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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR2016-00829
Patent 9,095,559 B2

Before TONI R. SCHEINER, DEBORAH KATZ, and GRACE KARAFFA OBERMANN, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

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

I. BACKGROUND

Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Petitioners") filed a request for an *inter partes* review ("IPR") of claims 1–15 of U.S. Patent No. 9,095,559 B2 (Ex. 1001 ("the '559 patent")) (Paper 3 ("Pet.")), which was accorded a filing date of April 1, 2016 (Paper 4). Horizon

Therapeutics, Inc. ("Patent Owner") timely filed a Preliminary Response (Paper 9 ("Prelim. Resp.")).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless Petitioners show that there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Petitioners make that showing with respect to the grounds for unpatentability of claims 1–15. Therefore, we institute review as to claims 1–15.

Our findings of fact and conclusions of law are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. If a final decision is issued in this case, it will be based on the full record developed during trial.

A. Related proceedings

Petitioners and Patent Owner report that Patent Owner served Petitioners with a complaint in the District Court for the District of New Jersey (Case No. 1:15-cv-07624) alleging that Petitioners infringed the '559 patent, as well other related patents. Pet. 7; Prelim. Resp. 2.

Petitioners also report that patent 8,404,215, which issued from the parent application of the '559 patent, was the subject of IPR2015-01127, filed by Par Pharmaceutical, Inc., and IPR2016-00284, which was instituted and joined with the IPR2015-01127 proceeding.

Petitioners report further that PR2015-01117 and IPR2016-00283 were instituted and joined, both involving Horizon's U.S. Patent 8,642,012,[1] although that patent is not related by lineage to the '559 patent.

B. The '559 Patent (Ex. 1001)

The '559 patent issued from an application filed February 22, 2013. Ex. 1001. It cites two provisional applications filed November 29, 2011 and September 30, 2011, for priority. Ex. 1001, at [60].

C. Applied Prior Art

Petitioner relies on the following prior art references:

Abbreviation	Citation	Exhibit Number
Blau	PHYSICIAN'S GUIDE TO THE LABORATORY DIAGNOSIS OF METABOLIC DISEASES, 261–76 (Nenad Blau et al. eds., 2d ed. 1996).	1006
Simell	Olli Simell et al., *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 PEDIATRIC RESEARCH 1117–21 (1986).	1005
'859 Publication	U.S. Patent Publication 2010/0008859 A1, filed January 7, 2009, published January 14, 2010.	1007
Brusilow '84	Saul W. Brusilow et al., *Treatment of Episodic Hyperammonia in Children with Inborn Errors of Urea Synthesis*, 310 THE NEW ENGLAND JOURNAL OF MEDICINE 1630–34 (1984).	1004

[1] The application that became U.S. Patent 8,642,012 was published as U.S. Patent Publication 2010/0008859, which was cited as prior art in Petitioner's challenges.

D. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of '559 patent claims 1–15 under 35 U.S.C. § 103 over the following groups of references:

Ground	References	Claims
1	Blau, Simell, and the '859 Publication	1, 2, 4, 5, 7–10, 12, and 13
2	Blau, Simell, the '859 publication, and Brusilow '84	3, 6, 11, 14, and 15

II. Analysis

Under 35 U.S.C. § 103, subject matter is unpatentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), the Supreme Court explained that, where there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, if the person of ordinary skill could have arrived at the claimed subject matter using common sense to combine different teachings of the prior art, then that subject matter is likely obvious, not innovative.

A. Ground 1

The claims of the '559 patent are directed to methods of using a drug, glyceryl tri-[4-phenylbutryate], to treat subjects with urea cycle disorders. Petitioner's witness, Keith Vaux, M.D., Ph.D.[2], testifies that subjects

[2] Petitioner relies on the testimony of Keith Vaux, M.D. Ex. 1002. Dr. Vaux testifies that he is Professor and Clinical Chief of the Division of

suffering from urea cycle disorders ("UCDs") are unable to remove excess nitrogen waste, which is normally excreted in the urine. *Id.* ¶ 30. When the body functions normally, dietary amino acids are converted first to ammonia and then to urea in the urea cycle and, finally, excreted in the urine. *Id.* ¶ 31. In those with UCDs, the enzymes controlling the urea cycle are deficient, leading to high levels of ammonia in the blood and toxicity. *Id.* ¶ 32.

