

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACUTICALS INC.,
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner.

Case IPR2016-01565
Patent 8,853,156 B2

Before TONI R. SCHEINER, BRIAN P. MURPHY, and ZHENHU YANG,
Administrative Patent Judges.

SCHEINER, *Administrative Patent Judge.*

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. (“Petitioner” or “Mylan”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1, 2, 4–8, 10–18, and 23–25 of U.S. Patent No. 8,853,156 B2 (Ex. 1001, “the ’156 patent”). Boehringer Ingelheim International GmbH (“Patent Owner” or “Boehringer”) filed a Preliminary Response to the Petition (Paper 11, “Prelim. Resp.”). We have statutory authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the arguments and evidence presented in the Petition and the Preliminary Response, we are persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenge to claims 1, 2, 4, 5, and 23 of the ’156 patent. Accordingly, we institute an *inter partes* review of claims 1, 2, 4, 5, and 23.

A. Related Proceedings

The ’156 patent has been asserted in *Boehringer Ingelheim Pharm. Inc. v. Mylan Pharmaceuticals*, Case No. 1:15-cv-00145-JPB (N.D.W.Va.) (inactive), and *Boehringer Ingelheim Pharm. Inc. v. HEC Pharm Group*, Case No. 3:15-cv-05982 (D.N.J.) (consolidated). Pet. 3; Paper 7, 3.

U.S. Patent Nos. 8,673,927, 8,846,695, and 9,173,859 also have been asserted in the consolidated litigation, and Petitioner has filed IPR2016-

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01563, IPR2016-01564, and IPR2016-1566, requesting *inter partes* review of those patents, respectively. Pet. 3.

B. The Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

References	Basis	Claims Challenged
Mikhail ¹	§ 102(a)	1, 2, 4, 5, and 23
The Januvia Label, ² Huettner, ³ and Mikhail or the Knowledge of a POSA	§ 103(a)	1, 2, 4–8, 10–18, and 23–25

Petitioner supports its challenges with the Declaration of Mayer B. Davidson, M.D, dated August 10, 2016 (Ex. 1002, “Davidson Declaration”).

¹ Nasser Mikhail, *Incretin mimetics and dipeptidyl peptidase 4 inhibitors in clinical trials for the treatment of type 2 diabetes*, 17 EXPERT OPIN. INVESTIG. DRUGS 845–853 (2008) (Ex. 1003, “Mikhail”).

² JanuviaTM (sitagliptin phosphate tablets) Prescribing Information (2006) (Ex. 1006, “the Januvia Label”).

³ Silke Huettner et al., *BI 1356, a Novel and Selective Xanthine Based DPP-4 Inhibitor, Demonstrates Good Safety and Tolerability with a Wide Therapeutic Window*, Poster No. 0586P, ADA (June 22–25, 2007) (Ex. 1004, “Huettner”).

C. The '156 Patent (Ex. 1001)

The '156 patent, titled “Treatment for Diabetes in Patients Inappropriate for Metformin Therapy,” issued October 7, 2014, names inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. Ex. 1001 (54), (75).

“One of the typical long-term complications of diabetes is diabetic neuropathy,” which can lead to renal impairment, and “can progress to renal failure in some cases.” *Id.* at 1:17–25. The '156 patent teaches that “[m]etformin is an antihyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes mellitus,” but “treatment with metformin can be associated with adverse symptoms, such as e.g. gastrointestinal symptoms or, occasionally, as a severe adverse effect, lactic acidosis (which can be fatal), for which one putative risk factor is decreased renal function.” *Id.* at 1:51–62. “Further, since metformin is largely eliminated unchanged by the kidneys via glomerular filtration and tubular secretion, it is contraindicated in patients with renal disease or kidney impairment.” *Id.* at 1:62–65. “Thus, conventional metformin therapy can be inappropriate for certain patients, e.g. due to intolerability or contraindication against metformin.” *Id.* at 1:65–67.

