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. IPR2017-01166
Patent No. 8,329,172 B2
Issued: December 11, 2012
Filed: August 18, 2007

Title: COMBINATION THERAPIES FOR B-CELL LYMPHOMAS COMPRISING ADMINISTRATION OF ANTI-CD20 ANTIBODY

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

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I. INTRODUCTION AND PRECISE RELIEF REQUESTED

Petitioner requests rehearing of a fractured decision denying *inter partes* review of U.S. Patent No. 8,329,172 (Paper 9), which claims a method of treatment that involves, among other steps, administering 375 mg/m^2 of the antibody rituximab (Rituxan™) in four weekly doses. Over a forceful dissent, the panel majority denied institution because Petitioner did not prove that the specific copy of a prior art reference cited in the Petition as teaching the claimed dosing regimen—the "Rituxan™ label" (Ex. 1004)—was a publicly accessible "printed publication" under 35 U.S.C. § 102(b). The majority's decision was premised on both an erroneous conclusion of law and a clear error of fact. Rehearing is warranted.

First, the majority assumed that Petitioner bore the burden to prove the public accessibility of the specific "version of the Rituxan Label in Exhibit 1004," which included extraneous "handwriting" on that particular copy. Maj. 15. But that is not the law. "Accessibility goes to the issue of whether interested members of the relevant public could obtain the *information*" in a prior art reference—not the precise format of an individual copy. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988) (emphasis added). As other panels of the Board have held, there is no "authority that requires the same physical paper to be in evidence for a reference to qualify as prior art." *Activision Blizzard, Inc. v. Acceleration Bay, LLC*, IPR2015-01996, Paper 101 at 17 (PTAB Mar. 29, 2017). *Infra* 8–11.

Second, the majority mistakenly found that Petitioner did not "contend that Rituxan was on sale … prior to the critical date for the '172 patent," which, given FDA regulations that require labels for marketed drugs, is dispositive of "when any Rituxan package insert [*i.e.*, the label] was made available." Maj. 13; 21 C.F.R. § 201.59 (1997). That was clear error. The Petition, in fact, contended that "the Rituxan™ label was accessible in the public domain *and in use* before [the critical date]," and supported that contention with prior art indicating that Rituxan™ "is marketed … in the United States." Pet. 25 (emphasis added); Ex. 1016, 51. Under the correct legal standard, and in light of the evidence in the Petition that the majority overlooked, there can be no dispute that the relevant dosing information in the Rituxan™ label was publicly accessible before the critical date. *Infra* 11–14.

At a minimum, as the dissent recognized, the panel majority should have replaced the Rituxan™ label in the Petition with another, undisputed printed publication—Maloney (Ex. 1008)—that taught the same dosing regimen on which Petitioner relied to support its obviousness ground. *Infra* 14–15. Indeed, Petitioner will be filing shortly a new, but substantially similar, petition that expressly includes Maloney in the grounds (IPR2018-00285). Petitioner respectfully requests that the Board institute IPR based on its new petition, which will render this rehearing request (filed in an abundance of caution) moot. Moreover, this new petition is not subject to discretionary denial as an improper "follow-on" petition, because the

Board in this proceeding did not reach the *merits* of Petitioner's challenge. *See Panduit Corp. v. CCS Tech., Inc.*, IPR2017-01323, Paper 8 at 8–9 (PTAB Nov. 8, 2017) (instituting IPR where the Board "previously denied institution … because one of the asserted references was not shown to have been a printed publication," which "do[es] not present a situation in which Petitioner is 'using our decisions as a roadmap'"). To the extent the Board nevertheless denies the new petition on that basis, rehearing in this proceeding should be granted.

II. STATEMENT OF MATERIAL FACTS

A. As confirmed by FDA, Patent Owner's own website, the PDR, and Maloney, the Rituxan™ label and the relevant information it contains were publicly accessible in the prior art.

There is no dispute that the relevant information in the Rituxan™ label—*i.e.*, the claimed dosing regimen—was known and publicly accessible. First, the Rituxan™ label itself discloses that regimen. Ex. 1004, 2. As Petitioner's declarant Dr. Bennett showed, the version of the Rituxan™ label that Petitioner principally cited in the Petition (Ex. 1004) was obtained directly from FDA's official website, which represents that it is a reproduction of the original approved labeling for Rituxan™ as of November 26, 1997. Pet. 24 & n.3 (citing Ex. 1016 ¶ 50).

