UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,

Petitioner,

v.

ABBVIE BIOTECHNOLOGY LTD.,

Patent Owner.

CASE IPR2018-00002
Patent 9,512,216 B2

SANDOZ INC.'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141(c), 142; 28 U.S.C. §1295(a)(4)(A); 5 U.S.C. §§ 702, 704, and 706, and in accordance with 37 C.F.R. § 90.3, Petitioner Sandoz Inc. ("Sandoz") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Decision of the Patent Trial and Appeal Board ("Board") Denying Institution of *Inter Partes* Review entered on May 3, 2018 (Paper 13, a copy of which is attached as Exhibit A), and from all adverse underlying orders, decisions, rulings, and opinions.

For the limited purpose of providing the Director with the information requested in 37 CFR §90.2(a)(3)(ii), Sandoz anticipates that the issues on appeal may include, but are not limited to, the following, as well as any underlying findings, determinations, rulings, decisions, opinions, or other related issues:

- The Board's refusal to consider all evidence of record;

- The Board's determination that Petitioner failed to demonstrate a reasonable likelihood that Patent Owner's Humira 2002 Label and Humira 2003 Label are publicly accessible printed publications for purposes of 35 U.S.C. §§ 102(b) and 311(b); and

- The Board's decision to deny Petitioner's request for authorization to file a reply addressing Patent Owner's arguments regarding the public accessibility of

Patent Owner's Humira Label before the priority date of the '216 patent (Paper 11).

Simultaneous with this filing and in accordance with 37 CFR 90.2(a)(1), this Notice of Appeal is filed with the Director of the United States Patent and Trademark Office; filed with Board; and served upon the Petitioner in accordance with 37 C.F.R. §42.6(e). In addition, a copy of this Notice of Appeal, along with the required fees, are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit.

Dated: July 5, 2018

Respectfully Submitted,
ARNOLD & PORTER KAYE SCHOLER LLP

s/ Deborah E. Fishman

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Notice of Appeal was served on July 5, 2018, via electronic mail upon the following counsel of record for Patent Owner AbbVie Biotechnology Ltd.:

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Dated: July 5, 2018

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/s/ Deborah E. Fishman

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Notice of Appeal is being electronically filed with the Board on July 5, 2018 and is being delivered by hand delivery to the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
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Dated: July 5, 2018

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/s/ Deborah E. Fishman

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing PETITIONER'S NOTICE OF APPEAL was electronically filed on July 5, 2018 with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, at the following address:

United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W., Suite 401
Washington, DC 20005

Dated: July 5, 2018

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Exhibit A

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571-272-7822

Paper No. 13
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 IPR2018-00002
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
Dismissing as Moot Petitioner's Motions for *Pro Hac Vice* Admission
37 C.F.R. § 42.10

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."). With our prior authorization, Petitioner filed a Reply addressing whether we should exercise discretion to deny institution of an *inter partes* review under 35 U.S.C. § 314(a) and/or 35 U.S.C. § 325(d). *See* Paper 11, 4; Paper 12. In the same Order authorizing a Reply to address §§ 314(a) and 325(d), we denied Petitioner's additional request to address in a Reply Patent Owner's arguments in the Preliminary Response regarding the public availability of certain references asserted as prior art in the Petition. Paper 11, 3–4.

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]

[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 8, respectively).

II. BACKGROUND

A. Related Matters

The parties do not identify any litigation, interference proceedings, or reexamination proceedings involving the ’216 patent. *See* Pet. 7–8; 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. 7 (identifying *AbbVie Inc. v. Amgen Inc.*, No. 1:16-cv-00666-MSG (D. Del. Aug. 4, 2016)).

Petitioner also directs us to a previous petition it filed requesting an *inter partes* review of claims 1–16 of the ’216 patent—IPR2017-01824 (the “1824 IPR”). Pet. 4. We denied institution in the 1824 IPR on February 9, 2018. 1824 IPR, Paper 14. Petitioner subsequently filed a Request for Rehearing in the 1824 IPR. Paper 15. We issue a decision denying Petitioner’s Request for Rehearing in the 1824 IPR concurrently with this decision.