The '156 patent discloses another class of drugs, DPP-IV inhibitors, which “are considered to be promising drugs for the treatment of diabetes mellitus.” Ex. 1001, 4:12–13. DPP-IV inhibitors act through a different mechanism than metformin. Ex. 1002 ¶ 29. A highly simplified explanation

of the mechanism is as follows: the enzyme DPP-IV (dipeptidyl peptidase IV) breaks down certain bioactive peptides, including glucagon-like peptide (GLP-1) (Ex. 1001, 4:6–11), a naturally occurring peptide “that helps reduce blood glucose by stimulating the pancreas to produce insulin and by inhibiting the release of glucagon, a substance that causes the liver to release glucose” (Ex. 1002 ¶ 29), but DPP-IV inhibitors block the activity of the DPP-IV enzyme, thereby preventing the breakdown of GLP-1 and helping to lower blood glucose levels (*id.*).

The '156 patent discloses a number of DPP-IV inhibitors (Ex. 1001, 16:35–19:28), including a particularly preferred species, 1-[(4 -methyl-quinazolin-2 -yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine—also known as “BI 1356” or “linagliptin” (Ex. 1001, 16:39–40; Ex. 1002 ¶ 17). According to the '156 patent, DPP-IV inhibitors are “particularly suitable for treating and/or preventing (including preventing or slowing the progression) of metabolic diseases, particularly diabetes (especially type 2 diabetes mellitus) and conditions related thereto (e.g. diabetic complications), particularly in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin.” Ex. 1001, 9:33–39. Such patients include those ineligible for metformin therapy due to renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, or hereditary galactose intolerance. *Id.* at 27:51–60.

D. Illustrative Claim

Petitioner challenges claims 1, 2, 4–8, 10–18, and 23–25 of the '156 patent, of which claims 1 and 23–25 are independent claims. Claim 1, reproduced below, is illustrative.

1. A method of treating and/or preventing metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of:
 - renal disease, renal impairment or renal dysfunction,
 - unstable or acute congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance.

Ex. 1001, 29:1–11.

E. Patent Owner's Motion to Seal & Proposed Protective Order

Patent Owner filed a Motion to Seal (Paper 10), seeking authorization to file “confidential versions of Exhibits 2010, 2011, 2012, 2013, 2014, and 2015 under seal, pursuant to 37 C.F.R. § 42.54” (*id.* at 2).

Patent Owner asserts that Exhibits 2010–2015 are copies of internal Boehringer clinical development plans, management summaries, nonclinical and clinical study reports, and industry communications strategy documents, containing confidential and commercially sensitive technical and business information. *Id.* Patent Owner contends that public disclosure of this information would significantly harm Boehringer's competitive position because it would allow competitors to access sensitive technical and

business information related to, among other things, Boehringer's drug-development and marketing strategy. *Id.* "To the best of Boehringer's knowledge, none of the confidential, proprietary information in Exhibits 2010-2015 has previously been made publicly available and Boehringer has taken reasonable steps to prevent the public disclosure of this information."

Id.

Patent Owner indicates that the parties have met and conferred and have agreed that the Board's Default Protective Order (attached to the Motion to Seal as Appendix A) shall govern Exhibits 2010-2015, to the extent they are found to contain confidential information. *Id.* at 2-3.

At this stage of the proceeding, we have not found it necessary to discuss explicitly Patent Owner's confidential information, but we remind Patent Owner that there is an expectation that confidential information subject to a protective order will be made public should the need to refer to it arise. Although we reserve ruling on the Motion to Seal and entry of the Default Protective Order, Exhibits 2010-2015 will remain under seal in the interim.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under this standard, we presume that a claim term carries its "ordinary and customary meaning,"

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which “is the meaning the term would have to a person of ordinary skill in the art in question” at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) (“Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.”).

Petitioner “believes that no terms or phrases require specific construction for purposes of this IPR.” Pet 6. Patent Owner does not address claim construction in its Preliminary Response. We determine that no claim term requires express construction for purposes of deciding whether to institute a review in this case. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

*B. Asserted Anticipation of Claims 1, 2, 4, 5, and 23
by Mikhail*

Petitioner asserts that Mikhail discloses all the limitations of claims 1, 2, 4, 5, and 23, and therefore, anticipates those claims. Pet. 17–19. Patent Owner opposes, contending that Mikhail “is not prior art to the ’156 patent.” Prelim. Resp. 2, 9–11.

