**UNITED STATES PATENT AND TRADEMARK OFFICE**

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SANDOZ INC.,

Petitioner,

v.

ABBVIE BIOTECHNOLOGY LTD.,

Patent Owner.

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CASE IPR2017-01824
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 February 9, 2018 (Paper 14, a copy of which is attached as Exhibit A), the Decision Denying Petitioner's Request for Rehearing entered May 3, 2018 (Paper 16, a copy of which is attached as Exhibit B) 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 available 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 (1) to file a reply addressing Patent Owner's arguments regarding the public accessibility of its Humira Label before the priority date of the '216 patent, and (2) to file a motion for leave to take targeted discovery under CFR 42.51 related to the public accessibility of Patent Owner's own Humira Labels (Exhibit 1070; Paper 13).

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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*Attorneys for Petitioner*

## 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.:

| Lead Counsel | Back-up Counsel |
|---|---|
| **William B. Raich (Reg. No. 54,386)**<br>Finnegan, Henderson,<br>Farabow, Garrett & Dunner,<br>901 New York Avenue, NW<br>Washington, DC 20001-4413<br>Telephone: 202-408-4210<br>Facsimile: 202-408-4400<br>Email: william.raich@finnegan.com | **Michael J. Flibbert (Reg. No. 33,234)**<br>**Maureen D. Queler (Reg. No. 61,879)**<br>Finnegan, Henderson, Farabow,<br>Garrett & Dunner, LLP<br>901 New York Avenue, NW<br>Washington, DC 20001-4413<br>Telephone: 202-408-4493<br>Facsimile: 202-408-4400<br>Email: michael.flibbert@finnegan.com<br>maureen.queler@finnegan.com<br><br>**Jessica L.A. Marks (Reg. No. 67,451)**<br>Finnegan, Henderson, Farabow,<br>Garrett & Dunner LLP<br>Two Freedom Square<br>11955 Freedom Drive<br>Reston, VA 20190-5675<br>Telephone: 571-203-2791<br>Facsimile: 202-408-4400<br>Email: jessica.marks@finnegan.com |

Dated: July 5, 2018

**ARNOLD & PORTER KAYE SCHOLER LLP**

*/s/ Deborah E. Fishman*

Deborah E. Fishman (Reg. No. 48,621)

## 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
Madison Building East, 10B20
600 Dulaney Street
Alexandria, VA 22314-5793

Dated: July 5, 2018

**ARNOLD & PORTER KAYE SCHOLER LLP**

*/s/ Deborah E. Fishman*

Deborah E. Fishman (Reg. No. 48,621)

## 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

**ARNOLD & PORTER KAYE SCHOLER LLP**

*/s/ Deborah E. Fishman*

Deborah E. Fishman (Reg. No. 48,621)

# Exhibit A

Trials@uspto.gov
571-272-7822

Paper No. 14
Entered: February 9, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SANDOZ INC.,
Petitioner,

v.

ABBVIE BIOTECHNOLOGY LTD.,
Patent Owner.

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Case IPR2017-01824
Patent 9,512,216 B2

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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 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 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.

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[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*.

PETITIONER:

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# Exhibit B

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Paper No. 16
Entered: May 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Case IPR2017-01824
Patent 9,512,216 B2

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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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