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Paper 32
Entered: January 20, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,
Petitioner,

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.,
Patent Owner.

IPR2020-01053
Patent 9,815,827 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Granting Patent Owner's Motion to Seal
37 C.F.R. § 42.55

Dismissing Petitioner's Motion to Seal
37 C.F.R. § 42.55

I. INTRODUCTION

Slayback Pharma LLC ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 1–75 of U.S. Patent No. 9,815,827 B2 (Ex. 1001, "the '827 patent"). We instituted trial to review the challenged claims. Paper 7 ("Dec." or "Decision to Institute"). Thereafter, Sumitomo Dainippon Pharma Co., Ltd. ("Patent Owner") filed a Response to the Petition (Paper 14, "PO Resp."), Petitioner filed a Reply (Paper 21), and Patent Owner filed a Sur-reply (Paper 25). An oral hearing for this proceeding was held on August 11, 2021, and the transcript of that hearing is of record. *See* Paper 28 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–75 of the '827 patent are unpatentable.

A. Related Matters

According to the parties, the '827 patent is the subject of the following district-court litigations: 2:18-cv-02065 (NJD); 1:18-cv-00256 (DED); 2:18-cv-02620 (NJD); 1:18-cv-02107 (NYSD); 1:18-cv-01444 (NYED); 1:18-cv-00185 (NCMD); 1:18-cv-00369 (DED); 2:18-cv-13478 (NJD); 2:18-cv-13833 (NJD); 2:18-cv-14787 (NJD). Pet. 64; Paper 5, 2. Petitioner is not a party to any of those cases. Pet. 19. Patent Owner represents that "[n]one of the litigations is pending." Paper 5, 2.

B. The '827 Patent and Related Background

The '827 patent is titled "[a]gent for treatment of schizophrenia." Ex. 1001, Code (54). It relates to "a method for improving schizophrenia without being accompanied by extrapyramidal symptoms by orally administering a prescribed dose of a specific bicycloheptane dicarboximide derivative once a day, and a therapeutic agent used in said method." *Id.* at 1:15–20.

There are 75 claims in the '827 patent. Petitioner divides them into two groups: (1) claims comprising treating manic depressive psychosis[1] ("manic depressive claims"), including claims 8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, and 75; and (2) claims limited to treating schizophrenia ("schizophrenia claims"), including claims 1–7, 19–24, 29, 32, 45, 47, 61, 63, 65, 68, 70, 72, and 74. Pet. 13. Patent Owner adopts these groupings. *See* PO Resp. 27 (discussing "manic depressive claims"). For consistency, we do the same.

Patent Owner explains that schizophrenia and manic depressive psychosis, both chronic and severe mental disorders, "can have symptoms in common." PO Resp. 3–4, 29. According to the '827 patent, schizophrenia is mainly treated with medication, and the treatment should be continued for a long time. Ex. 1001, 1:37–39. Thus, "any side effects of medication may always be serious problems, and based on this perspective, it has been

[1] The parties agree that "manic depressive psychosis" is now known as "bipolar disorder." Pet. 21; PO Resp. 3. We use the two terms interchangeably in this Decision.

desired to develop a medicine being suitable for prolonged medication." *Id.* at 1:42–45.

The '827 patent explains that antipsychotics have been used to treat schizophrenia. *Id.* at 1:46–56. According to Patent Owner, "antipsychotics were known to treat schizophrenia and manic depressive psychosis by targeting the dopamine D_2 receptor." PO Resp. 29. The antipsychotics, however, have various drawbacks: the first generation, or "typical" antipsychotics are linked to severe side effects, such as extrapyramidal symptoms; whereas the second generation, or "atypical" antipsychotics are associated with substantial weight gain. PO Resp. 4–6. The '827 patent states "it has been desired to develop a safe medicament which exhibits an excellent effect on various schizophrenia as an antipsychotic without causing side effects." Ex. 1001, 2:1–4.

The '827 patent states that prior art teaches a genus of imide derivatives that "may be useful as an antipsychotic (c.f., neuroleptic agent, antia[n]xiety, etc.), especially as an agent for treatment of schizophrenia, senile insanity, manic depressive psychoses, and nervous breakdown." *Id.* at 2:5–39 (citing Ex. 1009[2]).

According to the '827 patent, its inventors found that a compound in this genus, (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptane-dicarboximide or a pharmaceutically acceptable salt thereof, "is effective for

[2] U.S. Patent No. 5,532,372, issued July 2, 1996 (Ex. 1009, "Saji"). Saji is one of the prior-art references asserted in this proceeding.

relieving the wide-ranging symptoms of schizophrenia, and may treat schizophrenia quite safely without being accompanied by extrapyramidal symptoms by orally administering a prescribed dose thereof once a day." *Id.* at 2:50–3:6. The parties agree this compound is lurasidone.

The '827 patent contains results from a Phase II clinical trial where patients with schizophrenia were treated with SM-13496, i.e., lurasidone hydrochloride. Ex. 1001, 4:47–10:25.

C. Illustrative Claims

Claim 1 is illustrative of the schizophrenia claims, and is reproduced below:

> 1. A method for treating schizophrenia in a patient without a clinically significant weight gain, comprising:
>
> administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Ex. 1001, 10:51–59.

Claim 8 is illustrative of the manic depressive claims, and is reproduced below:

> 8. A method for treating manic depressive psychosis in a patient without a clinically significant weight gain, comprising:
>
> administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to

> 120 mg/day such that the patient does not experience a clinically significant weight gain.

Id. at 11:12–21.

Claims 25, 40, and 56 are also independent claims. Each is directed to a method of "treating a patient with an antipsychotic," comprising orally administering lurasidone "once daily" at a dose of from 20 to 120 mg. *Id.* at 11:59–12:2, 12:34–43, 13:34–42. Claims 40 and 56 further require lurasidone is the "sole active ingredient." *Id.* at 12:34–43, 13:34–42.

