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Paper No. 16
Entered: May 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ABBVIE BIOTECHNOLOGY LTD.,
Patent Owner.

Case IPR2017-01824
Patent 9,512,216 B2

Before SUSAN L. C. MITCHELL, TINA E. HULSE, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

ANKENBRAND, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71

On March 9, 2018, Sandoz Inc. ("Petitioner") filed a Request for Rehearing (Paper 15, "Rehearing Request" or "Reh'g Req.") of our Decision denying institution of an *inter partes* review (Paper 14, "Decision" or "Dec.") of claims 1–16 of U.S. Patent No. 9,512,216 (Ex. 1001, "the '216 patent"). In the Decision, we found that Petitioner failed to provide sufficient evidence to show for the purposes of institution that Humira Package Insert[1] was publicly available before the effective filing date of the '216 patent.[2] Dec. 7–9. Given that Humira Package Insert was germane to Petitioner's asserted ground, we further found that Petitioner did not establish a reasonable likelihood of prevailing in showing that claims 1–16 of the '216 patent were unpatentable as obvious. *Id.* at 9.

We deny the Rehearing Request for the reasons set forth below.

I. ANALYSIS

When considering a request for rehearing from a decision whether to institute a petition, the Board reviews its decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The party requesting rehearing bears the burden of showing that the decision should be modified, and "[t]he request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed" in the Petition. 37 C.F.R. § 42.71(d).

Petitioner argues that we erred in our Decision by imposing a greater evidentiary burden on Petitioner than is required to establish that a reference

[1] Humira (adalimumab) Package Insert (Abbott Laboratories) (Ex. 1026).
[2] For purposes of the Petition, Petitioner assumed that the effective filing date of the challenged claims is the filing date of the earliest application to which the '216 patent claims priority—a provisional application having a filing date of April 9, 2004. Pet. 7.

is a printed publication at the institution stage of an *inter partes* review proceeding. Reh'g Req. 3–4, 7–10. In particular, Petitioner contends that although our Decision "pointed to certain indications of public availability on the face of the 2002 Humira Package Insert," we erroneously required Petitioner to come forward with "other indicia" of public availability for purposes of institution. *Id.* at 7–8. According to Petitioner, the "indicia of public availability on the face of the 2002 Humira Package Insert, including but not limited to the three features cited [in the Decision], are enough to meet [P]etitioner's threshold showing" at institution. *Id.* at 8; *see id.* at 6–7.

In the Decision, we explained that Petitioner must make a threshold showing in the Petition that Humira Package Insert is a "printed publication" within the meaning of 35 U.S.C. §§ 102 and 311(b) for the purposes of institution. Dec. 5 (citing 35 U.S.C. § 314(a); *see* 37 C.F.R. § 42.108(c)). We did not, as Petitioner appears to argue in the Rehearing Request, require Petitioner to establish by a preponderance of the evidence that Humira Package Insert was publicly accessible before the effective filing date of the '216 patent. Rather, we required that the Petition include argument and direct us to evidence sufficient to show that Petitioner would establish such public accessibility during the course of the trial. *Id.*

We then turned to Petitioner's arguments and evidence discussed in the Petition to determine whether Petitioner had met its threshold showing for purposes of institution. *Id.* at 6–8. Specifically, we noted that Petitioner: (1) identified Humira Package Insert as prior art under 35 U.S.C. § 102(b) and alleged that Humira Package Insert had a publication date of December 2002 in a table in the Petition; (2) asserted that the Humira drug product "was approved in December 2002 to treat [rheumatoid arthritis]"; and

(3) represented that Humira Package Insert is a "prior art FDA approved label." Dec. 6 (quoting Petition 23 and citing Petition 9). We also noted that the evidence to which Petitioner directed us in the Petition was limited to Humira Package Insert (Ex. 1026) itself and a December 31, 2002 letter from the U.S. Food and Drug Administration (FDA) approving the biologics license application for adalimumab ("FDA approval letter," Ex. 1004). Dec. 6–8.

As we explained in the Decision, although Humira Package Insert identifies "Abbott Laboratories" and contains the language "Issued: December 2002," such information is insufficient evidence of public availability for purposes of institution. *Id.* at 7 (citing *Frontier Therapeutics, LLC v. medac Gesellschaft für klinische Spezialpräparate mbH*, Case IPR2016-00649, slip op. at 22 (PTAB Sept. 1, 2016) (Paper 10) ("*Frontier Therapeutics*")).[3] In addition, we found that Petitioner failed to