1. Overview of Mikhail (Ex. 1003)

Mikhail discusses the results of clinical trials evaluating the efficacy of the DPP-4 inhibitors, sitagliptin and vildagliptin, orally administered to patients with type 2 diabetes mellitus. Ex. 1003, 847. Mikhail concludes that both DPP-4 inhibitors are useful as “add-on agent[s] to ongoing metformin therapy,” and as monotherapy agents in patients unable to tolerate metformin. *Id.* at 845, 847. In addition, Mikhail concludes that sitagliptin, in particular, can be used as monotherapy in “[p]atients who cannot take metformin due to . . . renal insufficiency.” *Id.* at 850, Table 1, 851.

2. Analysis

Petitioner, relying on the testimony of Dr. Davidson, contends that Mikhail discloses all the limitations of independent claims 1 and 23, as well as the limitations of dependent claims 2, 4, and 5. Pet. 17–19. In particular, Petitioner contends that “Mikhail discloses the use of DPP-IV Inhibitors, specifically sitagliptin and vildagliptin, through a single oral dose, for the treatment of type II diabetes,” a metabolic disorder, and “discloses that oral doses of sitagliptin should be used as monotherapy for ‘patients who cannot take metformin due to adverse effects or renal insufficiency.’” Pet. 17–18 (citing Ex. 1003, 845, 847, 851; Ex. 1002 ¶¶ 40, 43, 47).

Patent Owner does not address Mikhail’s disclosure at this stage of the proceeding. Nevertheless, we have reviewed the disclosures of Mikhail relied on by Petitioner, and are satisfied that Petitioner shows sufficiently that Mikhail discloses all the elements of claims 1, 2, 4, 5, and 23, in the

manner required by the claims. In particular, Mikhail discloses that sitagliptin, a DPP-IV inhibitor, can be used to treat type 2 diabetes in “patients who cannot take metformin due to adverse effects or renal insufficiency.” Ex. 1003, 847, 851. This disclosure appears to meet the limitations of claims 1 and 2, directed to treating or preventing metabolic diseases by orally administering a DPP-IV inhibitor to a patient for whom metformin therapy is contraindicated, wherein contraindications include renal disease, impairment or dysfunction, congestive heart failure, etc. This same disclosure also appears to meet the limitations of claims 4 and 5, which each depend from claim 1, and respectively specify that the metabolic disease is type 2 diabetes mellitus, and the contraindication is renal disease, impairment, or dysfunction. Finally, this same disclosure also appears to meet the limitations of claim 23, directed to treating or preventing type 2 diabetes mellitus by orally administering a DPP-IV inhibitor to a patient for whom metformin therapy is contraindicated, wherein contraindications include renal disease, impairment or dysfunction, congestive heart failure, etc.

As indicated above, Patent Owner does not address Mikhail’s disclosure at this stage of the proceeding. However, Patent Owner contends that Mikhail, published in June 2008, is not prior art because “the inventions of the ’156 patent were conceived and reduced to practice no later than August 7, 2007.” Prelim. Resp. 2.

“In an *inter partes* review, the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence’” “and that burden never shifts to the patentee.” *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Petitioner also has the initial burden of production to show that an asserted reference is prior art to the challenged claims under a relevant subsection of 35 U.S.C. § 102. *Id.* at 1379. Once Petitioner has met that initial burden, however, the burden of production shifts to Patent Owner. That shifting burden “may entail ‘producing additional evidence and presenting persuasive argument based on new evidence and evidence already of record.’” *Id.* (quoting *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008).

A threshold issue, then, is whether Petitioner has met its initial burden of showing that Mikhail is prior art to the ’156 patent. The parties agree that Mikhail has a publication date in June, 2008. Pet. 15; Prelim. Resp. 2. According to the face of the ’156 patent, however, the earliest possible effective filing date of the patent is August 6, 2008, the filing date of Provisional Application No. 61/086,620. Ex. 1001 (60). On this record, we determine that Petitioner has satisfied its initial burden of going forward with evidence that Mikhail is prior art to the ’156 patent, at least under 35 U.S.C. § 102(a). Therefore, the burden of producing evidence and/or argument in rebuttal shifts to Patent Owner.

As discussed above, Patent Owner contends that the subject matter of the challenged claims was conceived and reduced to practice by the

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inventors of the '156 patent prior to August 7, 2007. To remove Mikhail as a prior art reference, Patent Owner must produce evidence showing either (1) conception and reduction to practice before Mikhail's publication date; or (2) conception before Mikhail's publication date combined with reasonably continuous diligence up to reduction to practice after that date. *See Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1323 (Fed. Cir. 2013).

