Board is not constrained to the cited column and line numbers of a reference in evaluating the evidence for a given claim element. The Board has previously instituted review by considering prior art that was cited in the petition, but not cited against particular challenged claims. *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012–00001, slip op. at 22 (PTAB Jan. 9, 2013) (Paper 15);

see also, 10X Genomics, Inc. v. Raindance Techs., Inc., Case IPR2015–01558, slip op. at 3–4 (PTAB Feb. 24, 2016); *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1313 (Fed. Cir. 2015) (governing statutory provisions do not limit the Board's authority to proceed with AIA trial proceedings only on the specific statutory grounds alleged in the petition).

In summary, the majority finds fault with each individual piece of evidence proffered by Petitioner, but fails to consider the record as a whole. When the record is viewed as a whole, the information establishes a reasonable likelihood that Petitioner would be able to meet its burden of showing that Rituxan Label, a label for a drug approved by the FDA in November 1997 and posted to the manufacturer/distributor's website in January 1998, was disseminated to the public prior to August 11, 1998.[6] While the majority identifies shortcomings in Petitioner's evidence, Petitioner should be allowed to address those shortcomings at trial. To require Petitioner to fully establish public availability at this stage of the proceeding ignores the fact that, during trial, there are opportunities for a petitioner to introduce additional evidence. The Petitioner may not provide evidence to convincingly establish that either Rituxan Label (Ex. 1004) or Rituxan Website (Ex. 1016, Attachment 2b) are printed publications.

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[6] *Concrete Pipe & Products of California, Inc. v. Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 622 (1993), states that the burden of showing something by a preponderance of the evidence simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.

However, in my view, Petitioner has presented sufficient evidence to make a "threshold showing" of public availability as to either Rituxan Label (Ex. 1004) or Rituxan Website (Ex. 1016, Attachment 2b), which is all that is necessary at this stage of *inter partes* review. I would then proceed to consider the merits of Petitioner's unpatentability arguments, and determine that institution of an *inter partes* review is justified. Because the majority's decision does not do so, I respectfully dissent.

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