D. Instituted Grounds of Unpatentability

We instituted trial to determine whether the challenged claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §[3]	Reference(s)
8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, 75	102	Latuda Information[4]
8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, 75	103	Latuda Information, Loebel[5]

[3] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013 ("AIA date"). The parties dispute whether the manic depressive claims are entitled to a priority date earlier than the AIA date. Pet. 26–31; PO Resp. 27–32. We do not need to resolve this issue because, as explained below, we find all challenged claims obvious over Saji. *See infra*, Section II.E. Saji predates the earliest possible priority date on the face of the '827 patent, and thus, qualifies as prior art regardless. For purposes of this Decision, we apply the pre-AIA version of § 103. Our conclusion, however, remains the same under the AIA version of § 103.

[4] *Latuda*, Information published in American Journal of Psychiatry, Vol. 170, No. 8, August 2013 (Ex. 1007).

[5] Loebel et al., *Lurasidone Monotherapy for the Treatment of Bipolar*

Claims Challenged	35 U.S.C. §[3]	Reference(s)
1–75	103	Saji

To support their respective arguments, Petitioner relies on the Declarations of Thomas R. Kosten, M.D. (Exs. 1002, 1051); and Patent Owner relies on the Declarations of Stephen Stahl, Ph.D. (Ex. 2131) and Brian C. Reisetter, RPh, M.B.A., Ph.D. (Ex. 2132).

II. ANALYSIS

A. Principles of Law

To prevail in this *inter partes* review, Petitioner "shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2019).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *KSR*, 550 U.S. at 406.

Depression: Results of the 6-Week, Double-blind, Placebo-controlled PREVAIL-2 Study, 38 NEUROPSYCHOPHARM. 109–10 (2012) (Ex. 1008).

When the prior art discloses a range that overlaps with the claimed range, there is a presumption of obviousness. *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018). This presumption may be rebutted by showing the criticality of the claimed range, that the prior art taught away from the claimed range, or that the parameter was not recognized as "result-effective." *Id.*

We analyze the instituted grounds of unpatentability in accordance with these principles.

B. Level of Ordinary Skill in the Art

Petitioner contends that an ordinarily skilled artisan would have "the education and experience of a medical doctor trained in psychiatry who spent several years using psychiatric medications to treat patients with schizophrenia and bipolar disorders and had several years['] experience developing or investigating psychiatric medications and was familiar with the literature on drugs for schizophrenia and bipolar disorders." Pet. 23.

Patent Owner argues that an ordinarily skilled artisan

> is a person with a scientific degree (either M.D., Ph.D., or Pharm. D.), who has at least 2-3 years of experience developing or investigating methods for treating patients with psychiatric disorders such as schizophrenia or bipolar disorder. The POSITA may also work in collaboration with other scientists and/or clinicians who have experience developing or characterizing antipsychotic drugs, running clinical trials related to such drugs, treating patients with such drugs, or researching the effects of such drugs. Collaborators of the POSITA could include, for example, pharmacologists and /or neuropharmacologists, psychiatrists, endocrinologists, statisticians and/or biostatisticians and analytical and/or medicinal chemists.

PO Resp. 24–25.

We do not discern an appreciable difference in the parties' respective definitions of the level of ordinary skill in the art, and any perceived distinction does not impact our Decision. Indeed, as Patent Owner acknowledges, the parties' proposed definitions of the ordinary skill level do "not differ significantly." *Id.* at 25. Nevertheless, for purposes of this Decision, we adopt Patent Owner's definition of the skill level, as it is consistent with the '827 patent disclosures and the prior art of record, and more inclusively describes the suitable experience for one of ordinary skill in the art.

We further note that, in this case, the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Claim Construction

In an *inter partes* review, we construe a claim term "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b). Under that standard, the words of a claim "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner proposes the following constructions:

Term(s)	**Proposed Construction**
"a patient"/"the patient"	"one or more patients"

Term(s)	Proposed Construction
"treating a patient with an antipsychotic" (claims 25, 40, and 56)	includes both "treating a patient for schizophrenia with an antipsychotic" and "treating a patient for manic depressive psychosis with an antipsychotic"
"manic depressive psychosis"	"bipolar disorders"
"a pharmaceutical composition comprising…a sole active ingredient" (claims 40 and 56)	limits the "pharmaceutical composition" of claims 40 and 56 to a "sole active ingredient"

Pet. 18–23.

Patent Owner states that it "does not concede that [Petitioner] Slayback's proposed constructions are correct and submits that no construction is necessary." PO Resp. 24.

On this record, we find Petitioner's proposed constructions are supported by intrinsic and extrinsic evidence. *See* Pet. 18–23. We agree with Petitioner here that "a patient" or "the patient" should have its ordinary and customary meaning of "one or more patients," as opposed to a "patient population" as Patent Owner has previously argued in a district court litigation involving another party. *See id.* at 19–20. Indeed, Patent Owner agrees. *See* Reply 19 ("There is no dispute that 'a patient,' as recited in the '827 claims, refers to 'one or more patients.'").

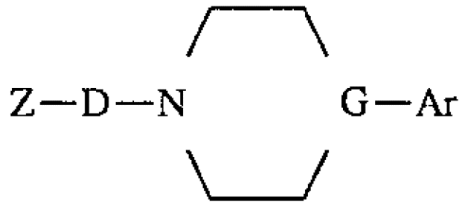
We also agree with Petitioner that the dependent claims requiring treating patients with schizophrenia and manic depressive psychosis supports the conclusion that "treating a patient with an antipsychotic" in independent claims 25, 40, and 56 includes treatment of a patient with these particular diseases. *See* Pet. 20–21.

On this record, we further agree with Petitioner that "manic depressive psychosis" would be interpreted by a person or ordinary skill in the art as "bipolar disorder," which includes Bipolar I Disorder, Bipolar II Disorder, Cyclothymia, and Bipolar Disorder Not Otherwise Specified. *See id*. at 21–22 (citations omitted); *see also* PO Resp. 3 ("Bipolar disorder, once known as manic depressive psychosis."). Thus, for purposes of this Decision, we adopt Petitioner's proposed constructions.