Second, Petitioner showed that another copy of the Rituxan™ label—indisputably identical to Exhibit 1004 in all relevant respects, including the dosing regimen—appeared on the website of Patent Owner's licensee, Genentech, before

the August 1998 critical date. Pet. 24 (citing Ex. 1016 ¶ 51).

Third, Petitioner cited an article by Leget and Czuczman, which cited the Rituxan™ label. Pet. 24 (citing Ex. 1016 ¶ 52). Although the paper was published in November 1998 (after the critical date but before the August 1999 priority date), given the time required for peer review, Dr. Bennett declared that, in his opinion, the paper was written before the critical date. *Id*. As Petitioner explained, the article "confirms that the Rituxan™ label was accessible in the public domain *and in use* before that time." *Id*. (emphasis added). Indeed, it indicates that "[r]ituximab … *is marketed* … in the United States." Ex. 1016, 51 (emphasis added).

Fourth, Petitioner cited the 1999 edition of the *Physician's Desk Reference*® ("PDR"), a well-known publication that reproduces approved drug labels. Pet. 25 (citing Ex. 1039). In particular, the PDR includes yet another version of the Rituxan™ label, which is, again, indisputably identical to Exhibit 1004 in all relevant respects, including the dosing regimen. *Id*. The date stamp on the PDR shows that the National Library of Medicine received it in December 1998 (after the critical date but before the priority date). *Id*. Notably, there are no substantive differences (certainly none related to dosing) between the label in the 1999 PDR and the 1997 version on FDA's website or the 1998 version on Genentech's website.

Fifth, Petitioner explained that "the relevant information cited [ ] 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," and is undisputed § 102(b) prior art. Pet. 25 (citing Ex. 1008, 1). Indeed, almost every time Petitioner cited the Rituxan™ label in its analysis of obviousness, it also cited Maloney. *See* Pet. 25, 31, 34, 36, 38, 40 (all citing Ex. 1008).

B. The Board has instituted grounds based on the Rituxan™ label in three IPRs, and granted additional discovery on its accessibility.

Panels of the Board have previously instituted IPRs based on grounds that relied on exactly the same document as Exhibit 1004. *See* IPR2015-00415, Paper 13 at 30; IPR2016-01614, Paper 12 at 12; IPR2017-01115, Paper 13 at 6.[1]

In one of those IPRs, the panel granted additional discovery "relating to public availability of the FDA label for … Rituxan®." IPR2016-01614, Paper 31 at 1. The panel found that the Rituxan™ label itself constitutes "a threshold amount of evidence … tending to show beyond speculation that something useful will be uncovered …. from Patent Owner regarding [its] public availability." *Id.* at 3.

Following that decision, Patent Owner admitted that "vials of rituximab that were sold under the brand name Rituxan® in the U.S. prior to May 7, 1999, were shipped by Genentech with labels," and denied that any were shipped "without labels." IPR2016-01614, Ex. 1081 at 9–10. Patent Owner admitted that these labels

[1] The Board denied another petition that relied on Exhibit 1004, but that petition included *none* of the other evidence above. IPR2017-01093, Paper 12 at 19.

"included a section … called 'DOSAGE AND ADMINISTRATION'"—the same section Petitioner cites here for the claimed dosing regimen. *Id*. at 11–12.

Since then, the panel has heard oral argument, including on the issue of the Rituxan™ label's prior art status, and the parties are awaiting a final written decision. *See* IPR2016-01614, Paper 57 (scheduling hearing for Oct. 31, 2017).

C. The majority did not consider the teachings of the Rituxan™ label because Petitioner did not prove that the exact photocopy in the Petition was made available in the prior art, "handwriting and all."

Despite those prior decisions, the majority here denied institution solely because Petitioner did not prove that "the Rituxan Label embodied in Exhibit 1004—the only version of that label relied upon as prior art in this proceeding—was itself disseminated or otherwise made available." Maj. 12–13. Based on its assumption that Petitioner was legally required to make that showing, the majority discounted all evidence that "the same or substantially the same *information* as set forth in the Rituxan Label of Exhibit 1004" was, in fact, accessible. Maj. 13.

