

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

I. INTRODUCTION

Sandoz Inc. (“Petitioner”) requests an *inter partes* review of claims 1–16 of U.S. Patent No. 9,512,216 B2 (“the ’216 patent,” Ex. 1001). Paper 1 (“Pet.”). AbbVie Biotechnology Ltd. (“Patent Owner”) filed a Preliminary Response. Paper 7 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review “unless . . . 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). Applying that standard, and upon consideration of the information presented in the Petition and the Preliminary Response, we deny the Petition and do not institute an *inter partes* review.¹

II. BACKGROUND

A. Related Matters

The parties do not identify any litigation, interference proceedings, or reexamination proceedings involving the ’216 patent. *See* Pet. 3–4; Paper 4, 1. Petitioner identifies litigation involving two patents that Petitioner contends are related to the ’216 patent because all three patents claim priority to the same application. Pet. 3 (identifying *AbbVie Inc. v. Amgen Inc.*, No. 1:16-cv-00666-SLR-SRF (D. Del. Aug. 4, 2016)). Petitioner also identifies several *inter partes* review proceedings in which the Board previously found claims of certain of Patent Owner’s patents unpatentable,

¹ Because we deny the Petition, we dismiss as moot Petitioner’s pending motions for Daniel L. Reisner and Abigail Langsam to appear *pro hac vice* in this proceeding (Papers 3 and 9, respectively).

but concedes that those patents and the '216 patent do not claim priority to any of the same applications. Pet. 4–6. Petitioner and Patent Owner further identify a number of United States patent applications and patents that claim the benefit of priority to the '216 patent, or to which the '216 patent claims the benefit of priority. *Id.* at 6; Paper 4, 1–2.

B. The '216 Patent

The '216 patent, titled “Use of TNF α Inhibitor,” issued on December 6, 2016. Ex. 1001, [45], [54]. The '216 patent relates to methods for treating moderate-to-severe chronic plaque psoriasis with a human anti-tumor necrosis factor α (TNF α) antibody. Ex. 1001, Abstract; *see, e.g., id.* at 57:36–43 (claim 1). According to the '216 patent, psoriasis is “a skin inflammation . . . characterized by frequent episodes of redness, itching, and thick, dry, silvery scales on the skin[,]” with a pathophysiology that is linked to tumor necrosis factor. Ex. 1001, 26:20–26. “Psoriasis is often associated with other inflammatory disorders, for example arthritis, including rheumatoid arthritis, inflammatory bowel disease (IBD), and Crohn’s disease.” *Id.* at 26:37–40.

The methods of the claimed invention involve subcutaneously administering to a patient an initial dose of 80 mg of adalimumab (also referred to as D2E7), a known recombinant human anti-TNF α antibody, followed by 40 mg of adalimumab every other week starting one week after the initial dose. *Id.* at 41:10–27, 57:36–43, 58:35–40. Some of the claimed methods also test the efficacy of the adalimumab using a Psoriasis Area and Severity Index (PASI) score, or composite measure of the erythema, induration, desquamation and body surface area of a particular patient that the psoriasis affects. *Id.* at 4:63–5:13, 28:24–27. The specification explains

that efficacy is tested by determining the percentage of patients achieving at least a 75% reduction in the PASI score at treatment week 12. *Id.* at 41:52–58, 57:41–43.

C. Illustrative Claim

Of the challenged claims, claims 1 and 9 are independent. Claim 1 is illustrative of the claimed subject matter and recites:

1. A method for treating moderate to severe chronic plaque psoriasis, comprising subcutaneously administering to an adult patient having moderate to severe chronic plaque psoriasis an initial dose of 80 mg of adalimumab, followed by 40 mg of adalimumab every other week starting one week after said first dosing, wherein the patient achieves at least Psoriasis Area and Severity Index (PASI) 75 response at week 12 of the treatment.

Ex. 1001, 57:36–43.

D. The Asserted Ground of Unpatentability

Petitioner asserts claims 1–16 of the '216 patent are unpatentable under 35 U.S.C. § 103(a) over the combination of Humira Package Insert,² Psoriasis Press Release,³ Aulton,⁴ and Weinstein,⁵ in view of Marzo-

² Humira (adalimumab) Package Insert (Abbott Laboratories) (Ex. 1026).

³ Immune Tolerance Network, *Abbott laboratories initiates clinical trials to explore use of Humira™ (adalimumab) in psoriasis and psoriatic arthritis*, available at

https://web.archive.org/web/20030701072200/https://www.immunetolerance.org/artman/publish/article_148.html (Ex. 1052).