Claim 1 of the '559 patent is representative of the claims challenged in Petitioners' Ground 1 and recites:

> A method for adjusting the dosage of glyceryl tri-[4-phenylbutyrate] in a subject being treated for a urea cycle disorder who has previously been administered an initial dosage of glyceryl tri-[4-phenylbutyrate] and who has a fasting plasma ammonia level less than the upper limit of normal for plasma ammonia level, the method comprising:
>
> (a) measuring a fasting plasma ammonia level for the subject;
>
> (b) comparing the fasting plasma ammonia level to the upper limit of normal for plasma ammonia level; and
>
> (c) administering an adjusted dosage of glyceryl tri-[4-phenylbutyrate], wherein the adjusted dosage is greater than the initial dosage if the fasting plasma ammonia level is greater than half the upper limit of normal for plasma ammonia level.

Ex. 1001, 24:20–35. Independent claim 2, the only other independent claim challenged in Ground 1, is similar to claim 1, differing mostly in the

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Medical Genetics in the Department of Medicine at UC San Diego. Ex.1002 ¶ 1. Dr. Vaux testifies that he regularly prescribes nitrogen scavenging drugs and treats patients who are maintained on therapy with nitrogen scavenging drugs. *Id.* ¶ 2. Dr. Vaux testifies that he has published articles in peer reviewed journals on metabolic disorders and speaks at national and international conferences on genetics and metabolic and genomic medicine. *Id.* ¶ 4. At this stage of the proceeding, we find Dr. Vaux to be qualified to provide opinions on the subject matter at issue.

preamble.[3] Patent Owner does not argue separately for the patentability of claim 2.

Petitioners argue that claim 1 would have been obvious because the '859 publication teaches using nitrogen scavenging drugs, including glyceryl tri-[4-phenylbutyrate], which is also called "HPN-100," to treat urea cycle disorders. Pet. 22–23, citing Ex. 1007 ¶¶ 88–91, 95–99, 107–108, 226, and 232; also citing Ex. 1002 ¶ 53. For example, the '859 publication states: "In some embodiments, HPN-100 is the PBA prodrug of choice for these methods" of starting or adjusting doses of nitrogen scavenging drugs in patients with UCDs. Ex. 1007 ¶¶ 88 and 108.

Petitioners also argue that the '859 publication teaches adjusting the dosage of nitrogen scavenging drugs such as HPN-100 on the basis of plasma ammonia values, wherein if plasma levels are too high, drug dosages can be increased. Pet. 23, citing Ex. 1007 ¶ 83 ("If the ammonia control is inadequate, the dosage of the nitrogen scavenging drug may need to be

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[3] Claim 2 recites:

> A method of treating a subject with a urea cycle disorder who has previously been administered an initial dosage of glyceryl tri-[4-phenylbutyrate] and who has a fasting plasma ammonia level less than the upper limit of normal for plasma ammonia level, the method comprising:
>
> (a) measuring a fasting plasma ammonia level for the subject;
>
> (b) comparing the fasting plasma ammonia level to the upper limit of normal for plasma ammonia level; and
>
> (c) administering an adjusted dosage of glyceryl tri-[4-phenylbutyrate] that is greater than the initial dosage if the fasting plasma ammonia level is greater than half the upper limit of normal for plasma ammonia level.

Ex. 1001, 24:36–48.

increased if that can be done . . ."); Ex. 1007 ¶¶ 88–91, 95–99, 226, and 232; and Ex. 1002 ¶ 53.

Petitioners argue further that the '859 publication demonstrates it was known to compare measured plasma ammonia levels to normal levels. Pet. 26–27, citing Ex. 1007 ¶ 94 ("As used herein, plasma levels are acceptable when they are at or below a level considered normal for the subject, and commonly this would mean a plasma ammonia level is below about 40 μmol/L."). The '859 publication also teaches that it was known that normal levels vary depending on the way they are measured. Ex. 1007 ¶ 94; *see* Pet. 26–27.

Petitioners argue that it would have been known to those in the art to carry out the steps of the method of claim 1 on a subject "who has a fasting plasma ammonia level less than the upper limit of normal for plasma ammonia level," as recited in claim 1, because it was known that maintenance of ammonia levels within normal limits is the objective of therapy with nitrogen scavenging drugs and because ammonia levels were also known to vary during the day, for example after eating. Pet. 24–25, citing Ex. 2007 ¶ 83; Ex. 1020; Ex. 1016 at S58; and Ex. 1002 ¶ 54. Petitioners rely on Dr. Vaux's testimony to show that one of skill in the art would have considered it obvious to administer more drug to reduce ammonia levels in patients whose fasting plasma ammonia level is approaching the upper limit of normal, but still below it. Pet. 24–25, citing Ex. 1002 ¶¶ 51 and 55.

