UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner

v.

BIOGEN, INC.,
Patent Owner

Inter Partes Review No. IPR2017-01167
Patent No. 8,557,244 B1
Issued: October 15, 2013
Filed: July 28, 2000

Title: TREATMENT OF AGGRESSIVE NON-HODGKIN'S LYMPHOMA WITH ANTI-CD20 ANTIBODY

PETITIONER'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

I. INTRODUCTION AND STATEMENT OF REQUESTED RELIEF

Pursuant to 37 C.F.R. § 42.71(d), Pfizer, Inc. ("Petitioner") requests rehearing of the Board's Decision Denying Institution of *Inter Partes* Review of U.S. Patent No. 8,557,244 (Paper 8) ("Decision"). Specifically, this request seeks rehearing of the Decision denying to institute *inter partes* review of the '244 patent as obvious over the combination of prior art references asserted in Grounds I and II. This is Petitioner's first rehearing request, and it is timely filed. *See* 37 C.F.R. § 42.71(d).

Rehearing is warranted because the panel overlooked key evidence cited in the Petition that undermines the Board's rationale for denying institution of both grounds. The panel denied institution after finding that, "[w]ithout more" evidence, it would not accord persuasive weight to the sworn opinion of Petitioner's expert Dr. Ozer that there are "no significant distinctions in treating" patients with intermediate-grade Non-Hodgkin's Lymphoma ("NHL") classified as Grades F, G, or H. Decision at 10. The panel overlooked that "more" evidence—including three prior-art references that support Dr. Ozer's opinion—were, in fact, presented in the Petition on pages 9 and 10 to support this precise point. This oversight led to a clearly erroneous factual finding, thus warranting rehearing.

As background, the '244 patent covers methods of administering rituximab and CHOP chemotherapy to treat patients over 60 years old with a form of NHL called diffuse large cell lymphoma ("DLCL") who also have bulky disease. The

panel construed DLCL as limited to "Working formulation" (IWF) Grade G, and excluded IWF Grades F and H. Decision at 5.

There was no dispute that the prior-art Shipp reference disclosed the successful use of CHOP to treat intermediate-grade NHL patients (IWF Grades F, G, and H) over 60 with bulky disease. *Id.* at 6. In view of prior art encouraging the use of rituximab with CHOP, Petitioner argued it was obvious to combine the CHOP therapy used in Shipp with rituximab, thus rendering all claims of the '244 patent obvious.

In support, Petitioner's expert, Dr. Ozer, acknowledged that Shipp does not expressly say whether the studied patients with IWF Grade G were over 60, but he explained that this omission was immaterial because "'there were no significant distinctions in treating these three intermediate and high-grade lymphomas (types F, G, H), all of which are very similar.' Ex. 1002 ¶ 52." *Id.* at 10. The panel, however, denied institution on the ground that, "[w]ithout more" evidence, it would "not accord persuasive weight to Dr. Ozer's opinion that the understanding of those in the art is that there are 'no significant distinctions in treating' the three intermediate and high-grade lymphomas disclosed in Shipp." *Id.* (emphasis added); *see also id.* at 13.

This was clear error, because the panel overlooked that the Petition actually relied on and cited "more" evidence that supports Dr. Ozer's opinion. Pages 9-10

of the Petition not only explained that "[l]ymphomas categorized as intermediate- or high-grade were often studied together, as treatments were considered to be the same," but also cited three prior-art references (including not only Shipp, but also Link and Coiffier) confirming Dr. Ozer's sworn opinion on this point. Petition at 10; Ex. 1002 ¶ 52.

It appears that the panel overlooked this discussion, because it did not address the relevant teachings in Shipp in view of the related teachings in Link and Coiffier—all of which corroborate Dr. Ozer's opinion. Indeed, despite Petitioner's citation to three prior-art references and an expert declaration, Patent Owner cited nothing to refute Dr. Ozer's opinion that there are "no significant distinctions in treating" patients classified with IWF Grades F, G, or H. A POSA would have been motived by other prior art cited in the Petition that indisputably encouraged combining the CHOP chemotherapy used in Shipp with rituximab to render the claimed invention as a whole obvious. *See* Decision at 6-9, 12. Petitioner thus presented at least "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See* 35 U.S.C. § 314(a).

By overlooking key evidence cited in the Petition, the panel clearly erred in denying institution on the ground that "more" evidence was needed. For the reasons explained below, Petitioner respectfully requests that institution be granted on both grounds set forth in the Petition.