⁴ PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN 275–288 (M. E. Aulton ed., 2d ed. 2002) (Ex. 1051).

⁵ THERAPY OF MODERATE-TO-SEVERE PSORIASIS (Gerald D. Weinstein & Alice B. Gottlieb eds., 2d ed. 2003) (Ex. 1003).

Ortega.⁶ Petitioner supports its assertions with the testimony of Simon M. Helfgott, M.D. (Ex. 1002) and John Posner, Ph.D. (Ex. 1050).

III. ANALYSIS

A. Humira Package Insert (Ex. 1026) as “Printed Publication” Prior Art Under 35 U.S.C. § 102(b)

Before turning to Petitioner’s asserted ground, a threshold issue is whether Petitioner makes an adequate showing for purposes of institution that Humira Package Insert is prior art. Under 35 U.S.C. § 311(b), a petitioner in an *inter partes* review may only challenge the claims of a patent based on “prior art consisting of patents or printed publications.” Petitioner has the initial burden of production to establish that there is prior art that renders the challenged claims unpatentable. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)). For institution purposes, Petitioner has the burden to establish a reasonable likelihood that it will prevail on the merits, which includes, *inter alia*, making a sufficient showing in the Petition that Humira Package Insert is a “printed publication” within the meaning of 35 U.S.C. §§ 102 and 311(b). 35 U.S.C. § 314(a); *see* 37 C.F.R. § 42.108(c).

Whether a reference qualifies as a “printed publication” involves a case-by-case inquiry into the facts and circumstances surrounding the reference’s disclosure to members of the public. *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). The key inquiry is whether the reference was made “sufficiently accessible to the public interested in the art” before

⁶ H. Marzo-Ortega et al., *Infliximab is Effective in the Treatment of Resistant Psoriatic Arthritis & Skin Psoriasis: A Clinical & MRI Study*, 41 RHEUMATOLOGY [OP11] D21 (2002) (Ex. 1060).

the effective filing date. *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989)). A reference is considered “publicly accessible” upon a satisfactory showing that the 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.” *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (citation and internal quotation marks omitted). A party seeking to introduce a reference, therefore, “should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents.” *In re Wyer*, 655 F.2d 221, 227 (CCPA 1981) (quoting *Philips Elec. & Pharm. Indus. Corp. v. Thermal & Elecs. Indus., Inc.*, 450 F.2d 1164, 1171 (3d Cir. 1971)).

Petitioner asserts that the Humira drug product “was approved in December 2002 to treat [rheumatoid arthritis]” and represents that Humira Package Insert is a “prior art FDA approved label” disclosing that the recommended dose for the Humira product is 40 mg adalimumab, administered by subcutaneous injection every other week. Pet 23 (citing Ex. 1004, 2; Ex. 1026, 14); *see id.* at 9 (table alleging that Humira Package Insert has a publication date of December 2002 and identifying Humira Package Insert as prior art under § 102(b)). Patent Owner responds that Humira Package Insert cannot qualify as a printed publication because Petitioner does not establish sufficiently for purposes of institution that the insert was publicly accessible in December 2002. Prelim. Resp. 41–44.

We agree with Patent Owner that Petitioner does not demonstrate that Humira Package Insert was publicly accessible to the extent required to establish it as a “printed publication” for purposes of institution. In other words, we find Petitioner does not provide sufficient evidence at this stage of the proceeding to show a reasonable likelihood that it ultimately will establish by a preponderance of the evidence that Humira Package Insert was publicly accessible in December 2002. Petitioner merely asserts, without further elaboration, that the Humira drug product was approved in December 2002 and that Humira Package Insert is a “prior art FDA approved label.” Pet. 23. Humira Package Insert indicates that Abbot Laboratories created the insert and that it was “[i]ssued” in December 2002. *See* Ex. 1026, 16 (last page of Humira Package Insert identifying Abbott Laboratories and stating “Issued: December 2002”). Humira Package Insert further contains the date December 20, 2002 in the header of each of its pages. *See id.* at 1–16. Such dates, however, are insufficient on their own to show a reasonable likelihood that Humira Package Insert was publicly available in 2002. *See, e.g., Frontier Therapeutics, LLC v. medac Gesellschaft für klinische Spezialpräparate mbH*, Case IPR2016-00649, slip op. at 22 (PTAB Sept. 1, 2016) (Paper 10) (finding that dates on an alleged “printed package insert” were inadequate to show that the document was a printed publication). And Petitioner does not direct us to any source-identifying information from the FDA (e.g., a copy of the insert on the FDA’s website), a publication date, or other indicia indicating when Humira Package Insert, or the information contained therein, became publicly available.