Petitioners rely further on the testimony of Dr. Vaux to show that because of the goal to maintain a patient at normal ammonia levels, one of skill in the art would have also known to increase drug doses when fasting

ammonia levels approach the upper limit of normal and, thus, are above half of the upper limit of normal. Pet. 28–29, citing Ex. 1002 ¶ 65; Ex. 1006, at 268 (Table 11.5); Ex. 1012 at 213; Ex. 1017, at 164 (Table II).

Dr. Vaux also testifies that those of ordinary skill in the art would have had reason to combine these references because they each contribute knowledge about dosing nitrogen scavenging drugs when treating UCDs. Ex. 1002 ¶¶ 47–50; Pet. 19–20.

In regard to the claim limitation of measuring a fasting ammonia level, Petitioners cite to Blau and Simell for their teachings of collecting blood from UCD patients for measuring plasma ammonia levels after a fast. Pet. 25–26, citing Ex. 1006, at 273 (Table 11.9). Petitioners rely on the testimony of Dr. Vaux to argue that these teachings would have indicated to those in the art that blood for plasma ammonia measurement should be collected after a fast. Pet. 25–26, citing Ex. 1002 ¶¶ 58 and 59; *see also* Ex. 1002 ¶ 46, n.2., citing Ex. 1015.

Petitioners' arguments regarding claims 1 and 2 are supported by evidence. At this point in the proceeding, Patent Owner's arguments do not persuade us that Petitioners do not have a reasonable likelihood of prevailing.

Specifically, we are not persuaded at this time by Patent Owner's argument that the '859 publication teaches away from reliance on plasma ammonia levels because it discusses why such measurements are inconvenient and unreliable. *See* Prelim. Resp. 13–14, citing Ex. 1007 ¶ 73. We are also not persuaded that the '859 publication teaches away from reliance on plasma ammonia levels because it teaches using other indicators,

such as excreted PAGN[4], to determine the effectiveness of treatment. Prelim. Resp. 14, citing Ex. 1007 ¶ 135.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 2004). Even though the '859 publication teaches alternatives to evaluating treatment with plasma ammonia levels, it also teaches relying on these levels. *See* Ex. 1007 ¶ 83 ("The plasma or blood level of ammonia is optionally also determined, in addition to measuring urinary PAGN, to assess the effectiveness of the overall drug and dietary regimen for a particular patient."). Mere disclosure of an alternative does not indicate that a reference teaches away from what is claimed. *See In re Fulton,* 391 F.3d 1195, 1201 (Fed. Cir. 2004).

We are also not persuaded at this time by Patent Owner's argument that the '859 publication "teaches away from reliance on a single plasma ammonia measurement (under fed or fasted conditions) in assessing the dosage of nitrogen scavenging drugs." Prelim. Resp. 14–15. The challenged claims are not shown to be limited to a single measurement.

Patent Owner argues further that the '859 teaches away from increasing the dosage of nitrogen scavenging medication when a patient's plasma ammonia level is below the upper limit of normal but above half the upper limit of normal. Prelim. Resp. 15–18. Patent Owner cites to two

[4] Dr. Vaux explains that drugs such as HPN-100 provide an alternative mechanism for the clearance of glutamine from proteins, wherein "PAGN" acts like urea to carry nitrogen out of the body. (Ex. 1002, ¶ 32.)

apparently conflicting reports of "normal" plasma ammonia levels in the '859 publication: (1) at paragraph 85, where a level of "less than about 40 μmol/L, or of not greater than 35 μmol/L" is considered to be normal, and (2) at paragraph 94 where a plasma level of between 26 and 35 μmol/L is considered to be the "upper limit of normal." Patent Owner suggests that because 40 μmol/L, or 44 μmol/L when the term "about" is considered, is considered to be normal, the '859 publication contemplates normal plasma ammonia levels as being above the upper limit of normal (26–35 μmol/L). Thus, according to Patent Owner, the '859 publication teaches that plasma ammonia levels above one half the upper limit, or even above the upper limit of normal, are adequately controlled. Prelim. Resp. 16–17.

