UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner

v.

ABBVIE BIOTECHNOLOGY LTD.,
Patent Owner

U.S. Patent No.: 9,512,216
Issue Date: Dec. 6, 2016
Title: Use of TNF-Alpha Inhibitor

PETITIONER SANDOZ INC.'S MOTION FOR REHEARING UNDER 37 CFR § 42.17(d)

Case No. IPR2017-01824

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Petitioner Sandoz Inc., pursuant to 37 C.F.R. §42.71(d), respectfully requests rehearing of the Board's February 9, 2018, decision denying *inter partes* review of claims 1-16 of U.S. Patent No. 9,512,216 B2 ("the '216 patent").

I. INTRODUCTION

The Board erred by imposing upon Petitioner a greater evidentiary burden than is required to establish that a reference is a printed publication at the institution stage. As a consequence of this legal error, the Board improperly found that Petitioner did not adequately demonstrate that Exhibit 1026 (the "2002 Humira Package Insert") was a printed publication for purposes of institution. (Paper 14 at 5). The Board denied institution of IPR2017-01824 solely based on this erroneous finding on the printed publication status of the 2002 Humira Package Insert.

Exhibit 1026 is a label for Patent Owner AbbVie's own Humira product. AbbVie has represented to the U.S. Patent Office that the document submitted as Exhibit 1026 is the "HUMIRA (adalimumab) Patient Information Label (December 2002)". (Ex. 2011 at 18, "CE7"). This representation constitutes, at a minimum, an admission that Exhibit 1026 is what AbbVie represented it to be – *i.e.*, the 2002 Humira Label. By law, therefore, Exhibit 1026 was necessarily publicly disseminated upon the sale of AbbVie's Humira drug product. 21 C.F.R. §201.59 (2002) (labeling requirement for drugs initially introduced into interstate commerce on and after December 26, 1979). AbbVie has provided no factual

information in its Preliminary Response that disputes that the 2002 Humira Package Insert was, in fact, the labelling for its Humira drug product in 2002 that was publicly distributed in the prior art as was required by law.

AbbVie's admission that Exhibit 1026 is its December 2002 Humira Label, coupled with the clear indicia on the face of the document that it was publicly available as of that date, at a minimum establish a reasonable likelihood that Petitioner could prove the printed publication status of the 2002 Humira Package Insert through post-institution discovery. This is sufficient for Petitioner's threshold showing at institution – *i.e.,* to "show a reasonable likelihood that [Petitioner] ultimately will establish by a preponderance of the evidence that Humira Package Insert was publicly accessible" before the April 9, 2004 priority date of the '216 patent. (Paper 14 at 7).

Accordingly, the Board's decision not to institute based on the finding that Petitioner failed to make a threshold showing that the 2002 Humira Package Insert is a printed publication was legal error and warrants rehearing.

II. ARGUMENT

A. Legal Standard for Rehearing

A party may request rehearing of a decision by the Board whether to institute a trial pursuant to 37 C.F.R. §42.71(d). "The request must specifically identify all matters the party believes the Board misapprehended or overlooked,

and the place where each matter was previously addressed in a motion, opposition, or reply." *Id.* When rehearing a decision on petition, a panel will review the decision for an abuse of discretion. *Id*. at §42.71(c). "An abuse of discretion occurs where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." *Star Fruits S.N.C. v. United States,* 393 F.3d 1277, 1281 (Fed. Cir. 2005).

B. Legal Standard for Printed Publication Determination at the Institution Stage

To ultimately prevail in an *inter partes* review, the petitioner bears the burden of establishing unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. §316(e). However, "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial." *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016). At the institution phase, therefore, the relevant question for the Board is whether there is a reasonable likelihood that Petitioner will ***later*** be able to prove by a preponderance of the evidence that a reference is a prior art printed publication – at the close of evidence and conclusion of trial , and after post-institution discovery.

Accordingly, the Board has repeatedly found sufficient for institution of *inter partes review* "threshold" showings of printed publication status that do not

rise to the level of proof required at the close of trial. *See, e.g., EMC Corp. v. PersonalWeb Techs., LLC*, IPR2013-00085, Paper 18 at 14, 2013 WL 8595564 at *8 (P.T.A.B. May 17, 2013) (instituting *inter partes* review and finding that Petitioner made a threshold showing that challenged references were printed publications, despite not having submitted testimony, declaration, or other evidence addressing the public accessibility of the references). Numerous Board decisions have found, for example, that facial indicia on challenged documents – including copyright information, trademarks, company logos, and dates, in addition to the overall appearance of the documents themselves – are sufficient evidence of printed publication status to meet the "reasonable likelihood" threshold for purposes of institution. *See, e.g., Oracle Am., Inc. v. Realtime Data LLC,* IPR2016-00374, Paper 7 at 17, 2016 WL 5232950 at *10 (P.T.A.B. June 27, 2016) (finding "Petitioner has made a threshold showing that [the document] is a 'printed publication'" because its facial "format and appearance are consistent with that of a published article in a technical journal"); *Am. Megatrends, Inc. v. Kinglite Holdings Inc.,* IPR2015-01197, Paper 14 at 5, 2015 WL 9599216 at *3 (P.T.A.B. Nov. 23, 2015) (finding a copyright notice on the face of the document to be sufficient evidence of public availability for institution phase); *Informatica Corp. v. Protegrity Corp.*, CBM2015-00021, Paper 14 at 29-30, 2015 WL 3523401 at *18 (P.T.A.B. June 1, 2015) (finding a printed date on a reference to be "a

sufficient threshold showing" of public availability at the institution stage); *Toshiba Corp. v. Optical Devices, LLC,* IPR2014-01447, Paper 9 at 29-30, 2015 WL 1090309 at *17-18 (P.T.A.B. Mar. 10, 2015) (finding the "logo of the manufacturer," the "product number" and the date printed on the face of the asserted reference "provide[] sufficient evidence at this stage of the proceeding to establish that [the document] was publicly available and accessible" as of the printed date).