[3] Petitioner cites to several Board decisions in support of its argument that we committed error by imposing too high a burden for the threshold showing at institution that Humira Package Insert qualifies as a printed publication. Reh'g Req. 6–7. None of those decisions, however, addresses drug package inserts or labels. In contrast, Board decisions explicitly addressing drug package inserts and labels have found that company information and/or dates on such documents are insufficient to meet the threshold showing that a Petitioner must make in the Petition for purposes of institution. *See, e.g.*, *Mylan Pharms. Inc. v. Boehringer Ingelheim Int'l GmbH*, Case IPR2016-01565, slip op. at 19–20 (PTAB Feb. 9, 2017) (Paper 17) (finding that dates on an alleged "printed package insert" were inadequate to make a threshold showing at institution that the document was a printed publication); *Frontier Therapeutics*, Paper 10, 22 (same); *see also Mylan Pharms. Inc. v. Boehringer Ingelheim Int'l GmbH*, Case IPR2016-01563, slip op. at 14 (PTAB Feb. 3, 2017) (Paper 16) (finding that drug sponsor company and revision date on an alleged drug label were

explain how regulatory approval of the Humira drug product on December 31, 2002 evidenced that Humira Package Insert was publicly accessible in 2002, especially given the statement in the FDA approval letter suggesting that the Humira drug product was not yet marketed or available to the interested public. *Id.* at 8 (quoting Ex. 1004, 2). That is, we determined that the limited evidence that Petitioner directed us to in the Petition failed to indicate that Humira Package Insert was publicly available before the effective filing date of the '216 patent and, therefore, Petitioner failed to meet the threshold showing of public availability required for purposes of institution. Petitioner's disagreement with our determination is not a proper basis for rehearing.

Petitioner further argues that we should have viewed the alleged "facial indicia of public accessibility on the 2002 Humira Package Insert" "in the context of other relevant facts and evidence before the Board[;]" namely, "Patent Owner's admission" in an Information Disclosure Statement ("IDS") from the prosecution history of the '216 patent that Humira Package Insert "is the 2002 Humira Label and the fact that [the] Humira drug product cannot legally have been distributed without its label, per 21 C.F.R. §201.59 (2002)." Reh'g Req. 8; *see id* at 3–4. According to Petitioner, such facts and evidence, when viewed together, "establish that there is a reasonable likelihood that Petitioner will be able to prove by a preponderance of the evidence that the 2002 Humira Package Insert is a prior art printed publication." *Id.*

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insufficient to make a threshold showing at institution that the document was a printed publication).

Petitioner's argument is not a proper basis for rehearing, because it is raised for the first time in the Request for Rehearing. That is, Petitioner fails to identify in its Request for Rehearing where in the Petition it directed us to Patent Owner's IDS, argued that 21 C.F.R. § 201.59 requires a label to be included with the sale of a drug product, or argued that the IDS and labeling regulations, when coupled with Humira Package Insert and the FDA approval letter, show sufficiently for purposes of institution that Humira Package Insert was publicly accessible before the effective filing date of the '216 patent.[4] In eight pages of argument encompassing both the Introduction and Argument sections of the Rehearing Request, Petitioner does not provide a single citation to the Petition. Rather, Petitioner directs us to the IDS, which Patent Owner submitted as an exhibit with the Preliminary Response, and the parties' arguments from a teleconference during which Petitioner requested—and we denied—authorization to file a reply to address Patent Owner's arguments in the Preliminary Response regarding the public availability of, *inter alia*, Humira Package Insert. Reh'g Req. 8, n.1 (citing Preliminary Response 41 n.6; Ex. 2011, 18 (IDS entry "CE7"); Ex. 1070 (Transcript of Nov. 30, 2017 teleconference with the Board), at 7:19–8:14, 8:22–9:13, 20:21–21:3).

[4] Notably, the Petition does not include any discussion regarding the date on Humira Package Insert, the identification of "Abbott Laboratories" on Humira Package Insert, the information contained in the FDA approval letter, or what any of the information in the two exhibits indicates about whether Humira Package Insert was publicly accessible during the relevant timeframe. Rather, as we explained in the Decision, "Petitioner merely asserts, *without further elaboration*, that the Humira Package Insert is a 'prior art FDA approved label.'" Dec. 7 (emphasis added) (citing Pet. 23).

A request for rehearing is not an opportunity to develop new arguments or direct us to new or additional evidence. Put simply, we could not have overlooked or misapprehended arguments or evidence that Petitioner did not present in the Petition.

Moreover, Petitioner's attempt in the Rehearing Request to point us to additional evidence it contends is sufficient to make a threshold showing that Humira Package Insert qualifies as a printed publication is not only untimely, but also appears to circumvent our Order (Paper 13) denying Petitioner's request to file a reply on that very issue. As we explained in the Order, "Petitioner could have reasonably foreseen . . . arguments" regarding whether Humira Package Insert was publicly available before the effective filing date of the '216 patent, "given that a petitioner bears the initial burden of production to establish the existence of prior art that renders the claims unpatentable." Paper 13, 3 (citing *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015)). Thus, it was incumbent upon Petitioner to make those arguments and point us to that evidence *in the Petition*—not for the first time during a teleconference or in a Rehearing Request—if Petitioner wanted us to consider it in determining whether Petitioner made a threshold showing that Humira Package Insert is a prior art printed publication.

II. ORDER

Accordingly, it is hereby

ORDERED that Petitioner's Request for Rehearing is *denied*.

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