At this point in the proceeding, Patent Owner's argument does not persuade us that Petitioner is reasonably likely to fail in its challenges. Patent Owner's argument appears to be based on specific plasma ammonia levels that have not yet been shown to be accepted by those of skill in the art as the only levels considered to be "normal" or the "upper limit of normal."

In addition, at this point in the proceeding, we credit the testimony of Dr. Vaux that the goal of maintaining a patient at normal ammonia levels would have lead one of ordinary skill in the art to increase drug doses when fasting ammonia levels approach the upper limit of normal and, thus, are above half of the upper limit of normal. *See, e.g.* Pet. 28–29, citing Ex. 1002 ¶ 65; Ex. 1006, at 268 (Table 11.5); Ex. 1012 at 213; Ex. 1017 at 164 (Table II). Patent Owner's bare argument regarding a teaching away from increasing the dosage of nitrogen scavenging medication when a patient's plasma ammonia level is below the upper limit of normal but above half the

upper limit of normal does not outweigh Dr. Vaux's testimony at this point in the proceeding.

Patent Owner argues that Petitioners fail to provide sufficient explanation or evidence to support its argument about the goals of treatment and the knowledge in the art to administer drug when fasting ammonia levels approach the upper limit of normal. Prelim. Resp. 17–18. At this point in the proceeding we disagree. Dr. Vaux's testimony and the evidence on which he relies is reasonable, wherein a goal of treatment would be to avoid having a patient exceed the upper limit of normal during the day. Dr. Vaux's testimony is also supported by the evidence he cites, for example, that plasma ammonia levels vary a different times of the day (Ex. 1012) or after eating (Ex. 1006, 268 (Table 11.5) and Ex. 1017). *See, e.g.,* Ex. 1002, ¶ 55.

Patent Owner's argument that the '859 publication does not teach comparison of fasting plasma ammonia levels (Prelim. Resp. 19–20) is not persuasive either because, at this point in the proceeding, we are persuaded that Blau and Simell teach this element of the challenged claims. Patent Owner argues that Simell does not render the challenged claims obvious because it reports only an experimental study on patients who are not usually treated with nitrogen scavenging medication. Prelim. Resp. 21–23. Patent Owner also argues that Blau teaches only diagnosis, not treatment. *Id*. at 23. We are not persuaded by these arguments at this time because Dr. Vaux testifies that those of ordinary skill in the art would have looked to the references. Ex. 1002 ¶ 46, n.2. Furthermore, Dr. Vaux testifies that it was known to use fasting levels when measuring plasma ammonia levels because

it was known that plasma ammonia levels vary after eating. *See* Ex. 1007 ¶ 49.

Patent Owner argues further that Blau cautions against "over-reliance" on plasma ammonia levels in making treatment decisions because it can lead to over-restriction of amino acids. Prelim. Resp. 23, citing Ex. 1006, at 275. At this point in the proceeding, we are not persuaded that this caution would discourage those of skill in the art from ever using plasma ammonia levels to determine drug dosage, particularly in light of the specific teachings in the '859 publication and other references to do so.

Patent Owner does not provide arguments against Petitioners' challenge to the dependent claims recited in Ground 1 at this point in the proceeding. We determine that Petitioners are reasonably likely to prevail in these challenges based on the evidence and arguments presented in the Petition. *See* Pet. 31–35.

For example, Petitioners argue that dependent claim 4, which recites the method of claim 1 or 2 and requires that "administering the adjusted dosage of glycerol tri[4-phenylbutyrate] produces a normal average daily ammonia level in the subject" (Ex. 1001, 24:61–63), would have been obvious because maintenance of plasma ammonia levels within normal limits was an objective of therapy with nitrogen scavenging drugs. Pet. 30, citing Ex. 1007, ¶ 83, Ex. 1002, ¶ 67.

After considering Petitioners' evidence and arguments and the specific arguments in Patent Owner's Preliminary Response, we are persuaded that it is reasonably likely Petitioners will prevail in the challenges of the claims recited in Ground 1.

B. Ground 2

Claim 3 of the '559 patent recites:

> A method of administering glyceryl tri-[4-phenylbutyrate] to a subject having a urea cycle disorder, the method comprising:
>
> (a) measuring a first fasting plasma ammonia level for the subject:
>
> (b) comparing the first fasting plasma ammonia level to the upper limit of normal for plasma ammonia level; and
>
> (c) administering an initial dosage of glyceryl tri-[4-phenylbutyrate] to the subject if the fasting plasma ammonia level is greater than half the upper limit of normal for plasma ammonia level and less than the upper limit of normal for plasma ammonia level.