Petitioner also does not explain how regulatory approval of the Humira drug product in December 2002 evidences that Humira Package Insert was publicly accessible in 2002. Indeed, the only evidence on which Petitioner relies—a December 31, 2002 letter from the U.S. Food and Drug Administration (FDA) approving the biologics license application for adalimumab—states that the Humira drug product “*will be marketed* in 40 gm/0.8 mL single use” vials and syringes in accordance with approved labeling. Ex. 1004, 2 (emphasis added). The language in the FDA approval letter, therefore, indicates that, as of December 31, 2002, the Humira drug product was not yet marketed or available to the public.

Petitioner’s experts do not shed further light on whether Humira Package Insert was publicly accessible in December 2002. In that regard, Dr. Posner refers to Humira Package Insert as the “Humira® 2002 Package Insert,” but does not offer testimony regarding its public availability. *See, e.g.*, Ex. 1050 ¶¶ 50–51. Dr. Helfgott testifies “[i]n December 2002, the FDA approved Humira® to treat rheumatoid arthritis” and identifies Exhibit 1026 as the “accompanying Humira® 2002 Package insert.” Ex. 1002 ¶¶ 31, 56. As Patent Owner notes, however, Dr. Helfgott does not identify any evidence tying FDA approval of Humira in December 2002 to the public availability of Humira Package Insert. Prelim. Resp. 43. Moreover, Petitioner does not rely on that testimony as support for the assertion that Humira Package Insert is a prior art printed publication.

In the absence of further explanation or sufficient evidence from Petitioner tending to show that Humira Package Insert, or the dosing information contained therein, was either disseminated or otherwise accessible to the public interested in the art before the April 9, 2004 priority

date of the '216 patent, we find that Petitioner fails to demonstrate a reasonable likelihood that Humira Package Insert is a printed publication for purposes of 35 U.S.C. §§ 102(b) and 311(b).⁷

B. Asserted Obviousness over Humira Package Insert, Psoriasis Press Release, Aulton, and Weinstein, in View of Marzo-Ortega

Petitioner asserts that claims 1–16 of the '216 patent are unpatentable under 35 U.S.C. § 103(a) because the subject matter of those claims would have been obvious over the combination of Humira Package Insert, Psoriasis Press Release, Aulton, and Weinstein, in view of Marzo-Ortega. Pet. 19–22, 36–55, 57–61 (claim charts). The unavailability of Humira Package Insert as prior art undermines Petitioner's obviousness ground, which relies on Humira Package Insert as disclosing subcutaneously administering 40 mg of adalimumab every other week, as independent claims 1 and 9 require, as well as the additional limitations of claims 2–8, and 10–16. *See, e.g., id.* at 57–61 (claim charts). Petitioner's additional references do not cure this deficiency. Accordingly, we are not persuaded the record before us establishes a reasonable likelihood that Petitioner will prevail in showing that the subject matter of claims 1–16 would have been obvious over the combination of Humira Package Insert, Psoriasis Press Release, Aulton, and Weinstein, in view of Marzo-Ortega.

⁷ Patent Owner also argues Petitioner fails to establish that Psoriasis Press Release was publicly available on March 3, 2003, and Petitioner fails to establish that Weinstein was publicly available on March 19, 2003. Prelim. Resp. 44–48. Given our determination regarding Humira Package Insert and the role it plays in Petitioner's obviousness challenge, which we discuss *infra*, we do not reach Patent Owner's additional arguments regarding the public availability of Psoriasis Press Release or Weinstein.

IV. CONCLUSION

Taking account of the information presented in the Petition and the Preliminary Response, and the evidence of record, we determine that Petitioner fails to demonstrate a reasonable likelihood of prevailing at trial as to any challenged claim. Accordingly, the Petition is *denied*, and no trial is instituted.

V. ORDER

It is hereby

ORDERED that the Petition is *denied* as to all challenged claims of the '216 patent, and no trial is instituted;

FURTHER ORDERED that Petitioner's *Pro Hac Vice* Motion to Admit Daniel L. Reisner Pursuant to 37 C.F.R. § 42.10(c) (Paper 3) is *dismissed as moot*; and

FURTHER ORDERED that Petitioner's *Pro Hac Vice* Motion to Admit Abigail Langsam Pursuant to 37 C.F.R. § 42.10(c) (Paper 9) is *dismissed as moot*.

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