II. LEGAL STANDARD

Pursuant to 37 C.F.R. § 42.71(d), a party may request rehearing of the Board's decision to deny institution of a trial. The Board reviews its underlying decision for abuse of discretion when rehearing a decision on the petition. *Id.* § 42.71(c). An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or *clearly erroneous factual findings*, or . . . a clear error of judgment." *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (emphasis added) (citations omitted); *see also Lupid Ltd. v. Pozen, Inc.*, IPR2015-01774, Paper 21 at 3 (PTAB May 24, 2017). Further, the request must identify, specifically, all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d). Panels of the Board have granted rehearing based on clearly erroneous factual findings. *See, e.g., Asustek Comput., Inc. v. Avago Techs. Gen. IP (Singapore) Pte. Ltd.*, IPR2016-00647, Paper 23 at 2, 5-6 (PTAB Mar. 8, 2017) (granting rehearing on the basis that the panel "overlooked evidence in the Petition and supporting declaration"); *AVX Corp. v. Greatbatch Ltd.*, IPR2015-00710, Paper 13 at 6, 15-16 (PTAB Jan. 13, 2016) (granting hearing after the panel agreed that they "overlooked Petitioner's" evidence and was "persuaded that the [overlooked] evidence of record sufficiently supports [Expert's] testimony").

III. FACTS

The two claims of the ’244 patent are generally directed to a method (1) of treating a patient with DLCL by (2) administering rituximab (3) in combination with CHOP chemotherapy, (4) wherein the patient is >60 years old (5) and has bulky disease (tumor >10 cm in diameter). Ex. 1001, 8:41-49. The panel of the Board concluded that “DLCL” is “represented only by an IWF Grade G designation and does not include diffuse mixed cell NHL (IWF Grade F) or immunoblastic, large cell NHL (IWF Grade H).” Decision at 5.[1]

The Petition challenged both claims of the ’244 patent on two grounds. Petition at 6. Ground I challenged the ’244 patent claims as obvious over the combination of Shipp, McNeil, and Link. *Id.* Ground II challenged the ’244 patent claims as obvious over the combination of Shipp and Coiffier. *Id.*

[1] Although Petitioner did not agree to such a narrow construction, it accepts that construction for purposes of this rehearing request. *See* Decision at 5 (Petitioner argued that “DLCL would be categorized as an intermediate- or high-grade NHL according to the Kiel classification as well as the REAL classification, *or* as a ‘working formulation’ (‘WF,’ sometimes labeled ‘IWF’) type ‘G’ lymphoma.”) (emphasis added).

The Petition argued that "Shipp teaches all of the elements of claim 1, except for including rituximab in the treatment." Decision at 10, 12-13. For example, Shipp taught that CHOP was the "standard therapy" for treating DLCL patients. Petition at 12; Ex. 1009, 1. Shipp studied not only patients with IWF Grade G NHL, but also patients with IWF Grades F and H. Decision at 10. Four of the 30 patients in the study were older than 60, and all four had bulky disease in line with the patent claims (i.e., one tumor greater than 10 cm). *Id.* at 6, 10. As the panel noted, Dr. Ozer "acknowledges that 'Shipp does not say whether these elderly patients had 'diffuse [Grade F],' 'diffuse large cell [Grade G],' or 'immunoblastic large cell [Grade H]' lymphoma." *Id.* at 10 (quoting Ex. 1002).

The panel further recognized that, according to Dr. Ozer, this omission is not material to the obviousness analysis: "According to Dr. Ozer, Shipp's failure to distinguish which patients had which disease 'reflects the understanding of those in the art that there were no significant distinctions in treating these three intermediate and high-grade lymphomas ([Grades] F, G, H), all of which are very similar.'" *Id.* The panel nonetheless declined to credit Dr. Ozer's opinion: "However, Dr. Ozer has not identified any discussion in Shipp to support that reasoning, or referred us to any other evidence to support that assertion. *Without more, we do not accord persuasive weight to Dr. Ozer's opinion that the understanding of those in the art is that there are 'no significant distinctions in treating' the three intermediate and*

high-grade lymphomas disclosed in Shipp.'" *Id.* (emphasis added). For this reason, and because it also found that the remaining prior-art references relied upon by Petitioner did not "cure the deficiency in Shipp . . . ," the panel declined to institute Grounds I and II. *Id.* at 11, 13.

IV. BASIS FOR RELIEF REQUESTED

The panel clearly erred when it denied institution on the ground that "more" evidence—apart from Dr. Ozer's discussion of Shipp, which drew no distinctions among treating NHL Grades F, G, or H—was needed to show "no significant distinctions" in treating patients classified as Grades F through H. *Id.* at 10. The Petition itself provides the evidence that purportedly was missing "to support that assertion." *Id.* The panel overlooked this evidence and, therefore, rehearing should be granted.