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

D. Saji

Saji teaches an imide compound of the formula:



(I)

The figure above shows the chemical structure of compound (I) of Saji. Ex. 1009, 3:3–8. Saji further specifies the formula of groups Z, D, and Ar of compound (I). *Id.* at 3:10–44.

Saji teaches that the novel imide compounds and their acid addition salts of its invention can be used "as anti-psyc[h]otic agents (neuroleptic agents, anti-anxiety agents), especially for therapy of schizophrenia, senile insanity, manic-depressive psychosis, neurosis, etc." *Id.* at 1:8–12. According to Saji, for the therapeutic use as an anti-psychotic agent, the

imide compound (I) and its pharmaceutically acceptable salt may be formulated into tablets for oral administration. *Id.* at 11:66–12:6. According to Saji,

> While the dosage of the imide compound (I) or its pharmaceutically acceptable salt varies greatly with the symptom, age and weight of the patient, the dosage form, the administration mode and the like, it may be generally given to an adult at a daily dose of from about 1 to 1000 mg, preferably from about 5 to 100 mg, in case of oral administration . . . Said dose may be applied in a single time or dividedly in two or more times.

Id. at 12:15–24.

E. Obviousness over Saji

Petitioner argues that claims 1–75 of the '827 patent would have been obvious over Saji. Pet. 50–63. Petitioner argues that Saji teaches or suggests each limitation of the challenged claims. Pet. 54–63. According to Petitioner:

> a) Lurasidone HCl was disclosed in Saji Patent . . . to be effective for the treatment of schizophrenia and manic depressive psychosis;
>
> b) Oral dosing is preferred and disclosed in Saji Patent;
>
> b) The preferred oral daily dose was disclosed in Saji Patent to be "from about 5 to 100 mg;["]
>
> c) Treatment without a second antipsychotic was preferred and Saji Patent discloses tablets with one active ingredient;
>
> d) Once daily dosing is preferred and lurasidone's 18 hour half life led naturally to once a day dosing; and
>
> e) No weight gain in at least a patient was expected;

Id. at 62. Petitioner also contends that "given the disclosed range in Saji Patent ('about 5 to 100 mg') a POSA was motivated to conduct dose ranging

studies and would find the claimed dosing regimens," and would have "had a reasonable expectation that all the claimed dosing regimens would be effective for the intended purpose." *Id.* at 62–63.

After reviewing the entire record developed at trial, and as explained below, we determine Petitioner has shown, by a preponderance of the evidence, that Saji teaches or suggests each limitation of the challenged claims. Petitioner has also shown that an ordinarily skilled artisan would have had a reason to modify the dose range taught in Saji, and would have had a reasonable expectation of success when doing so.

Patent Owner counters that Saji does not suggest the claimed dosing regimen, which "unexpectedly does not cause weight gain." PO Resp. 37–52. According to Patent Owner, lack of weight gain is not inherent either. *Id.* at 52–53. Patent Owner further asserts that "[o]bjective evidence demonstrates that the claimed dosing regimen would not have been obvious." *Id.* at 53–59. We address these contentions below.

For our discussion, we divide the challenged claims into five groups as follows.

1. Group 1 Claims

Group 1 claims include claims 1–3, 5, and 8–11. These claims are directed to a method of treating either schizophrenia or manic depressive psychosis in a patient with lurasidone at a dose of 20–120 mg/day, wherein the patient does not experience clinically significant weight gain. Some of these claims require no weight gain after six weeks of administering lurasidone.

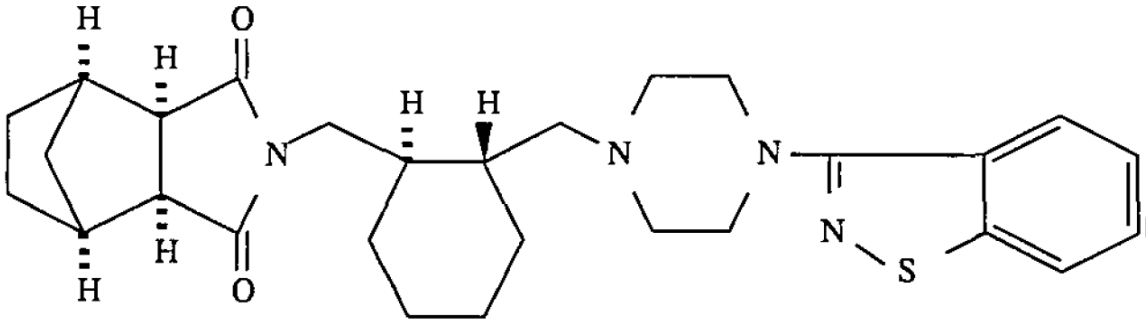
i. Saji Teaches Lurasidone as a Preferred Embodiment

As a preliminary matter, we note that the parties refer to different named compounds in Saji as lurasidone. According to Petitioner, the compound of claim 14 and Compound No. 101 in Saji are lurasidone. Pet. 56. Patent Owner argues that Compound No. 105 is lurasidone, whereas Compound No. 101 is "a racemic mixture of enantiomers." PO Resp. 38. Patent Owner contends that Compound No. 101 and Compound No. 105 have different "structure[s] and properties," and "[f]or this reason alone, Slayback's challenge," which focuses on Compound No. 101, "fails because it produces no evidence relating to the claimed dosing regimen, which requires lurasidone, not the racemic mixture." *Id.* We disagree.