Petitioner further identifies several *inter partes* review proceedings in which the Board previously found claims of certain of Patent Owner’s patents unpatentable, but acknowledges that those patents and the ’216 patent do not claim priority to any of the same applications. Pet. 5–6. Petitioner explains that it previously filed additional petitions requesting an *inter partes* review of certain other patents assigned to Patent Owner: IPR2017-01823 (challenging U.S. Patent No. 8,802,100), IPR2017-01987 (challenging U.S. Patent No. 8,911,737), IPR2017-01988 (challenging U.S. Patent No. 8,974,790), IPR2017-02105 (challenging U.S. Patent No. 9,090,689), and IPR2017-02106 (challenging U.S. Patent No. 9,067,992). *Id.* at 7.

Petitioner and Patent Owner collectively 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 6–7; Paper 4, 1–2.

B. The '216 Patent

The '216 patent, titled "Use of TNFα 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 (TNFα) 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-TNFα 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 2003 Label[2] or Humira 2002 Label,[3] Psoriasis Press Release,[4] Aulton,[5] and Weinstein,[6] in

[2] Humira (adalimumab) Label (Abbott Laboratories) (Ex. 1026).
[3] Humira (adalimumab) Label (Abbott Laboratories) (Ex. 1075).
[4] 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).
[5] PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN 275–288 (M. E. Aulton ed., 2d ed. 2002) (Ex. 1051).
[6] THERAPY OF MODERATE-TO-SEVERE PSORIASIS (Gerald D. Weinstein & Alice B. Gottlieb eds., 2d ed. 2003) (Ex. 1003).

view of Mease 2002.[7] 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 2002 Label (Ex. 1075) and Humira 2003 Label (Ex. 1026) as "Printed Publication" Prior Art Under 35 U.S.C. § 102(b)

Before turning to Petitioner's asserted ground, a preliminary issue is whether Petitioner makes an adequate showing for purposes of institution that Humira 2002 Label and/or Humira 2003 Label are 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 2002 Label and Humira 2003 Label each qualifies as 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); *see also, e.g.*, *Symantec Corp. v. Trs. of Columbia Univ.*, Case IPR2015-00371, slip op. at 5, 9 (PTAB June 17, 2015) (Paper 13) (denying institution where the Petition failed to include discussion or cite to evidence sufficient to show that the asserted reference

[7] P J Mease, *Tumour necrosis factor (TNF) in psoriatic arthritis: pathophysiology & treatment with TNF inhibitors*, 61 ANN RHEUM DIS 298–304 (2002) (Ex. 1009).

was a prior art printed publication). Petitioner is not required at this stage of the proceeding to establish by a preponderance of the evidence that Humira 2002 Label and Humira 2003 Label were publicly accessible before the effective filing date of the '216 patent[8] and, therefore, qualify as printed publications. To meet the initial burden of production under *Dynamic Drinkware*, however, the Petition must include argument and direct us to evidence sufficient to show that Petitioner would establish such public accessibility by a preponderance of the evidence during the course of the trial.

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 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

[8] For purposes of the Petition, Petitioner assumes 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. 9.

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 identifies Humira 2002 Label and Humira 2003 Label as prior art under § 102(b), and further alleges that Humira 2002 Label has a publication date of December 2002 and Humira 2003 Label has a publication date of January 2003. Pet. 10 (Table). Petitioner asserts that the Humira drug product "was approved in December 2002 to treat [rheumatoid arthritis]" and represents that each of Humira 2002 Label and Humira 2003 Label 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. *Id.* at 24 (citing Ex. 1004, 2;[9] Ex. 1026, 9; Ex. 1075, 14). Patent Owner responds that Petitioner fails to make a threshold showing that Humira 2002 Label and Humira 2003 Label were available as printed publications before the priority date of the '216 patent, because Petitioner provides insufficient evidence that the references were publicly accessible in December 2002 and January 2003, respectively. Prelim. Resp. 51–57.