“Priority of invention and its constituent issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings.” *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003).

“[C]onception must encompass all limitations of the claimed invention . . . and ‘is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.’” *Id.* at 1340 (quoting *Burroughs Wellcome Co. v. Barr Labs. Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)). To establish an actual reduction to practice, the inventor must prove that: (1) an embodiment of the invention was constructed that meets all the limitations of the claims at issue; and (2) the inventor appreciated that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998).

In addition, a showing of prior invention requires corroboration.

This court has developed a rule requiring corroboration where a party seeks to show conception through the oral testimony of an inventor. *Price*, 988 F.2d at 1195. This requirement arose out

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of a concern that inventors testifying in patent infringement cases would be tempted to remember facts favorable to their case by the lure of protecting their patent or defeating another's patent.

Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1577 (Fed. Cir. 1996); *see also Brown v. Barbacid*, 436 F.3d 1376, 1380 (Fed. Cir. 2006) (addressing conception, reduction to practice, and reasonable diligence in an interference case (citing *Price v. Symsek*, 988 F.2d 1187, 1196 (Fed. Cir. 1993))).

“Sufficiency of corroboration is determined by using a ‘rule of reason’ analysis, under which all pertinent evidence is examined when determining the credibility of an inventor’s testimony.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1170 (Fed. Cir. 2006) (citation omitted). Corroboration may be testimony of a witness, other than the inventor, to the actual reduction to practice, or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor. *Id.*

At this early stage of the proceeding, Patent Owner’s evidence in support of its contention consists of confidential internal documents detailing clinical development plans, management summaries, nonclinical and clinical study reports, and industry communications strategy documents. Prelim. Resp. 9–11 (citing Exs. 2010–2015). This evidence has neither been developed nor tested on this record. Merely by way of example, the evidence cited has not been shown persuasively to reflect the work of the named inventors of the ’156 patent. On this record, we conclude that Patent Owner’s evidence of prior invention is not sufficient to establish conception

and reduction to practice prior to Mikhail, nor to remove Mikhail as a prior art reference.

Moreover, this avenue is unavailable to antedate a reference that qualifies under 35 U.S.C. § 102(b)—i.e., a reference that constitutes a statutory bar—thus, Patent Owner must show that the '156 patent is entitled to the benefit of its Provisional Application No. 61/086,620 (filed August 6, 2008) or Provisional Application No. 61/105,915 (filed October 16, 2008).

Finally, as discussed above, on this record, we are satisfied that Petitioner has shown sufficiently that Mikhail discloses all the elements of claims 1, 2, 4, 5, and 23, in the manner required by the claims.

Accordingly, we determine that Petitioner has established a reasonable likelihood of prevailing in its assertion that claims 1, 2, 4, 5, and 23 are anticipated by Mikhail.

*C. Asserted Obviousness of claims 1, 2, 4–8, 10–18, and 23–25
over the Januvia Label, Huettner, and Mikhail*

Petitioner asserts that claims 1, 2, 4–8, 10–18, and 23–25 would have been obvious over the Januvia Label and Huettner together with either Mikhail or the knowledge of a person of ordinary skill in the art. Pet. 19–31. Patent Owner opposes, contending that Petitioner “has not shown that the Januvia Label and Huettner are ‘printed publications’” within the meaning of 35 U.S.C. § 311(b). Prelim. Resp. 11.

1. The Januvia Label (Ex. 1006)

The Januvia Label provides “Highlights of Prescribing Information” for Januvia™ (sitagliptin phosphate) tablets. Ex. 1006, 1. According to the Januvia Label, sitagliptin “is indicated as an adjunct for diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus” at a dose of 100 mg once daily, when used as monotherapy. *Id.* The Januvia label provides dosage adjustments (downward) for patients with moderate, severe, and end stage renal disease. *Id.* The Januvia label also states that “[t]hese highlights do not include all the information needed to use Januvia safely and effectively.” *Id.* The Januvia Label indicates an “Initial U.S. Approval” date of 2006, and also indicates it was “Revised: 10/2006.” *Id.*

2. Huettner (Ex. 1004)

Huettner describes BI 1356, i.e., linagliptin, as “a xanthine analogue, which exhibits a high potency for DPP-4 inhibition, increases the half-life of circulating incretin hormones, and improves glucose homeostasis in preclinical studies.” Ex. 1004, 1. Huettner reports the results of a randomized, double-blind, placebo controlled single rising dose study in healthy male volunteers, and concludes, among other things, that “[r]enal excretion was low and does not constitute the main pathway for elimination of BI 1356.” *Id.* Huettner appears to be a poster (Poster No. 0586P) associated with an American Diabetes Association (ADA) meeting held in Chicago, June 22–27, 2007.