C. Petitioner Established a Threshold Showing that the 2002 Humira Package Insert is a Printed Publication

The Board found that Petitioner did not demonstrate that the 2002 Humira Package Insert was publicly accessible to the extent required to establish it as a "printed publication" for purposes of institution. (Paper 14 at 7). Specifically, the Board pointed to certain indications of public availability on the face of the 2002 Humira Package Insert and concluded that these indicia were insufficient "on their own" to show a reasonable likelihood that the 2002 Humira Package Insert was publicly available in 2002. (*Id.*). The Board further faulted petitioner for not providing additional evidence such as "source identifying information from the FDA (e.g., a copy of the insert on the FDA's website), a publication date, or other indicia" of when the 2002 Humira Package Insert became publicly available.

As a preliminary matter, there is no requirement that Petitioner provide such "other indicia" of public availability at the institution stage, and the Board erred by

imposing one here. The indicia of public availability on the face of the 2002 Humira Package Insert, including but not limited to the three features cited by the Board, are enough to meet petitioner's threshold showing at this stage. *See, e.g., Toshiba Corp. v. Optical Devices, LLC,* IPR2014-01447, Paper 9 at 29-30, 2015 WL 1090309 at *17-18 (P.T.A.B. Mar. 10, 2015).

But even if the facial indicia of public accessibility on the 2002 Humira Package Insert were insufficient, these indicia do not exist in a vacuum. Rather, the indicia on the face of the 2002 Humira Package Insert, should be viewed in the context of the other relevant facts and evidence before the Board[1] – specifically, Patent Owner's admission that Exhibit 1026 is the 2002 Humira Label and the fact that AbbVie's Humira drug product cannot legally have been distributed without its label, per 21 C.F.R. §201.59 (2002). Viewed together, these facts and evidence establish that there is a reasonable likelihood that Petitioner will be able to prove by a preponderance of the evidence, through post-institution discovery, that the 2002 Humira Package Insert is a prior art printed publication.

During prosecution of the '216 Patent, Patent Owner submitted the 2002 Humira Package Insert to the U.S. Patent Office, and characterized the document , on an information disclosure statement ("IDS"), as the "HUMIRA (adalimumab)

[1] *See* Ex. 2011 at 18, "CE7" (IDS entry characterizing Exhibit 1026); *see also* Patent Owner's Preliminary Response at 41, FN 6 (acknowledging that Exhibit 1026 was cited on the IDS submitted as Ex. 2011); Transcript of Nov. 30, 2017 conference call with the Board, Ex. 1070 at 7:19-8:14,8:22-9:13, 20:21-21:3.

Patient Information Label December 2002." *See* Ex. 2011 at 18, "CE7" (IDS entry characterizing Exhibit 1026); *see also* Patent Owner's Preliminary Response at 41, FN 6 (acknowledging that Exhibit 1026 was cited on the IDS submitted as Ex. 2011); Ex. 1070 at 20:24-31. Pursuant to 21 C.F.R. §201.59 (2002), AbbVie's Humira product cannot have been legally distributed in the United States upon its December 2002 approval date unless accompanied by its product label. Therefore, Patent Owner's admission during patent prosecution that Exhibit 1026 is AbbVie's 2002 Humira label indicates that Exhibit 1026 was publicly disseminated in the prior art by Patent Owner itself. The Board can and should have taken Official Notice of these facts. *See* 37 C.F.R. §42.62; *see also Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1166 (Fed. Cir. 2012) (endorsing District Court's reasoning that "a person of ordinary skill in the art would know that medications are not simply handed out to patients…the FDA requires container labeling and information for prescription pharmaceutical products.").

Patent Owner asserts that its statements on the IDS are not an admission that Exhibit 1026 was available as prior art. But such statements must, at a minimum, be an admission by Patent Owner that the submitted document is what it purports to be – *i.e.*, Patent Owner's December 2002 Humira Label. Unlike with third-party-published references, Patent Owner was in a unique position to verify the authenticity of its own product label submitted in its IDS, and it had an affirmative

duty to describe the document accurately. *See C & F Packing Co., Inc. v. IBP, Inc.*, 916 F. Supp. 735, 749 (N.D. Ill. 1995) ("Since an applicant's duty to the PTO is one of good faith and candor it is apparent that an applicant may not misrepresent information it supplies."). Moreover, Patent Owner provides no factual information in its Preliminary Response that disputes that the 2002 Humira Package Insert was publicly distributed in the prior art, and has never affirmatively denied that fact. On this record, there is a reasonable likelihood that Petitioner will be able to prove by a preponderance of the evidence, through post-institution discovery, that the 2002 Humira Package Insert is a prior art printed publication.

III. CONCLUSION

For the foregoing reasons, Petitioner Sandoz Inc. respectfully requests that the Board institute *inter partes* review of claims 1-16 of the '216 patent on the ground that the claims are obvious over the 2002 Humira Package Insert, the AbbVie Press Release, Aulton, and Weinstein, in view of Marzo-Ortega.

Dated: Mar. 9, 2018

Respectfully Submitted,
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document PETITIONER SANDOZ INC.'S MOTION FOR REHEARING UNDER 37 CFR § 42.17(d) is being served on March 9, 2018 via electronic mail upon the following counsel of record for Patent Owner AbbVie Biotechnology Ltd.:

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