Ex. 1001, 24:49–60. Claim 3 is similar to claim 1 of the '559 patent but does not have the limitation of a subject "who has a fasting plasma ammonia level less than the upper limit of normal for plasma ammonia level" in the preamble and recites measuring a "first" fasting plasma ammonia level in step (a). Claim 3 also includes the limitation of administering an "initial" dosage of drug in step (c).

Petitioners cite to Brusilow '84 in addition to the '859 publication, Blau, and Simell, to argue that claim 3 would have been obvious to those of skill in the art. Brusilow '84 teaches measuring a patient's fasting plasma ammonia level upon admission and determining that it was 111 μmol/L and 145 μmol/L one hour later. Ex. 1004, 1631. Sodium benzoate and phenylacetate and another drug were administered intravenously, causing the patient's plasma ammonia level to drop to 79 μmol/L after three hours. *Id.* Maintenance therapy of sodium benzoate plus another drug was administered orally over the next six hours, resulting in a plasma ammonia

level of 33 μmol/L, which was determined to be within normal limits, after 19 hours. *Id.*

As in Ground 1, Petitioners rely on the testimony of Dr. Vaux to show that the limitation of administering an initial dosage of HPN-100 "if the fasting plasma ammonia level is greater than half the upper limit of normal for plasma ammonia level and less than the upper limit of normal for plasma ammonia level" would have been obvious to those in the art. Pet. 42–43, citing Ex. 1002, ¶ 93. Dr. Vaux testifies that the goal of nitrogen scavenging therapy for UCD patients was known to be to maintain a stable, normal plasma ammonia level. Ex. 1002 ¶ 93, citing Ex. 1007 ¶¶ 83, 226, and 232, and Ex. 1020. Dr. Vaux testifies further that claim 3 recites the known premise that administering a nitrogen scavenging drug will decrease plasma ammonia levels and that it was known that variation of these levels due to the time of day or ingestion of food would potentially take a patient outside of the normal levels. *Id.* ¶ 93, citing Ex. 1006, 268, Table 11.5; Ex. 1012; Ex. 1017; and Ex. 1016. According to Dr. Vaux, those of skill in the art would have increased the dose of a nitrogen scavenging drug in a patient with a fasting plasma ammonia level approaching the upper limit of normal. Ex. 1002 ¶ 93.

Dr. Vaux testifies that those of ordinary skill would have had reason to combine the references because they all contribute knowledge of dosing with nitrogen scavenging drugs. Ex. 1002 ¶¶ 78–80; Pet. 38.

Patent Owner argues that Petitioners have failed to show that claim 3 would have been obvious for the same reasons argued against Ground 1. Prelim. Resp. 25. As explained above, these arguments are not persuasive at this point in the proceeding.

Patent Owner argues further that claim 3 requires administration of an "initial" dose of drug in step (c), but that Petitioners have failed to address this limitation and address only increasing the dose of drug. Prelim. Resp. 25–26 and 28–30. We are not persuaded by this argument at this time. Dr. Vaux's testimony about the knowledge of those of skill in the art to treat patients whose plasma ammonia levels approach the upper limit of normal is persuasive regarding increasing the dosage of drug or an initial treatment. At this point in the proceeding, we do not discern a meaningful difference in the goal of treating a patient as he or she approaches the upper limit of normal whether increasing drug dosages or providing an initial administration of a drug.

While acknowledging that Brusilow '84 teaches measuring fasting plasma ammonia levels, Patent Owner argues that it does not place any significance on measurement in a fasting state. Prelim. Resp. 27. Because at this time we find that other references teach measurement of plasma ammonia levels in a fasting state (*see* Ex. 1005 and 1006), we are not persuaded by this argument.

Patent Owner also argues that Brusilow '84 does not teach comparing the measured fasting plasma ammonia level to the upper limit of normal. Prelim. Resp. 28. Because at this point in the proceeding we are persuaded, as discussed above, that the '859 publication teaches this comparison, Patent Owner's argument is not persuasive.