*3. Analysis of the Januvia Label and the Huettner Poster
as Printed Publications*

35 U.S.C. § 311(b) states that “a petitioner in an *inter partes* review may request to cancel . . . claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” Thus, before considering Petitioner’s obviousness challenge, we must address whether Petitioner has provided a sufficient threshold showing that the Januvia Label and Huettner constitute prior art under section 102—a legal question based on underlying factual determinations. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987); *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

Petitioner has the ultimate burden of persuasion to prove unpatentability by a preponderance of the evidence. *Dynamic Drinkware*, 800 F.3d at 1378–79. Petitioner also bears the initial burden of production to establish the existence of prior art that renders the claims unpatentable. *Id.* To satisfy the initial burden of production, we have often required a petitioner to make a threshold showing that the reference relied upon was publicly accessible as a printed publication prior to the effective filing date of a challenged patent. *See, e.g., Frontier Therapeutics, LLC v. Medac Gesellschaft Fur Klinische Spezialpraparate MBH*, Case IPR2016-00649, slip op. at 22 (PTAB September 1, 2016) (Paper 10) (finding that an alleged “printed package insert” was not a printed publication); *Symantec Corp. v. Trs. of Columbia Univ.*, Case IPR2015-00371, slip op. at 5–9 (PTAB June

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17, 2015) (Paper 13); *Temporal Power, Ltd. v. Beacon Power, LLC*, Case IPR2015-00146, slip op. at 8–11 (PTAB Apr. 27, 2015) (Paper 10); *Dell, Inc. v. Selene Comm’n Techs., LLC*, Case IPR2014-01411, slip op. at 21–22 (PTAB Feb. 26, 2015) (Paper 23). “A given reference is ‘publicly accessible’ upon a satisfactory showing that such 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.” *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006) (citing *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)); *see also Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012).

A party seeking to introduce a reference “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.” *Wyer*, 655 F.2d at 227 (quoting *Philips Elec. & Pharm. Indus. Corp. v. Thermal & Elecs. Indus., Inc.*, 450 F.2d 1164, 1171 (3d Cir. 1971)). As explained by the Federal Circuit, a “determination of whether a reference is a ‘printed publication’ under 35 U.S.C. § 102(b) 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).

Petitioner, relying on the cover page of the Januvia Label, asserts that “[t]he Januvia Label published in 2006” and therefore, is “§ 102 prior art to the ’156 patent.” Pet. 19 (citing Ex. 1006, 1). Similarly, relying on the document itself, Petitioner asserts that “Huettner was published in June 2007 and is § 102(b) prior art to the ’156 patent.” Pet. 21 (citing Ex. 1004).⁴

Patent Owner contends that Petitioner has not shown that either of these documents was publically accessible before the priority date of the ’156 patent. Prelim. Resp. 11.

Specifically, Patent Owner contends that Petitioner “offers no evidence when (or even if) the [Januvia Label] was published and publically available,” but simply relies on “conclusory assertions.” *Id.* at 13. Patent Owner contends that:

The document, on its face, is labeled “Highlights of Prescribing Information” but contains no source-identifying information. Indeed, the front page notes that “[t]hese highlights do not include all the information needed to use JANUVIA safely and effectively” and direct the reader to “[s]ee full prescribing information.” . . . Moreover, [the Januvia Label] contains no information identifying when it became publically available. Even assuming the document to be the label that the FDA approved for JANUVIA in 2006, Mylan has provided no evidence that it became publically available at the same time as approval. The only date on the document appears on the first

⁴ Although not relied on in the Petition, we note that Dr. Davidson also states, without further elaboration, that “[t]he Januvia Label published in 2006,” and “Huettner was published in June 2007.” Ex. 1002 ¶¶ 52, 56.

page, noting that it was “Revised: 10/2006.” . . . By its plain terms, the 10/2006 date only indicates when the document was revised, and has no bearing on whether and when it became publically available.

