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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner.

Case IPR2016-01566
Patent 9,173,859 B2

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

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–22 of U.S. Patent No. 9,173,859 B2 ("the '859 patent," Ex. 1001). Paper 2 ("Pet."). Boehringer Ingelheim International GmbH ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We review the Petition under 35 U.S.C. § 314.

Based on this record, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Therefore, we decline to institute an *inter partes* review of claims 1–22 of the '859 patent. *See* 35 U.S.C. § 314(a).

Related Proceedings

Patent Owner informs us that it has asserted the '859 patent against Petitioner in *Boehringer Ingelheim Pharm. Inc. v. Mylan Pharm. Inc.*, Case No. 1:15-cv-00145 (N.D.W.Va.), which is currently inactive. Paper 6, 3.

According to the parties, the '859 patent is the subject of several other cases in district courts, which have been consolidated into *Boehringer Ingelheim Pharm. Inc. v. HEC Pharm Group*, Case No. 3:15-cv-05982 (D.N.J.). Pet. 5; Paper 6, 2. In that case, Patent Owner also asserted U.S. Patent Nos. 8,673,927, 8,846,695, and 8,853,156. Pet. 5. Petitioner has concurrently filed IPR2016-01563, IPR2016-01564, and IPR2016-01565, challenging those patents respectively. *Id.*

The '859 Patent

The '859 patent describes selected DPP-4 inhibitors that are useful for treating various diseases, including type 2 diabetes. Ex. 1001, 3:66–4:20, 16:45–17:2. Specifically, the '859 patent identifies DPP-4 inhibitor 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, as "particularly preferred." *Id.* at 5:20–35.

DPP-4 inhibitors "influence the plasma level of bioactive peptides including the peptide GLP-1 and are highly promising molecules for the treatment of diabetes mellitus." *Id.* at 1:21–23. The '859 patent states that the DPP-4 inhibitors disclosed therein may be used in conjunction with other antidiabetic agents, such as metformin, "either in a free combination or in a fixed combination in a tablet." *Id.* at 8:60–9:11, 20:25–51. According to the '859 patent:

> A particularly preferred example of an antidiabetic combination partner is metformin in doses of about 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or about 300 mg to 1000 mg once or twice a day, or delayed-release metformin in doses of about 100 mg to 1000 mg or preferably 500 mg to 1000 mg once or twice a day or about 500 mg to 2000 mg once a day.

Id. at 14:6–12.

Illustrative Claims

Among the challenged claims, claims 1, 13, 14, and 16–18 are independent. Claims 1 and 14 are representative and are reproduced below:

> 1. A method of treating type 2 diabetes comprising
>
> administering to a patient in need thereof (a) 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a therapeutically active salt thereof, in an oral dosage of 2.5 mg or 5 mg, and (b) metformin
>
> wherein the dose of metformin is 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or 300 mg to 1000 mg once or twice a day, or as delayed-release metformin in a dose of 500 mg to

1000 mg once or twice a day, or 500 mg to 2000 mg once a day, or

wherein the dose of metformin is 500 mg, 850 mg or 1000 mg as a single dose with a total daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form, or

wherein the dose of metformin is 500 mg to 1000 mg.

14. An oral tablet formulation comprising 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in an amount of 2.5 mg or 5 mg optionally in combination with metformin, and a pharmaceutically acceptable carrier or diluent.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims	Basis	Reference(s)
14–20	§ 103	The ’510 publication[1]
1–22	§ 103	The ’510 publication and Glucophage® Label[2]
1–22	§ 103	The ’510 Publication and Ahrén,[3] Hughes,[4] and/or Brazg[5]

[1] Himmelsbach et al., U.S. Patent Publication No. 2004/0097510, published May 20, 2004 (Ex. 1003).
[2] Glucophage® and Glucophage® XR Label (Ex. 1004).
[3] Ahrén et al., *Twelve and 52-Week Efficacy of the Dipeptidase IV Inhibitor LAF237 in Metformin-Treated Patients with Type 2 Diabetes*, DIABETES CARE 27:2874–80 (2004) (Ex. 1005).
[4] Hughes, Int’l Pub. No. WO 2005/117861, published December 15, 2005 (Ex. 1006).
[5] Brazg, et al., *Effect of Adding MK-0431 to On-going Metformin Therapy in Type 2 Diabetic Patients Who Have Inadequate Glycemic Control on Metformin*, DIABETES 54 (Suppl. 1):A3 (2005) (Ex. 1007).