Ground 2 includes challenges to dependent claims 6, 11, 14, and 15. Pet. 44–46. Claim 6 recites the method of claim 3, further comprising steps of measuring a second fasting plasma ammonia level for the subject, comparing it to the upper limit of normal for plasma ammonia levels, and

administering an adjusted dosage of drug that is greater than the initial dosage if the second fasting ammonia level is greater than half the upper limit of normal and less than the upper limit of normal. Ex. 1001, 25:1–10. Petitioners argue, relying on the testimony of Dr. Vaux, that it would have been obvious to take a second measurement of a patient's fasting plasma ammonia level to determine whether the dosage of nitrogen scavenging drug should be readjusted to maintain a level below the upper limit of normal because of the known variation in plasma ammonia levels throughout the date and after eating. Pet. 44, citing Ex. 1002 at ¶ 95.

Patent Owner responds to Petitioners' argument, asserting that Petitioners merely refer to their argument regarding claim 3 and fail to address the specific method of claim 6 or provide an articulated reason for its challenge. Prelim. Resp. 31–32. Patent Owner also argues that claim 6 is not obvious because the '859 publication teaches away from increasing drug dosages when the plasma ammonia level falls below 44 μmol/L, as that level is above the upper limit of normal recited in the '859 publication. Prelim. Resp. 32. Patent Owner argues further that Brusilow '84 teaches that plasma ammonia levels falling with the normal or near normal limits are satisfactory. Prelim. Resp. 32. In light of Dr. Vaux's testimony regarding treatment of patients as they approach the upper limit of normal, we are not persuaded by these arguments at this time.

Patent Owner does not provide arguments against Petitioners' challenge to the other dependent claims (claims 11, 14, and 15) recited in Ground 2 at this point in the proceeding. We determine that Petitioners are reasonably likely to prevail in these challenges based on the evidence and arguments presented in the Petition. *See* Pet. 44–46.

After considering Petitioners' evidence and arguments and the specific arguments in Patent Owner's Preliminary Response, we are persuaded that it is reasonably likely Petitioners will prevail in the challenges of the claims recited in Ground 2.

C. Patent Owner's Other Arguments

In addition to Patent Owner's specific arguments against Grounds 1 and 2, Patent Owner also argues we should deny the Petition under 35 U.S.C. § 325(d) because the Examiner previously considered the art cited in Grounds 1 and 2 during prosecution and Petitioners add nothing new. Prelim. Resp. 33–34. Under that section of the statute, "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). We exercise the discretion delegated to us to institute review on the basis of Grounds 1 and 2 because Petitioner has presented new evidence, such as Dr. Vaux's testimony, and therefore new arguments that were not before the Examiner.

Patent Owner also argues that the Petition should be denied under 37 C.F.R. § 42.104(b)(4) and 42.22(a)(2) because it hinges on conclusory statements, citing to Dr. Vaux's testimony, which according to Patent Owner, "parrots the same assertions without citation or explanation of how his conclusions are supported by the prior art of record." Prelim. Resp. 34–41. As discussed above, we disagree with Patent Owner's characterization of Dr. Vaux's testimony because he cites evidence to support it. As the Supreme Court noted, "[i]n many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design

trends." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). At this time, we are not persuaded by Patent Owner's arguments.

III. CONCLUSION

We are persuaded that there is a reasonable likelihood that Petitioner will prevail as to the unpatentability of claims 1, 2, 4, 5, 7–10, 12, and 13 of the '559 patent under 35 U.S.C. § 103(a) over Blau, Simell, and the '859 publication.

We are also persuaded there is a reasonable likelihood that Petitioner will prevail as to the unpatentability of claims 3, 6, 11, 14, and 15 of the '559 patent under 35 U.S.C. § 103 over Blau, Simell, the '859 publication, and Brusilow '84.

Our findings of fact and conclusions of law are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. If a final decision is issued in this case, it will be based on the full record developed during trial.

IV. ORDER

For the reasons given, it is

ORDERED that an *inter partes* review is instituted as to claims 1, 2, 4, 5, 7–10, 12, and 13 under 35 U.S.C. § 103 over Blau, Simell, and the '859 Publication;

FURTHER ORDERED that an *inter partes* review is instituted as to claims 3, 6, 11, 14, and 15 under 35 U.S.C. § 103 over Blau, Simell, the '859 publication, and Brusilow '84;

FURTHER ORDERED that no *inter partes* review is instituted on any other grounds;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '559 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 a trial.

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