On pages 9-10 of the Petition, Petitioner identified the following evidence to support the proposition that "*[l]ymphomas categorized as intermediate- or high-grade were often studied together, as treatments were considered to be the same*. Ex. 1002 ¶ 37; *see also, e.g.*, Ex. 1009, Shipp at 2 (studying diffuse mixed, DLCL, and immunoblastic large cell lymphomas together); Ex. 1006, Coiffier at 2-3 (*studying four types of intermediate- and high-grade lymphomas*); Ex. 1005, Link at 5 (*studying types D, G, and H together*)." Petition at 9-10 (emphases added). To be sure, the panel found that "Dr. Ozer has not identified any discussion in Shipp to

support that reasoning." Decision at 10. But the panel did not address, and apparently overlooked, supporting evidence from the Link and Coiffier prior art references cited in the Petition that support this very point.

The Petition's discussion of Link and Coiffier provide the "more" evidence the panel found necessary to "accord persuasive weight to Dr. Ozer's opinion"—particularly at the institution stage—that "'there were no significant distinctions in treating these three intermediate and high-grade lymphomas (types F, G, H).'" *Id.* (quoting Ex. 1002). In both of these references, as in Shipp, the same treatments were used for NHL patients regardless of whether they were classified as having IWF Grade F, G, or H. For example, Link states: "Patients were eligible for the present trial if they had previously untreated intermediate or high grade B-NHL (*IWF D-H*) with measurable disease." Ex. 1005, 5 (emphasis added). Coiffier similarly states: "Patients were eligible for inclusion in this study if they had intermediate- or high-grade non-Hodgkin's lymphoma (NHL) according to the Working Formulation, *subtypes D to H*." Ex. 1006, 1 (emphasis added) (citations omitted).

Although the panel discussed the Link and Coiffier references, it did not do so for purposes of this proposition. For example, the panel found that "Link does not cure the deficiency in Shipp as the reference does not teach treating patients over 60 years of age with DLCL accompanied with bulky disease," and "Coiffer [does

not] address that deficiency." Decision at 11, 13. Petitioner is not arguing otherwise. Instead, the point is that *three* prior-art references (Shipp, Link, and Coiffier) all treated intermediate-grade NHL patients with the same therapy regardless of whether they had IWF Grades F, G, or H. Taken collectively, these three references strongly bolster Dr. Ozer's sworn opinion that "a POSA would understand that treatment findings as to one of these types of NHL would apply equally to the others." Ex. 1002 ¶ 52. Thus, as Dr. Ozer further opined, "a POSA reading Shipp would conclude that CHOP therapy successfully treats bulky disease in patients [over 60] with intermediate- and high-grades of lymphoma, including DLCL." *Id.*

In view of the statements quoted above from Shipp, Link and Coiffier, the panel clearly erred in not according persuasive weight to Dr. Ozer's opinion. This error particularly warrants rehearing because Patent Owner never disputed that IWF Grades F, G, H are treated the same way. To be sure, Patent Owner argued that Dr. Ozer's opinion "is refuted by the Petitioner's own admissions" that "different classifications of lymphoma respond differently to chemotherapy." Preliminary Response at 12 (quoting Petition at 8). But this argument is misleading. Although *low-grade* NHL is treated differently than *intermediate-* (e.g., DLCL) and *high-*grade NHL, Petition at 8 (citing Ex. 1011, at 2-3), this is irrelevant here. Patent Owner provided no support—literally, nothing—showing that patients with DLCL

(an intermediate-grade NHL) were treated differently depending on whether they were classified as any of IWF Grades F, G, or H.

Given that the record overwhelmingly supports—indeed, there is no refuting evidence—that IWF Grades F, G, and H are all treated the same way, Petitioner showed at least "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See* 35 U.S.C. § 314(a). Once Dr. Ozer's opinions are properly "accord[ed] persuasive weight" in view of the record as a whole and the standard for institution, Decision at 10, Petitioner is reasonably likely to show by a preponderance of the evidence that "Shipp teaches all of the elements of claim 1, except for including rituximab in the treatment method." Decision at 10; *see also* Ex. 1002 ¶ 52; *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012) ("A reference may be read for all that it teaches, including uses beyond its primary purpose."). And, as argued in the Petition, it also would have been obvious for a POSA to combine this teaching from Shipp with either McNeil and Link (for Ground I) or with Coiffier (for Ground II) to arrive at the methods of treatment claimed in the '244 patent.

Therefore, Petitioner has satisfied its burden of showing that the decision to deny institution "was based on . . . clearly erroneous factual findings." *PPG Indus.*, 840 F.2d at 1567. Rehearing is warranted here.

V. CONCLUSION

For the reasons described above, Petitioner respectfully submits that the Decision be reversed and institution granted based on Petitioner's Grounds I and II.

Dated: December 5, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I certify that, on December 5, 2017, I caused to be served true and correct copies of the foregoing "PETITIONER'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71," by electronic mail on the following attorneys:

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