In support of its patentability challenge, Petitioner relies on the Declaration of Dr. Mayer B. Davidson. Ex. 1002.

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, we see no need to construe any term expressly.

Anticipation by the '510 Publication

Petitioner asserts that the '510 publication anticipates claims 14 and 20. Pet. 30–31. Based on the current record, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

The '510 publication discloses a genus of substituted xanthine compounds that act as DPP-IV inhibitors, particularly for the prevention and treatment of type 2 diabetes. Ex. 1003, Abstract, ¶¶ 3, 4. It discloses linagliptin as one in a series of 30 "[m]ost particularly preferred" substituted

xanthine compounds. *Id.* ¶¶ 232, 245. It also lists the IC_{50} values of nearly 50 DPP-IV inhibitor compounds, including linagliptin.[6] *Id.* ¶ 295. Linagliptin is one of six compounds listed as having the highest potency in the group, with the lowest IC_{50} value of 1 nM. *Id.*

According to the '510 publication, the substituted xanthine compounds disclosed therein, due to their "ability to inhibit DPP-IV activity," are expected to be suitable "for the prevention or treatment of diseases or conditions such as type 1 and type 2 diabetes mellitus." *Id.* ¶ 297. The '510 publication discloses that "[t]he compounds according to the invention may also be used in conjunction with other active substances," including antidiabetics, such as metformin. *Id.* ¶ 298.

Claim 14 of the '859 patent recites "[a]n oral tablet formulation comprising [linagliptin] in an amount of 2.5 mg or 5 mg optionally in combination with metformin, and a pharmaceutically acceptable carrier or diluent." Claim 20 recites "[a] method of treating type 2 diabetes comprising administering to a patient in need thereof the oral tablet of claim 14, wherein the daily oral amount of [linagliptin] administered to said patient is 5 mg."

Petitioner refers to the '510 publication for disclosing that the substituted xanthine compounds thereof may be orally administered in the amount of "1 to 1000 mg, preferably 1 to 100 mg, in each case 1 to 4 times therein a day," to achieve a therapeutic effect. Pet. 22 (citing Ex. 1003 ¶ 300). According to Petitioner, because the '510 publication discloses "the

[6] Linagliptin is Example 2 (142)). Ex. 1003 ¶¶ 1933–1937, 2400.

most preferable oral dosage range for linagliptin" that encompasses the doses recited in claims 14 and 20, it anticipates those claims. *Id.* at 22, 30. We are not persuaded.

To anticipate a claim, a single prior art reference must disclose all limitations "arranged as in the claim," either expressly or inherently. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983). To be "arranged as in the claim," the anticipatory reference must "show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a particular order." *NetMoneyIn, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Whether a generic disclosure necessarily anticipates everything within the genus depends on the factual aspects of the specific disclosure and the particular products at issue. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008).

The Federal Circuit's opinion in *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698 (Fed. Cir. 2012) is instructive. In that case, the dispute centered on whether the prior art disclosure of "approximately 1 torr or less" anticipates the limitation "less than 0.5 torr" in the challenged claim. *Id.* at 706. The Federal Circuit reversed the district court's granting of summary judgment of anticipation. *Id.* According to the Federal Circuit, the patent challenger there relied on "the conclusory claim that less than 0.5 torr necessarily falls within 'approximately 1 torr or less' as a matter of fact." *Id.* The court explained:

> While true, the inquiry does not end there. How one of ordinary skill in the art would understand the scope of the disclosure or,

> stated differently, how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance.

Id.