When previously asserting Saji against certain entities, Patent Owner made a different argument and explained that Saji "illustrates a series of preferred embodiments, including lurasidone hydrochloride (Compound No. 105), lurasidone's enantiomer in a hydrochloride salt form (Compound No. 104), and a mixture of this enantiomeric pair in a hydrochloride salt form (Compound No. 101)." Ex. 1052, 12; *see also* Ex. 1053, 4–5 (the same). In the previous proceedings, Patent Owner argued that "Claim 14 [of Saji] is not narrowly drawn to a racemic mixture. Rather, Claim 14 encompasses lurasidone, lurasidone's enantiomer, and mixtures thereof." *Id.* at 13. The district court, apparently persuaded by Patent Owner's argument, "construed the two-dimensional drawing in Claim 14 [of Saji] to mean 'lurasidone, lurasidone's enantiomer, as well as mixtures of these enantiomers.'" Ex. 1053, 6. Patent Owner argued to the Federal Circuit that

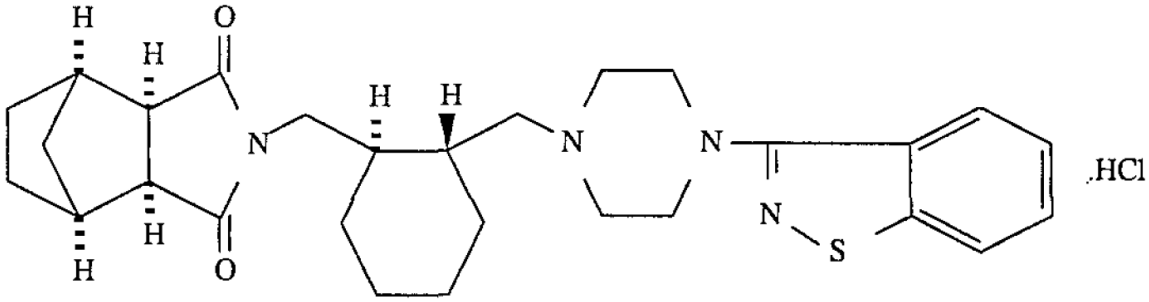
"the district court's construction was correct and should be affirmed." *Id.* at 16.

Claim 14 of Saji is directed to an imide compound with the following formula, or an acid addition salt thereof:



The figure above shows the chemical structure of the compound of claim 14. *Id.*, claim 14.

Saji also teaches Compound No. 101, which has the following structure:



(101)

The figure above shows the chemical structure of Compound No. 101. Ex. 1009, col. 30, at the bottom.

The compound of claim 14 and Compound 101 in Saji are the same, with Compound 101 showing the addition of HCl in the two-dimensional drawing, and claim 14 reciting "an acid addition salt" in the body of the

claim. Thus, based on Patent Owner's previous argument that "Claim 14 encompasses lurasidone, lurasidone's enantiomer, and mixtures thereof," we find Compound 101, contrary to Patent Owner's argument in this proceeding, "is not narrowly drawn to a racemic mixture." *See* Ex. 1053, 13.

Moreover, as Patent Owner acknowledges, Compound 105 is a preferred embodiment of Saji. Sur-reply 10; *see also* Ex. 1054, 93:15–18 (Dr. Stahl, Patent Owner's expert, testifying that an ordinarily skilled artisan "would be focused on" Compound 105 after reading Saji). Dr. Kosten, Petitioner's expert, explained during his deposition that, although he "indicate[d] compound No. 101" in his declaration, "it might be compound 105. They're both there, and either one would be fine." Ex. 2134, 75:18–20. Indeed, Saji teaches the binding affinity of both Compound 101 and Compound 105 for the D_2 receptor. Ex. 1009, 13:5–10. Patent Owner does not dispute this. *See* PO Resp. 37 ("For Compound No. 105, Saji '372 discloses its *in vitro* binding affinity for the D_2 receptor, a receptor commonly targeted by antipsychotic drugs."). Thus, we disagree with Patent Owner that Petitioner's evidence relates to only the racemic mixture, and not lurasidone.

Patent Owner also argues that "[l]urasidone is identified as one of many compounds within Saji '372's genus, not as 'lurasidone' but as 'Compound No. 105.'" PO Resp. 37 (citing Ex. 1009, 30:30–32:23). This emphasis, although correct, is incomplete and insignificant. Saji may disclose many compounds; it, however, only *claims* six specific compounds (*see* Ex. 1009, claims 14–19), one of which is lurasidone (*id.*, claim 14). And

because Saji discloses the chemical structure of lurasidone, it matters not what name it is given in Saji.

In sum, we find Saji teaches lurasidone as a preferred embodiment.

ii. Saji Teaches Treating Schizophrenia and Manic Depressive Psychosis

Petitioner refers to Saji for teaching that the disclosed novel imide compounds and their acid addition salts can be used as anti-psychotic agents for therapy of schizophrenia and manic depressive psychosis. Pet. 54 (citing Ex. 1009, 1:8–13).

Petitioner also relies on the Saji Amendment, which is a response to an office action filed on December 29, 1994, during the prosecution of Saji. *Id.* at 50–51 (citing Ex. 1026). In the Saji Amendment, the applicant pointed out that Saji's specification shows Compound Nos. 101 and 105 "have high affinity to the dopamine D_2 receptors." Ex. 1026, 4. According to Saji applicant, "these test results would be sufficient to one skilled in the art to establish that the claimed compounds have anti-psychotic activity and would be useful for the treatment of schizophrenia." *Id.*

Saji applicant also argued that "[i]t is well known to those skilled in the art that anti-psychotic drugs, i.e., neuroleptics, are generally effective in treatment of manic-depressive psychosis." *Id.* at 6. Based on the test results in Saji's specification, Saji applicant argued "it would be understood to those skilled in the art that the claimed compounds would be useful as anti-psychotic agents for therapy of manic depressive psychosis with minimal side effects." *Id.* at 7.