The majority focused on the fact that, in Exhibit 1004, the word "'Rituximab' is partially written by hand." Maj. 14. It thus held Petitioner to the burden of proving the public accessibility of the "version of the Rituxan Label in Exhibit 1004, *handwriting and all*." Maj. 15 (emphasis added). The majority noted that Exhibit 1004 and the label on Genentech's website have "different layouts," and the version in the PDR is "not the same document." Maj. 14–15. At no point, however, did the

majority suggest that the documents were different in *substance*, including the relevant dosing regimen disclosure on which the Petition's ground relied.

D. The dissent found a "reasonable likelihood" that the Rituxan™ label is prior art and that Petitioner would prevail on the merits.

In contrast, the dissent found "a reasonable likelihood Petitioner would prevail on the merits of Petitioner's contention that claim 1 of the '172 patent would have been obvious." Diss. 2. As the dissent observed, the "Rituxan Label contains a 'November 1997' copyright notice" and "appears to be the type of literature that would be disseminated to physicians and provided with the drug upon purchase." Diss. 4–5. While Exhibit 1004 itself "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." Diss. 5. "Indeed, this 'handwritten' version of the Rituxan drug label is the exact version obtainable from the FDA website." *Id*.

The dissent noted that the 1997 (FDA) and 1998 (online) versions of the Rituxan™ label bear "the identical copyright notice and document number," which "corroborates Petitioner's position that the commercially approved drug label for Rituxan was publicly available." *Id*. The dissent thus would have "proceed[ed] to consider the merits of Petitioner's unpatentability arguments, and determine[d] that institution of an *inter partes* review is justified." Diss. 8; *see* Pet. 27–52.

III. STANDARD OF REVIEW

Pursuant to 37 C.F.R. § 42.71(d), a party may request rehearing of a denial of institution. The Board reviews its decision for "abuse of discretion" (*id.* § 42.71(c)), which 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).

IV. BASIS FOR GRANTING REQUESTED RELIEF

The majority's requirement that Petitioner show the public accessibility of a particular copy of a prior art reference, "handwriting and all," was legally erroneous. Under the correct legal standard, Petitioner needed to show only that the relevant information was known. *Infra*, Part A. Additionally, the majority clearly erred when finding that Petitioner never contended that the Rituxan™ product was sold in the prior art. The Petition made this contention *and* provided supporting evidence. *Infra*, Part B. Thus, there is at least "a reasonable likelihood" that the relevant information in the Rituxan™ label on which the Petition's ground relied was publicly accessible in the prior art. *Infra*, Part C. At a minimum, the majority should have credited Petitioner's implicit reliance on Maloney. *Infra*, Part D.

A. By focusing on the public accessibility of a particular photocopy of the Rituxan™ label, "handwriting and all," the majority based its decision on an erroneous conclusion of law.

The legal inquiry of whether a reference is a "printed publication" under § 102(b) turns on the public accessibility of the reference's *substance*, not its *form*.

As the Federal Circuit has held: "Accessibility goes to the issue of whether interested members of the relevant public could obtain the *information* if they wanted to." *Constant*, 848 F.2d at 1569 (emphasis added). "Thus, the question to be examined under § 102(b) is the accessibility to at least the pertinent part of the public, of a perceptible description of the invention, *in whatever form it may have been recorded*." *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981) (emphasis added).

Consistent with the underlying purpose of § 102(b), the Federal Circuit has never required proof of public accessibility for a *specific copy* of an otherwise disseminated reference, copying errors "and all." On the contrary, in *In re Enhanced Security Research*, the Court held that a manual submitted to the Office with multiple pages missing in their entirety was a "printed publication," even with no evidence that any copy of the reference without those pages ever existed in the prior art. 739 F.3d 1347, 1356 (Fed. Cir. 2014). In rejecting the patentee's argument that the manual was not a printed publication, the Court found that "nothing in the Manual here suggests that the missing pages were necessary to an understanding of *the pertinent parts of the reference*." *Id*. (emphasis added); 37 C.F.R. § 1.510(b)(3) (requiring submission of only "pertinent parts" of translated references).