The facts in this case are similar to those in *OSRAM*. Here, Petitioner relies on a conclusory statement that "the most preferable oral dosage range for linagliptin [disclosed in the '510 publication] encompasses and thus anticipates the claimed dose recited" in the challenged claims. Pet. 22, 30; *see also* Ex. 1002 ¶ 51 (stating the same). But, Dr. Davidson does not testify, and Petitioner does not argue, that an ordinary artisan would understand any dosage within the preferred dose of 1 to 100 mg administered "1 to 4 times a day" disclosed in the '510 publication to be efficacious.

We emphasize that in an *inter parte* review, Petitioner has the ultimate burden of persuasion to prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015). Here, the only evidence Petitioner relies on is a broad range of potential linagliptin dosages. That does not amount to a preponderance of the evidence.

Petitioner cites *Perricone v. Medicis Pharma. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005). Pet. 22, 25. The facts in this case are distinguishable from those in *Perricone*. There, the prior art discloses a composition having an active ingredient in a concentration range that not only encompasses, but also "does not significantly deviate from," the claimed ranges. *Perricone*, 432 F.3d at 1377. In contrast, in the present case, the dosage range disclosed

in the prior art is from 20% to 160 times the claimed dosages (i.e., 1 mg in the '510 publication versus 5 mg claimed (20%), and 400 mg in the '510 publication versus 2.5 mg claimed (160 times)). Petitioner does not explain why, based on the disclosure of a genus of dosage ranges for DPP-4 inhibitors, a person of skill in the art would immediately envisage administering linagliptin in the dosage amounts recited in the challenged claims 14 and 20. *See OSRAM*, 701 F.3d at 706 (explaining that "prior art's teaching of a broad genus does not necessarily disclose every species within that genus").

As a result, we determine Petitioner has not shown a reasonable likelihood of prevailing in its assertion that the '510 publication anticipates claims 14 and 20 of the '859 patent.

Obviousness over the '510 Publication and Glucophage® Label

Petitioner asserts that claims 1–22 would have been obvious over the combination of the '510 publication and Glucophage® Label. Pet. 18–30. Based on the current record, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

Claims 1–13, 15–19, 21, and 22

The Glucophage® Label provided by Petitioner as Exhibit 1004 includes a cover page stating it is the "FINAL PRINTED LABELING" for application number 20-357/S019 at the Food and Drug Administration ("FDA") Center for Drug Evaluation and Research. Ex. 1004, 1. Glucophage® is described in the document as metformin hydrochloride tablets and Glucophage® XR is described as metformin hydrochloride extended release tablets, both indicated for the treatment of type 2 diabetes.

Id. at 2. The Glucophage® Label contains a date "Revised January 2001." *Id.* at 7.

Relying on the Davidson Declaration, Petitioner contends that the Glucophage® Label qualifies as prior art under 35 U.S.C. §102(b) because it was approved and published by the FDA for treating type 2 diabetes in February 2001. Pet. 19 (citing Ex. 1002 ¶ 48). Patent Owner counters Mylan has not met its burden to show that Exhibit 1004, "purporting to be the Glucophage label as-approved, is, in fact, a printed package insert, much less one that was publically available prior to" the priority date of the '510 patent. Prelim. Resp. 14–17. We agree with Patent Owner.

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." 35 U.S.C. § 311(b). Petitioner has the ultimate burden of persuasion to prove unpatentability by a preponderance of the evidence. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015). 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 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). Here, the Glucophage® Label does not contain any source identifying information, e.g. as an FDA-approved label, or other indicia of when the document became publicly available. *See* Prelim. Resp. 15. For example, the Glucophage® Label submitted by Petitioner contains no indicia that it (1) is a certified copy of a public record, (2) is copied from an official 2001 publication such as the United States Pharmacopoeia–National Formulary, (3) is copied from a recognized periodical published in 2001 such as the Physicians' Desk Reference, or (4) otherwise bears the hallmarks of a self-authenticating document published in 2001. *See* Fed. R. Evid. 902 (4)–(7), (11). Exhibit 1004 indicates the label was revised in January 2001, but it bears no source identifying information from the FDA, a copyright date, or any other indicia of a publication date.