Patent Owner does not dispute, and we agree, that Saji teaches treating schizophrenia and manic depressive psychosis with lurasidone, a

preferred compound of its invention. *See* Sur-reply 9–10 ("[T]he data in the Saji '372 specification demonstrated that Compound 105 could successfully treat psychoses," including schizophrenia and manic depressive psychosis).

iii. Saji's Preferred Dose Range Overlaps with the Claimed Dose Range

Patent Owner contends that Saji does not suggest the claimed dosing regimen. PO Resp. 38; Sur-reply 13. According to Patent Owner, Saji "generically states that the compounds covered by its genus may be provided in any of four broad dose ranges . . . but includes ***nothing*** to suggest which dose range might work for which compounds, or which route of oral administration or intravenous injection might work for which compounds." Sur-reply 13–14; PO Resp. 38–39. Patent Owner's arguments are unavailing.

Saji lists three routes to administer the compounds of its invention: oral, intravenous, and rectal. Ex. 1009, 12:5–7. Dr. Kosten testifies that "[o]ral is a preferred route to administer an antipsychotic." Ex. 1002 ¶ 123 (citing Ex. 1039, 1788). Neither Patent Owner nor Dr. Stahl points to any evidence or argues otherwise. Thus, we credit Dr. Kosten's unrebutted testimony that an ordinarily skilled artisan would have had a reason to administer lurasidone orally. *See id.*

For oral administration, only two of Saji's four dose ranges Patent Owner refers to are relevant, and only one is preferred. Ex. 1009, 12:18–21 (teaching the compounds of its invention may be given to an adult at a "daily dose" of "preferably from about 5 to 100 mg, in case of oral administration"). Given that lurasidone is admittedly a preferred

embodiment of Saji (*see* Sur-reply 10), we are persuaded that an ordinarily skilled artisan would have started from this preferred dose range.

The challenged '827 patent discloses treating schizophrenia by orally administering lurasidone "at a daily dose of 5 mg to 120 mg" (Ex. 1001, 3:56–62), a range broader than the "from about 5 to 100 mg" preferred range taught in Saji. According to Dr. Stahl, neither range is "a lucky guess," because "every antipsychotic . . . out there is basically working, except for maybe [one], in the five to 100 [mg] range." Ex. 1054, 104:20–105:1, *see also id.* at 104:23–105:3 ("I think it's basically an extrapolation from what is known about agents in this class."). Dr. Stahl's testimony, thus, confirms our determination that an ordinarily skilled artisan would have started from Saji's preferred dose range.

Based on Saji's preferred dose range of 5 to 100 mg/day, which overlaps with the "from 20 to 120 mg/day" range required by each challenged independent claim, Petitioner argues that an ordinarily skilled artisan would have been "motivated to conduct dose ranging studies and would find the claimed dosing regimens." Pet. 62; *see also id.* at 55 (contending that "dose ranging was a routine part of drug development" (citing Ex. 1030)). Dr. Stahl's testimony supports Petitioner's argument.

Indeed, Dr. Stahl testifies that, although with some drugs, it can be difficult to find a safe and effective dose, or to get an effective dose into the patient, neither is the case with lurasidone. Ex. 1054, 141:3–14; *see also id.* at 142:2–6 ("Q. [A]re you aware of any particular difficulties with lurasidone hydrochloride and finding a safe and effective dose for schizophrenia and manic depressive psychosis? A. No."); 135:18–25

(Dr. Stahl testifying that he is "not aware of anything unusual about [lurasidone's] dose range"). Thus, we agree with Petitioner that an ordinarily skilled artisan, starting from Saji's preferred dosing range, would have conducted routine dose ranging studies and identified the claimed dosing regimens.

iv. Lack of Weight Gain Is Not Unexpected

Acknowledging that "the prior art discloses a range that encompasses the claim," Patent Owner asserts that "a relevant inquiry is whether there would have been a motivation to select the claimed composition from the prior art ranges." PO Resp. 39–40 (quoting *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1304-05 (Fed. Cir. 2015)). Patent Owner contends that the claimed dosing regimen produces unexpected results, because it "unexpectedly does not cause weight gain." *Id.* at 40.

Petitioner argues that "[n]o clinically significant weight gain in one or more patients is inherent." *Id.* at 55, 56, 57, 59. Relying on Horisawa[6] and other prior art, Petitioner also contends that lack of weight gain was not an unexpected result of treatment. Pet. 55, 56, 57, 59. We agree with Petitioner,

[6] Horisawa et al. *Pharmacological Characteristics of the Novel Antipsychotic SM-13496: Evaluation of Action on Various Receptors in the Brain*, 19 JPN. J. NEUROPSYCHOPHARMACOL. 363 (1999). Petitioner submits Exhibit 1028, which includes a certified English translation of Horisawa. Patent Owner disputes the accuracy of this translation and provides Exhibit 2040, "a correct translation" of Horisawa that "the parties agreed to." PO Resp. 44 n.144. For purposes of this Decision, we cite to Exhibit 2040.

and find Patent Owner's evidence and argument insufficient to rebut the presumption of obviousness created by the overlapping ranges.

Horisawa teaches the pharmacological characteristics of SM-13496. Ex. 2040, 7. Horisawa does not provide the chemical structure of SM-13496. According to Petitioner, however, during the prosecution of the challenged '827 patent, the applicant admitted SM-13496 was known as lurasidone. Pet. 51–52 (citing Ex. 1014–1016). Patent Owner contends that it "never admitted that 'SM-13496' was known in the prior art to be lurasidone." PO Resp. 41–42. We do not need to resolve this issue because, as Petitioner points out and Patent Owner does not dispute, "SM-13496 was identified as lurasidone no later than October 18, 2001," before the earliest possible priority date on the face of the challenged '827 patent. Pet. 53 (citing Ex. 1040, 22).

Horisawa reports that its "results suggest that SM-13496 [i.e., lurasidone] ameliorates symptoms of schizophrenia via D_2 and 5-HT2 receptor blocking effects and also has low binding affinity for α_1, H_1 and 5-HT_{2C} receptors; therefore it is suggested that its cardiovascular system and central suppressive side effects and *weight gain effect are weak*." Ex. 2040, 7 (emphasis added); Reply 26. This, according to Petitioner, demonstrates that lurasidone "would lead to no weight gain in at least some patients." Pet. 53.