We agree with Patent Owner that Petitioner does not demonstrate that Humira 2002 Label or Humira 2003 Label was publicly accessible to the

[9] Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, Approval Letter(s) for Application Number 125057/0, dated December 31, 2002 ("FDA approval letter," Ex. 1004).

extent required to establish either asserted reference as a "printed publication" for purposes of institution. That is, the Petition does not include sufficient discussion, nor does it direct us to sufficient evidence, to show a reasonable likelihood that Petitioner would establish by a preponderance of the evidence that Humira 2002 Label was publicly accessible in December 2002, or that Humira 2003 Label was publicly accessible in January 2003.

Petitioner merely asserts, without further elaboration, that the Humira drug product was approved in December 2002 and that Humira 2002 Label and Humira 2003 Label are "prior art FDA approved label[s]." Pet. 24; *see also id.* at 41 ("The prior art Humira® 2003/2002 Label"). As support, Petitioner directs us to the following evidence: (1) Humira 2002 Label; (2) Humira 2003 Label; and (3) the FDA approval letter. *See id.* at 10 (citing Ex. 1026; Ex. 1075), 24 (citing Ex. 1004, 2; Ex. 1026, 9; Ex. 1075, 14).

With respect to Humira 2002 Label and Humira 2003 Label, we note that Humira 2002 Label identifies Abbott Laboratories and contains the language "Issued: December 2002." Ex. 1075, 16. Humira 2002 Label further contains the date December 20, 2002 in the header of each of its pages. *See id.* at 1–16. Similarly, Humira 2003 Label identifies Abbott Laboratories and contains the language "Revised: January, 2003" on several of its pages. Ex. 1026, 10, 13. Such information, however, is insufficient on its own to show a reasonable likelihood that Humira 2002 Label and Humira 2003 Label were publicly available in December 2002 and January 2003, respectively. *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, LLC v. medac Gesellschaft für klinische Spezialpräparate mbH*, Case IPR2016-00649, slip op. at 22 (PTAB Sept. 1, 2016) (Paper 10) (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 insufficient to make a threshold showing at institution that the document was a printed publication).

Petitioner also does not direct us to any source-identifying information from the FDA (e.g., a copy of the labels on the FDA's website), a publication date, or other indicia indicating when Humira 2002 Label or Humira 2003 Label became publicly available. Nor does the Petition include or cite to information related to how one might have obtained a copy of Humira 2002 Label or Humira 2003 Label, or whether the labels were generally accessible during the relevant timeframe such that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence could have located them. *Kyocera*, 545 F.3d at 1350. Such evidence could include in this case, for example, testimony from a person interested in the art explaining how one could have located the labels by searching the FDA's website; or evidence of indexing on the internet such that a search "using any combination of search words, would have led to the [labels] appearing in the search results," *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1349 (Fed. Cir. 2016).

Petitioner also does not explain how regulatory approval of the Humira drug product in December 2002 evidences that Humira 2002 Label

was publicly accessible in late 2002, or that Humira 2003 Label was publicly accessible in early 2003. Indeed, the only evidence on which Petitioner relies—the FDA approval letter pertaining to 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, suggests that, as of December 31, 2002, the Humira drug product was not yet marketed or available to the public, and the Petition points to no further evidence linking FDA approval of Humira to any specific date that either Humira label was made publicly accessible.

Petitioner's experts do not shed further light on whether Humira 2002 Label and Humira 2003 were publicly accessible in December 2002 and January 2003, respectively. In that regard, Dr. Posner refers to the labels as "the Humira® 2003 Label and the Humira® 2002 Label," but does not offer testimony regarding whether or when either became publicly available. *See, e.g.*, Ex. 1050 ¶¶ 50–51. Dr. Helfgott testifies "[i]n December 2002, the FDA approved Humira® to treat rheumatoid arthritis" and identifies Exhibits 1026 and 1075 as "the Humira® 2003 Label and the Humira® 2002 Label." Ex. 1002 ¶¶ 31–32. Dr. Helfgott further testifies that, "the 2002 Humira® Label would have been available on the date Humira® was approved in 2002 and FDA-approved labels are publicly available for use by physicians and the public on the date printed on the insert." *Id.* ¶ 15.