Dr. Davidson states that Glucophage® IR, a metformin hydrochloride immediate release tablet, has been available since 1994, and Glucophage® XR, a long-acting extended-release form of metformin, has been available since 2000. Ex. 1002 ¶¶ 29, 49. He, however, cites the January 2001

revision of the Glucophage® Label in support. *Id.* ¶ 29. With regard to the Glucophage® Label, Dr. Davidson merely parrots the same statement in the Petition, that is, the label was approved and published by the FDA for treating type 2 diabetes in February 2001. *Id.* ¶ 48.

Dr. Davidson does not provide a sufficient explanation or foundation to establish his personal knowledge of the Glucophage® Label's alleged publication in February 2001. The statements that Glucophage® was approved by the FDA in 1994 and Glucophage® XR in 2000, by themselves, are insufficient as a threshold showing that the Glucophage® Label was a publicly available printed publication as of February 2001. Earlier FDA approval of the Glucophage® drug products is not co-extensive with a February 2001 publication date of the revised Glucophage® Label, on which Petitioner relies for proof of the specific metformin doses recited in claims 1–13, 15–19, 21, and 22. *See* Pet. 21–29.

In sum, Petitioner has not satisfied its burden to show that the Glucophage® Label was available as a prior art printed publication. Therefore, we determine Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claims 1–13, 15–19, 21, and 22 of the '859 patent would have been obvious over the '510 publication and the Glucophage® Label.

Claims 14 and 20

Neither claim 14 nor claim 20 recites a specific metformin dose. Nevertheless, we find Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claims 14 and 20 of the '859 patent would have been obvious over the '510 publication and the Glucophage® Label.

Each of claims 14 and 20 recites a specific linagliptin dosage. Claim 14 requires an oral tablet formulation of linagliptin in an amount of 2.5 mg or 5 mg, and claim 20 requires administering linagliptin in a daily amount of 5 mg. In its obviousness challenge, Petitioner relies on the same conclusory statement of linagliptin dosage as in its anticipation argument, that is, the '510 publication discloses "the most preferable oral dosage range for linagliptin encompasses and thus anticipates the claimed dose recited" in the challenged claims. Pet. 22, 30. Again, such a single sentence, devoid of any further analysis, does not satisfy Petitioner's burden to prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e).

For example, Petitioner does not explain why an ordinary artisan would have had a reason to modify the teachings of the '510 publication to arrive at the claimed linagliptin dosage of 2.5 mg or 5 mg. Indeed, the '510 publication teaches drug formulation for oral administration with 75 mg to 150 mg DPP-4 inhibitor. Ex. 1003 ¶¶ 2898–911. While this does not, as Patent Owner asserts, amounts to teaching away from the claimed linagliptin dosage (*see* Prelim. Resp. 29), Petitioner presents no credible evidence or otherwise explains why one of ordinary skill in the art, in view of such a teaching, would have had a reason to pursue a dosage more than 10-fold lower than suggested in the '510 publication.

As a result, we determine Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claims 14 and 20 of the '859 patent would have been obvious over the '510 publication and the Glucophage® Label.

Obviousness over the '510 Publication and Ahrén, Hughes, and/or Brazg

Petitioner asserts that claims 1–22 would have been obvious over the combination of the '510 publication and Ahrén, Hughes, and/or Brazg. Pet. 31–43. Based on the current record, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

Ahrén describes the clinical effect of DPP-4 inhibitor LAF237 (vildagliptin) when combined with metformin to treat patients with type 2 diabetes. Ex. 1005, 2874–75. Ahrén compares two groups of type 2 diabetes patients treated with either metformin monotherapy (1500 to 3000 mg per day), or metformin (1,500 to 3,000 mg per day) and vildagliptin (50 mg once per day) combination therapy. *Id.* at 2874. Ahrén shows that "when added to metformin treatment, LAF237 was effective at improving glycemic control for at least 1 year in patients with type 2 diabetes and appeared to be well tolerated." *Id.* at 2878.