Patent Owner disagrees, arguing that there is "a poor correlation between receptor binding affinity and a drug's tendency to cause weight gain." PO Resp. 44. Patent Owner labels Horisawa's teaching as "speculation" (*id.*), and contends that "the receptor binding affinity data in

Horisawa fails to create a reasonable expectation that the claimed lurasidone dosing regimen would not cause weight gain" (*id.* at 42). Patent Owner's argument is unavailing.

We acknowledge the prior art's teaching that the "plethora of neurotransmitter and neurohumoral systems and receptors involved in body weight regulation make the weight gain liability of a potential novel agent difficult to predict." *Id.* at 43 (quoting Ex. 2028, 5–6). Yet, for an obviousness analysis, a reference "qualifies as prior art . . . for whatever is disclosed therein." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003). Indeed, even "an inoperative device . . . is prior art for all that it teaches." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Horisawa suggests that lurasidone ameliorates symptoms of schizophrenia and its effect on weight gain is "weak" in view of its receptor binding affinity profile. Ex. 2040, 7. An ordinarily skilled artisan, would not simply dismiss such a teaching.

Moreover, each challenged claim is directed to a method of treating "a patient," wherein the patient does not experience a clinically significant weight gain. As explained above, Patent Owner agrees that "[t]here is no dispute that 'a patient,' as recited in the '827 claims, refers to 'one or more patients.'" Sur-reply 19. Patent Owner also concedes that "[a] person of ordinary skill would recognize that there will *always* be some outliers" who would not gain weight with lurasidone treatment. *Id.* at 51 (emphasis added); *see also id.* at 20 (acknowledging "[t]he fact that some individual patients ultimately do not gain weight" on lurasidone). In other words, Patent Owner

admits that an ordinarily skilled artisan, when treating a patient with lurasidone, would expect that at least one patient would not experience clinically significant weight gain. This supports Petitioner's position that no weight gain in one or more patients is inherent.

Patent Owner contends that

> a person of ordinary skill seeking to understand the properties of a drug would not be focused on determining how any given individual patient will respond from the standpoint of side effects or efficacy. Rather, the relevant question is how a *population of patients* will respond. A person of ordinary skill's reasonable expectations would be based on the response of the population to the treatment.

Id. at 51 (emphasis added). We disagree.

Interestingly, the binding authority that informs our decision here is a case in which "a patient" means "a patient population." *Braintree Labs, Inc. v. Novel Labs, Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014). In *Braintree*, the claim-at-issue was directed to a "composition for inducing purgation of the colon of *a patient* . . . wherein the composition does not produce any *clinically significant electrolyte shifts*" *Id.* at 1353. The district court granted summary judgment of infringement in the patentee's favor. *Id.* In relevant part, the district court interpreted "a patient" to mean "one or more patients," and found that "at least one patient to whom [the alleged infringing product] is administered will experience, or has experienced, no clinically significant electrolyte shifts." *Id.* at 1357.

On appeal, the Federal Circuit vacated the grant of summary judgment of infringement because it concluded the district court's interpretation of "a patient" was incorrect. *Id.* Instead, it interpreted "a patient" to mean "a

patient population." *Id.* According to the Federal Circuit, "the district court's application of the claim terms 'a patient' leads to the absurd result of infringement even if a composition causes clinically significant electrolyte shifts in a large percentage of patients." *Id.*

In our case here, "a patient" means "one or more patients." This is undisputed. *See* Sur-reply 19 (Patent Owner acknowledging "[t]here is no dispute that 'a patient,' as recited in the '827 claims, refers to 'one or more patients.'"). Thus, under the logic explained in *Braintree*, a method would meet the challenged claims "even if 99 patients out of 100 experienced clinically significant [weight gain], as long as one patient did not." *See id.* As a result, we reject Patent Owner's argument that "[a] person of ordinary skill's reasonable expectations would be based on the response of the *population* to the treatment." PO Resp. 51 (emphasis added). Instead, the proper inquiry is whether an ordinarily skilled artisan would have had a reasonable expectation that at least one patient would not gain weight when treated with lurasidone. And the answer, as Patent Owner admits, is yes. *See* PO Resp. 20, 51.

Relying on the testimony of Dr. Kosten, Petitioner asserts that antipsychotics are "given for weeks or months or longer, making it routine and ordinary to test for weight gain after 6 weeks." Pet. 57 (citing Ex. 1002 ¶ 131). Patent Owner does not dispute, and we are persuaded by, this argument. Thus, we credit Dr. Kosten's testimony and find that an ordinarily skilled artisan would have been "motivated to administer lurasidone HCl to treat schizophrenia and manic depressive psychosis and detect no weight

gain after six weeks in at least one patient and had a reasonable expectation of success for its intended purpose." *See* Ex. 1002 ¶ 131.

v. Summary

In sum, Petitioner has shown, by a preponderance of the evidence, that Saji teaches or suggests a method of treating schizophrenia or manic depressive psychosis in a patient with lurasidone at a dose of 20–120 mg/day, wherein the patient does not experience clinically significant weight gain, even after six weeks of administering lurasidone. In other words, Petitioner has shown by a preponderance of the evidence that Saji teaches or suggests each limitation of challenged claims 1–3, 5, and 8–11.

2. Group 2 Claims

Group 2 claims include claims 7, 13–31, and 34–39. These claims require, in addition to the limitations of Group 1 claims,[7] that lurasidone is given once daily. Some of these claims recite a narrower dose range (e.g., "from 40 to 120 mg") or a specific dose amount (20, 40, 60, 80, or 120 mg).

Petitioner argues that lurasidone has a half-life of 18 hours, and with this "relatively long" half-life, an ordinarily skilled artisan would have been "highly motivated to administer a drug once daily, especially for compliance." Pet. 59 (citing Ex. 1002 ¶ 139).

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[7] Independent claims 25, 40, and 56, included in this group, are directed to a method of "treating a patient with an antipsychotic." The parties do not dispute, and we agree, that this term should be construed as comprising both "treating a patient for schizophrenia with an antipsychotic" and "treating a patient for manic depressive psychosis with an antipsychotic." Pet. 20–21; PO Resp. 24; *Supra* at Section II.C.