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 2002 Label or Humira 2003 Label. Prelim. Resp. 55. Accordingly, we accord Dr. Helfgott's testimony on that point little to no

weight. *See* 37 C.F.R. § 42.65(a). In any event, Petitioner does not rely on Dr. Helfgott's testimony as support for the assertion that Humira 2002 Label and Humira 2003 Label are prior art printed publications.

In its Reply—which we limited to addressing Patent Owner's arguments that we should use our discretion to deny institution under §§ 314(a) and 325(d)—Petitioner refers to other evidence of record in this proceeding that may bear on whether Humira 2003 Label was publicly accessible in 2003. Reply 2. For example, Petitioner directs us to a screenshot from the Internet Archive Wayback Machine depicting what appears to be a copy of Humira 2003 Label, as well as an affidavit from the Office Manager at the Internet Archive regarding the Uniform Resource Locator date code associated with an archived internet record. *Id.* (citing Ex. 1072; Ex. 1076).

Petitioner, however, neither discusses nor cites that evidence in the Petition. *Compare* Reply 2, *with* Pet. generally. Petitioner's attempt in the Reply to meet its threshold showing that Humira 2003 Label is a printed publication is not only untimely, but also appears to circumvent our Order (Paper 11) 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 labels or package inserts for the Humira product were publicly available before the priority 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 11, 3 (citing *Dynamic Drinkware*, 800 F.3d at 1379). Thus, it was incumbent upon Petitioner to direct us to that evidence *in the Petition* if Petitioner wanted us to consider it in determining whether Petitioner made a threshold

showing that Humira 2002 Label and Humira 2003 Label are printed publication prior art.

In the absence of further explanation or sufficient evidence in the Petition tending to show that Humira 2002 Label and Humira 2003 Label were either disseminated or otherwise accessible to the public interested in the art before the effective filing date of the '216 patent, we find that Petitioner fails to demonstrate a reasonable likelihood that those labels are printed publications for purposes of 35 U.S.C. §§ 102(b) and 311(b).[10]

B. Asserted Obviousness over Humira 2002 Label or Humira 2003 Label, Psoriasis Press Release, Aulton, and Weinstein, in View of Mease 2002

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 2002 Label or Humira 2003 Label (which Petitioner refers to collectively as "the Humira® 2003/2002 Label"), Psoriasis Press Release, Aulton, and Weinstein, in view of Mease 2002. Pet. 11, 20–23, 40–60, 61–65 (claim charts). The unavailability of Humira 2002 Label and Humira 2003 Label as prior art undermines Petitioner's obviousness ground, which relies on the labels as disclosing subcutaneously administering 40 mg of adalimumab every other week, as recited in independent claims 1 and 9, as well as the additional

[10] 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. 58–62. Given our determination regarding Humira 2002 Label and Humira 2003 Label, and the role each 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.

limitations of claims 3–8, and 11–16. *See, e.g.*, *id.* at 61–65 (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 2002 Label or Humira 2003 Label, Psoriasis Press Release, Aulton, and Weinstein, in view of Mease 2002.[11]

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;

[11] Because we deny institution based on Petitioner's failure to make a threshold showing that Humira 2002 Label and Humira 2003 Label are prior art printed publications, we decline to address Patent Owner's arguments that we should use our discretion to deny the Petition under §§ 314(a) and/or 325(d) because the Petition presents "nearly identical references and arguments" that Petitioner presented in the 1824 IPR. *See* Prelim. Resp. 21–29.

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 8) is *dismissed as moot*.

PETITIONER:

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