Like Ahrén, Hughes teaches a method of treating patients with type 2 diabetes using a combination of LAF237 (vildagliptin) and metformin over an extended period of time. Ex. 1006, Abstract, 3–4, 13[7]. It teaches that vildagliptin may be administered in an oral daily dosage "between 1 and 100 mg; preferably between 10 and 100 mg e.g. 10 mg; most preferably between 25 and 100 mg e.g. 25 mg or 30 or 40 or 50, 61, 70, 90, 100 mg." *Id.* at 23. Metformin is administered at a daily dosage in the range of about 50 mg to about 3000 mg, preferably from about 500 mg to about 2000 mg, using commercially available 500 mg tablets. *Id.* Hughes describes a clinical

[7] Page references are to the exhibit pages, not the internal document pages.

study treating patients with type 2 diabetes who were already receiving metformin. *Id.* at 25. In the Hughes study, patients were treated with vildagliptin (50 mg once daily) in addition to metformin (1500–3000 mg daily). *Id.* Hughes reports that the combination therapy achieved better clinical results when compared to metformin plus placebo treatment. *Id.* at 26–33.

Brazg reports the efficacy of combining the DPP-4 inhibitor MK-0431 (sitagliptin) with ongoing metformin therapy in type 2 diabetes patients. Ex. 1007, 2. Brazg notes that "[m]etformin is a commonly used first-line antihyperglycemic agent." *Id.* Brazg states that "[c]ombination treatment with MK-0431 [sitagliptin] and metformin may be useful since these agents target different pathophysiologic process leading to hyperglycemia in [type II diabetes]." *Id.* In the Brazg study, "the combination of MK-0431 [sitagliptin] and metformin was efficacious and generally well-tolerated as a treatment regimen" for patients with type 2 diabetes. *Id.*

Petitioner argues that the combination of the asserted prior art teaches each limitation in the challenged claims. Pet. 36–37, 40–43. Petitioner also contends that an ordinary artisan would have had a reason to combine the prior-art teachings and would have had a reasonable expectation of success in doing so. *Id.* at 38–39. Patent Owner challenges each assertion by Petitioner. *See* Prelim. Resp. 17–33.

For purposes of this Decision, we assume, without deciding, that one of ordinary skill in the art would have combined the teachings of the prior art. Petitioner, however, has not presented credible evidence or otherwise

persuasively argued that such an artisan would have arrived at the linagliptin dosages recited in the challenged claims.

Petitioner, again, in a conclusory fashion, argues that the '510 publication teaches the claimed linagliptin dosages. *See* Pet. 36 ("The '510 Publication discloses the combination of metformin and the recited oral doses of a DPP-IV Inhibitor (linagliptin)."); *id.* at 41 ("As described in Table 1 above in Ground 1, the '510 Publication discloses linagliptin dosages of 2.5mg and 5mg.") (citing Ex. 1003 ¶ 300). As explained above, based on the current record, we are not persuaded that an ordinary artisan would have had a reason to modify the teachings of the '510 publication—a preferred dose of 1 to 100 mg administered "1 to 4 times a day"—to arrive at the claimed linagliptin dosage of 2.5 mg or 5 mg.

We note Petitioner's assertion "the '510 Publication reports that linagliptin [is] more potent than vildagliptin or sitagliptin." Pet. 38 (citing Ex. 1002 ¶ 85; Ex. 1003, ¶ 295; Ex. 1011, 158). Dr. Davidson, however, testifies that "[l]inagliptin's *purported* higher potency would have *potentially* allowed for smaller doses of DPP-IV inhibitor to be administered to the patient." Ex. 1002 ¶ 85. Such testimony is speculative and again, does not amount to a preponderance of the evidence. As a result, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing claims 1–22 obvious over the combination of the '510 publication and Ahrén, Hughes, and/or Brazg.

CONCLUSION

For the foregoing reasons, we determine that Petitioner has not shown there is a reasonable likelihood that it would prevail in proving the unpatentability of claims 1–22 of the '859 patent.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), the Petition for *inter partes* review of the '859 patent is *denied* and no trial is instituted.

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