Patent Owner points out that lurasidone's half-life was not known until 2012, "a decade" after the earliest possible priority date on the face of the challenged '827 patent. Tr. 36:21–24. Thus, Patent Owner argues an ordinarily skilled artisan would not have been able to know whether lurasidone can be administered once daily. *Id.* at 36:24–37:1. Patent Owner's argument is unavailing.

As Patent Owner acknowledges, once-daily dosing regimen "promotes patient compliance." PO Resp. 58 (citing Ex. 2131 ¶¶ 160–161). Dr. Stahl testifies that once a day dosing is preferred if the drug has a sufficiently long half-life. Ex. 1054:2–15.

Although Patent Owner is correct that the half-life of lurasidone was not known until 2012, we are persuaded that "determining half life in the blood is a routine part of drug development." Pet. 59 (citing Ex. 1002 ¶ 139); *see also* Ex. 1002 ¶ 139 ("ICH-4 shows that it was an ordinary and routine part of drug development to consider the 'half-life of the drug' when developing 'the dose interval.'") (citing Ex. 1030, 4). Thus, we agree with Petitioner that "Lurasidone's half life of 18 hours would have been determined in the ordinary course of drug development." Pet. 59 (citing Ex. 1002 ¶ 139).

Dr. Stahl's testimony confirms our determination. Indeed, when asked whether he is aware of "any reason why it's difficult to detect the half life of lurasidone in a human being," he answered: "I'm not aware, and I don't believe there to be any." Ex. 1054, 139:1–8; *see also id.* at 138:21–25 (Dr. Stahl testifying he does not know of "anything out of the routine with respect to determining the half life of lurasidone in the body").

Dr. Stahl also testified that the half-life of 18 hours suggests to an ordinarily skilled artisan that "lurasidone has the potential to be once a day dosing." *Id.* at 137:20–138:1. This testimony support's Petitioner's argument that an ordinarily skilled artisan would have been "highly motivated to administer lurasidone HCl once a day." *See* Pet. 60.

Some challenged dependent claims recite specific dosing amounts. Petitioner argues dose ranging is a routine part of drug development. Pet. 59–60 (citing Ex. 1002 ¶¶ 140–141). For the same reason as explained above in Section II.E.iii, we agree with Petitioner that an ordinarily skilled artisan, starting from Saji's preferred dosing range, would have conducted routine dose ranging studies and identified the specific dosing amounts recited in the challenged claims. *See also* Ex. 1002 ¶ 140 ("It is prudent to carry out dose-ranging or concentration-response studies early in development as well as in later stages in order to avoid failed Phase 3 studies or accumulation of a database that consists largely of exposures at ineffective or excessive doses.") (quoting Ex. 1030, 13).

In sum, Petitioner has shown, by a preponderance of the evidence, that Saji teaches or suggests a method of treating schizophrenia or manic depressive psychosis in a patient with lurasidone at 40–120 mg once daily, or at 20, 40, 60, 80, or 120 mg once daily, wherein the patient does not experience clinically significant weight gain. In other words, Petitioner has shown Saji teaches or suggests each limitation of challenged claims 7, 13–31, and 34–39.

3. Group 3 Claims

Group 3 claims include claims 40–46, 49–62, and 65–75. These claims require, in addition to the limitations of Group 1 or 2 claims, that lurasidone is the sole active ingredient.

Petitioner contends that Saji teaches a "pharmaceutical preparation" with lurasidone or its salts with "suitable additives" but no other active ingredients. Pet. 58 (citing Ex. 1009, 12:8–14). According to Petitioner, an ordinarily skilled artisan would have been "highly motivated to not include other active ingredients."[8] *Id.* (citing Ex. 1002 ¶ 135); *see also* Ex. 1002 ¶ 133 ("Polypharmacy with multiple antipsychotic agents was the discouraged practice because of potential drug interaction, multiple side effects and less compliance.").

Patent Owner counters that Saji "says nothing about this point." PO Resp. 60. Patent Owner relies on other prior art, such as Wong.[9] Wong teaches a novel pharmaceutical composition that combines one or more norepinephrine reuptake inhibitors with one or more neuroleptic agents, including SM-13496 (i.e., lurasidone). Ex. 2032, 5:7–12. According to Wong, "[t]he composition is considered to be particularly effective against schizophrenia." *Id.* at 5:12–14.

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[8] Dr. Stahl's testimony also supports Petitioner's argument here. *See* Ex. 1054, 62:25–63:8 (Dr. Stahl testifying that before the earliest possible priority date on the face of the challenged '827 patent, monotherapy is something an ordinarily skilled artisan would strive for in general).

[9] U.S. Patent No. 6,964,962 B2, issued Nov. 15, 2005 (Ex. 2032).

Wong teaches that "it is believed that the addition of the norepinephrine reuptake inhibitor can significantly reduce the side effects associated with the neuroleptic treatments for schizophrenia." *Id.* at 10:8–11; *see also id.* at 10:15–18 ("[T]he incidence of weight gain typically associated with the administration of atypical neuroleptic agents is minimized by the administration of the norepinephrine reuptake inhibitor.").

Patent Owner contends that an ordinarily skilled artisan, "reading Wong, would have believed it necessary to combine an antipsychotic drug with a second different drug in a single formulation to avoid or reduce weight gain." PO Resp. 61 (citing Ex. 2131 ¶ 178). According to Dr. Stahl, this is consistent with his experience co-administering olanzapine with metformin to minimize the expected weight gain. Ex. 2131 ¶ 179. As a result, Patent Owner argues that "Prior Art Taught Away from Dosing Regimens in Which Lurasidone was the Sole Active Ingredient." *Id.* at 59. We disagree.