Until now, panels of the Board had followed the Federal Circuit's guidance in rejecting formalistic objections to specific copies of references. For example, the panel in *Activision Blizzard* rejected the patent owner's argument that a reference

"'was not the same paper that was presented at [a public] conference'" before the relevant date. IPR2015-01996, *supra*, Paper 101 at 15. As the panel explained: "Although Patent Owner is correct that the pages of [the] Exhibit [ ] were not the *actual* pages from the conference proceeding (as in physically obtained at the conference), but a reproduction, Patent Owner does not address [the evidence] that the content of the paper was identical in every respect to what was presented." *Id*. at 16. Nor did the panel find "any authority that requires the same physical paper to be in evidence for a reference to qualify as prior art." *Id*. at 17.

Likewise, in *SAP America, Inc. v. Realtime Data LLC*, another panel instituted IPR over the patent owner's objection that an exhibit in the petition was "a different version" of a reference in the prior art. IPR2016-00783, Paper 18 at 9 (PTAB Oct. 5, 2016). The panel rejected that argument because "Petitioner has provided evidence indicating that the version of [the reference]" that was in the prior art was "the same as [the Petition's] Exhibit [ ] in all relevant respects." *Id*.

Yet here, in conflict with precedent, the majority declined to focus on the "pertinent parts" of the Rituxan™ label. Nor did it consider the "information" the label disclosed, which was undisputedly in the public's possession "in all relevant respects." Instead, the majority focused exclusively on extraneous "handwriting" in the margins and concluded that, because that handwriting did not appear in *other* "versions" of the label, it could not be prior art to the '172 patent. That extreme

elevation of form over substance does not advance, but materially obstructs, the underlying purpose of § 102(b) "to prevent withdrawal by an inventor … of that which was already in the possession of the public." *In re Wyer*, 655 F.2d at 226.

The majority's logic also leads to absurd results that could have widespread implications: Any stray mark, copying error, stamp, or even an ink blot transforms an otherwise widely disseminated reference into an entirely new "document" whose individual accessibility—marks "and all"—may be impossible to prove. Nor is the majority's rule even justiciable in the context of electronic and online references, which render differently depending on the computer, platform, or browser used to view them. Electronic references *are* "the information" they contain. For them, the majority's hyper-formal emphasis on a single printed "format" is manifestly unworkable, and ignores § 102(b)'s continuing adaptability to "the state of technology in document duplication." *In re Wyer*, 655 F.2d at 226.

B. The majority's finding that Petitioner did not "contend that Rituxan was on sale" in the prior art overlooked explicit arguments and evidence in the Petition, and was clearly erroneous.

In addition to applying an erroneous legal standard, the majority also clearly erred in finding that Petitioner failed to "contend that Rituxan was on sale, or otherwise available to the public prior to the critical date for the '172 patent," as support for "when any Rituxan package insert was made available to interested artisans." Maj. 13. As an initial matter, "[t]his information is precisely the type of

specific facts that may be established at trial under additional discovery." Diss. 6. Yet even without discovery, the Petition *did* contend that "the Rituxan™ label was accessible in the public domain *and in use* before [the critical date]"—*i.e.*, it was disseminated with packages of Rituxan™ that were actually sold—and the Petition supported that contention with evidence. Pet. 25 (citing Ex. 1016 ¶¶ 52–53).

In particular, Leget and Czuczman—written before the critical date—cites the Rituxan™ label and states that rituximab "is marketed … in the United States." Ex. 1016, 51. Thus, it clearly supports the Petition's contention that the Rituxan™ label was "in use" before the critical date in marketed packages of Rituxan™. Pet. 25; 21 C.F.R. § 201.59 (1997). In finding otherwise, the majority clearly erred.[2]

C. Under the correct legal standard and in view of the evidence in the Petition, there is at least a "reasonable likelihood" that the relevant information in the Rituxan™ label was in the prior art.

Once it becomes clear that (a) Petitioner did not bear the (impossible) burden of proving that a *specific photocopy* was accessible to the public, "handwriting and all," and (b) Petitioner both contended and provided (undisputed) evidence that Rituxan™ was marketed with a label before the critical date, it becomes equally clear

[2] Patent Owner did not deny that Rituxan™ was sold before the critical date, but argued only that "[i]t is highly unlikely that a document with half the product name written in by hand was distributed with Rituxan®." Prelim. Resp. 13–14.

that Petitioner established more than "a reasonable likelihood" that the pertinent information in the Rituxan™ label was publicly accessible. 35 U.S.C. § 314(a). Indeed, putting aside the handwriting in Exhibit 1004, the evidence that the same information was publicly accessible by the relevant date is overwhelming.