Prelim. Resp. 14–15.

In addition, Patent Owner contends that Huettner “is a poster that was allegedly displayed at the June 22–26 2007 American Diabetes Association annual meeting.” *Id.* at 18. Citing *In Re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004) for factors relevant to determining whether a temporarily displayed reference constitutes a “printed publication” under section 102 (b), Patent owner contends that:

[Petitioner] has not presented any evidence suggesting that the poster was in fact displayed or, if it was indeed displayed, (i) the length of time the display was exhibited; (ii) the expertise of the target audience; (iii) the existence of reasonable expectations that the material displayed would not be copied; and (iv) the simplicity or ease with which the material displayed could have been copied. . . . Neither has Mylan provided allegations or evidence regarding if and when Huettner was published aside from being displayed at the ADA meeting.

Prelim. Resp. 18.

We agree with Patent Owner that Petitioner fails to provide a threshold showing that the Januvia Label and the Huettner poster constitute “printed publications” under 35 U.S.C. §§ 102 and 311(b). The above-quoted contentions constitute Petitioner’s entire argument that these documents qualify as prior art. Pet. 19 (citing Ex. 1006, 1), 21 (citing Ex. 1004). The Petition does not include or cite to any information related to

whether the Januvia label was publically accessible in the relevant time frame, how one might have obtained a copy of it, or whether it was reasonably accessible through generally available means. But as the Board recognized in *Frontier Therapeutics*, a date merely printed on a reference is not synonymous with a publication date. IPR2016-00649, Paper 10 at 22. Similarly, the Petition does not include or cite to any information related to the display or subsequent publication of the Huettner poster.

Without more, Petitioner's contentions do not rise to the level of "threshold evidence" that the Januvia Label or the Huettner poster qualify as "printed publication" prior art, and we determine Petitioner has not satisfied its initial burden of production to show that either document is available as a prior art printed publication.

Claims 1, 2, 4, 5, and 23

In challenging claims 1, 2, 4, 5, and 23 as obvious, Petitioner relies on the combined teachings of the Januvia Label and Mikhail, or the Januvia Label and the knowledge of one of ordinary skill in the art. Petitioner, however, has not established that the Januvia Label is available as a prior art printed publication.

Nevertheless, as discussed above in Section II.B.2, we are satisfied that Petitioner has shown sufficiently that Mikhail discloses all the elements of claims 1, 2, 4, 5, and 23, in the manner required by the claims.

Inasmuch as "anticipation is the epitome of obviousness" (*In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002)), we determine that

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Petitioner has established a reasonable likelihood of prevailing in its assertion that claims 1, 2, 4, 5, and 23 would have been obvious over Mikhail alone.

Claims 6–8, 10–18, 24, and 25

Petitioner’s challenge to these claims relies heavily on the Januvia Label and/or the Huettner poster. Pet. 25–43. As we have determined that Petitioner has not established that either the Januvia Label or the Huettner poster is available as a prior art printed publication, Petitioner has not shown a reasonable likelihood of prevailing in its assertion that the subject matter of claims 6–8, 10–18, 24, and 25 of the ’156 patent would have been obvious over the Januvia Label, Huettner, and Mikhail or the knowledge of one of ordinary skill in the art.

Accordingly, we do not institute an *inter partes* review of claims 6–8, 10, 18, 24, and 25 of the ’156 patent.

III. CONCLUSION

For the foregoing reasons, on this record, we are persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1, 2, 4, 5, and 23 of the ’156 patent are unpatentable.

We emphasize that at this stage of the proceeding, we have not made a final determination as to the patentability of the instituted claims. Our final decision will be based on the full record developed during trial.

IV. ORDER

Accordingly, it is

ORDERED that that pursuant to 35 U.S.C. § 314 an *inter partes* review of claims 1, 2, 4, 5, and 23 of U.S. Patent No. 8,853,156 B2 is hereby instituted on the following grounds:

Claims 1, 2, 4, 5, and 23 under 35 U.S.C. § 102 as anticipated by Mikhail; and

Claims 1, 2, 4, 5, and 23 under 35 U.S.C. § 103 as obvious over Mikhail; and

FURTHER ORDERED that the trial is limited to the grounds identified above and no other ground is authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '156 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of trial.

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