Not only has FDA—a disinterested federal agency with the exclusive mandate to regulate pharmaceutical products—represented that Exhibit 1004 is a reproduction of the first-approved labeling for Rituxan™ in November 1997, but Genentech itself uploaded substantially the same label to its own webpage before the critical date in 1998, and the well-known PDR reprinted the same label almost word-for-word before the 1999 priority date. Pet. 24–25 (citing Ex. 1016 ¶¶ 49–53). "There is no dispute that, in November 1997, the [FDA] approved the biologic rituximab under the brand name Rituxan" (Diss. 4–5), which was *required* to include the FDA-approved labeling in every package (*see* 21 C.F.R. § 201.59 (1997)).

"These indicia suggest that there is a reasonable likelihood the document was made available to the public." *Apple Inc. v. VirnetX Inc.*, IPR2015-00810, Paper 8 at 9 (PTAB Sept. 11, 2015). To conclude otherwise requires suspending disbelief and indulging in a fantastical chain of exceedingly unlikely events: Either both FDA *and* Genentech uploaded the wrong version of the label to their own websites, or every vial of Rituxan™ was shipped before 1999 *without* the FDA-mandated labeling, notwithstanding stiff criminal penalties for each omission. A "reasonable

likelihood" that the Rituxan™ label was accessible is an understatement—it is manifestly *un*reasonable to suggest it was not. Rehearing is warranted.

D. In declining to substitute the Rituxan™ label with another reference relied upon in the Petition that undisputedly contained the same information, the majority abused its discretion.

At a minimum, the majority should have recognized Petitioner's implicit argument that Maloney could be substituted for the Rituxan™ label. Even where a "Petitioner did not specifically articulate a ground of unpatentability," panels have repeatedly "exercise[d] discretion to recognize that the assertion was implicitly made." *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 15 at 22 (PTAB Jan. 9, 2013); *accord, e.g.*, *Valeo, Inc. v. Magna Elecs., Inc.*, IPR2014-00221, Paper 13 at 23 (PTAB May 29, 2014). That was the case here.

As the dissent recognized, Maloney is "an alternative reference for the relevant information that may be relied upon in [the] institution determination"—it teaches exactly the same dosing regimen claimed in the '172 patent. Diss. 6. Indeed, Maloney is one of the "clinical trials" that the majority recognized is "report[ed]" in the Rituxan™ label to support that regimen. Maj. 8; Ex. 1004, 2 n.11.

The majority acknowledged its authority to substitute references, yet declined to do so here because Maloney was not "relied upon in the Petition as prior art for any asserted ground of unpatentability" for some other claim. Maj. 21. But that is a distinction without a difference, especially since "the '172 patent includes only a

single claim." Maj. 20. Moreover, the Petition expressly discusses Maloney in the "prior art status" section for the Rituxan™ label, and cites Maloney repeatedly in the analysis of the ground presented—almost as many times as the Rituxan™ label itself. *Supra* 5. Petitioner's reliance on Maloney was at least implied.

As a policy matter, moreover, the majority's formalistic objection to substituting a reference that is not expressly in the grounds does not further the Board's mandate of ensuring "the just, speedy, and inexpensive resolution" of patentability disputes. 37 C.F.R. § 42.1(b). Worse, the majority's decision will encourage future petitioners to pack their grounds with cumulative references in an overabundance of caution—"bury[ing]" the Board with a "deluge" of prior art, which "strains the agency's examining resources." *Cf. Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289–90 (Fed. Cir. 2011) (en banc). Instead of assisting the Board in evaluating patentability, "[t]his tidal wave of disclosure makes identifying the most relevant prior art more difficult." *Id.* at 1289.

V. CONCLUSION

For the foregoing reasons, and the reasons given in the Petition, to the extent the Board does not institute IPR2018-00285, which expressly relies on Maloney, Petitioner respectfully requests that the Board rehear its decision denying institution in this proceeding, institute IPR based on Maloney or a finding that the Rituxan™ label was publicly accessible, and cancel claim 1 of the '172 patent.

Dated: December 12, 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 12, 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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