Wong's teaching does not come near to criticizing, discrediting, or otherwise discouraging administering a pharmaceutical composition comprising lurasidone as the sole active ingredient. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Wong states that its inventive composition contains two active components, and "[t]he dosages for each active component can be measured separately and can be given as a single combined dose or given separately. They may be given at the same or at different times as long as both actives are in the patient at one time over a 24-hour period." Ex. 2032, 9:23–28. In light of Wong's teaching that the two drugs may be administered separately at different times, we agree with

Petitioner that, contrary to Patent Owner's assertion, it is not necessary to combine the two drugs into a single formulation. Reply 30 (citing Ex. 1051 ¶ 5).

Patent Owner argues that "[t]he '827 claims, which recite a 'composition' in which lurasidone is the 'sole active ingredient,' exclude a second active ingredient to avoid weight gain, either combined in a single unit dose with lurasidone or *administered separately*." Sur-reply 24 (emphasis added). As support, Patent Owner cites "Ex. 1001, 4:13–25" as "describing a single unit dose as the preferred composition." *Id.* n.55. The cited excerpt of the challenged '827 patent does not support Patent Owner's argument. Indeed, the '827 patent discloses that

> The therapeutic agent used in the method for treatment of schizophrenia of the present invention is in the form of an oral preparation, which contains the compound of the above formula (1) or a pharmaceutically acceptable salt thereof, especially [lurasidone] in an amount of 5 mg to 120 mg, preferably in an amount of 10 mg to 100 mg, more *preferably in an amount of 20 mg to 80 mg per a single dosage unit*. The oral preparation includes, for example, tablets, granules, fine granules, powders, capsules, syrups, etc. These preparations should be in the form of a preparation for administration once a day.

Ex. 1001, 4:13–25. Instead of "describing a single unit dose as the preferred composition," as Patent Owner alleges, the language of the '827 patent is directed to the preferred dosing amount.

Nor are we persuaded that Dr. Stahl's experience co-administering olanzapine with metformin to minimize the expected weight gain supports Patent Owner's argument of teaching-away. As Petitioner points out, which Patent Owner does not dispute and we agree, "metformin is not an

antipsychotic, so metformin's use does not tell the POSA to use a second antipsychotic to mitigate weight [gain]." Reply 30 (citing Ex. 1051 ¶ 7).

In sum, Petitioner has shown, by a preponderance of the evidence, that Saji teaches or suggests a method of treating schizophrenia or manic depressive psychosis in a patient with a pharmaceutical composition with lurasidone as the sole active ingredient, wherein the patient does not experience clinically significant weight gain. In other words, Petitioner has shown Saji teaches or suggests each limitation of challenged claims 40–46, 49–62, and 65–75.

4. Group 4 Claims

Group 4 claims include claims 4, 12, 32, 33, 47, 48, 63, and 64. These claims require, in addition to the limitations of Group 1, 2, or 3 claims, that lurasidone is administered "without concurrently administering another antipsychotic medication."

Petitioner argues that Saji teaches a pharmaceutical preparation with lurasidone or its salts with no other antipsychotic medication. Pet. 57 (citing Ex. 1009, 12:8–14). According to Petitioner, an ordinarily skilled artisan would have been "motivated to use a single antipsychotic to treat schizophrenia or the manic phase of bipolar disorders," because polypharmacy is disfavored.[10] *Id.* at 57–58 (citing Ex. 1002 ¶ 133). Patent Owner does not address this additional limitation separately.

[10] This is consistent with Dr. Stahl's testimony. *See* Ex. 1054, 62:25–63:8 (Dr. Stahl testifying that "everybody is trying to" go with "the fewest number of meds" to "reduce the need for medications within whatever the patient can tolerate").

For the same reason explained above (*see supra* at Section II.E.3), we are persuaded that Petitioner has shown, by a preponderance of the evidence, that Saji teaches or suggests a method of treating schizophrenia or manic depressive psychosis in a patient with a pharmaceutical composition with lurasidone, "without concurrently administering another antipsychotic medication," wherein the patient does not experience clinically significant weight gain. In other words, Petitioner has shown Saji teaches or suggests each limitation of challenged claims 4, 12, 32, 33, 47, 48, 63, and 64.

5. Group 5 Claim

Group 5 includes claim 6, which depends from claim 1 and further recites "wherein said patient has a BPRS [Brief Psychiatric Rating Scale] score of at least 42 and wherein the patient's BPRS score is significantly reduced from a baseline measurement prior to the administering."

BPRS scores are "indexes for the effects on schizophrenia" of a therapeutic. Ex. 1001, 3:19–21; *see also* PO Resp. 15 ("BPRS scores are measures of psychotic activity."). Dr. Kosten notes that the '827 patent, when discussing the selection criteria of a subject for the clinical trial, lists as "Patients having 42 or more of Extracted-BPRS Score" as one of the criteria. Ex. 1002 ¶ 144 (citing Ex. 1001, 5:26). Dr. Kosten further testifies that

> a BPRS scope of 42 is a typical score in a psychiatric patient experiencing psychotic symptoms and a significant reduction in BPRS score following administration of an antipsychotic to at least a patient with a BPRS score of at least 42 was expected and a POSA was motivated to do this with a reasonable expectation of success.

Id.; Pet. 61 (the same). Patent Owner does not address this additional limitation separately.

We credit Dr. Kosten's unrebutted testimony on this issue. Thus, we are persuaded that Petitioner has shown, by a preponderance of the evidence, that Saji, when viewed in light of well-known knowledge in the art of BPRS scores, teaches or suggests the additional limitation of challenged claim 6.

6. Objective indicia

Objective indicia of non-obviousness guard against hindsight reasoning in an obviousness analysis, and are often "the most probative and cogent evidence in the record." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). As such, objective indicia of non-obviousness must be considered in every case in which they are presented. *Id.* Objective indicia of non-obviousness include commercial success, long-felt but unsolved needs, failure of others, copying, industry praise, unexpected results, and industry acceptance. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc*., 229 F.3d 1120, 1129 (Fed. Cir. 2000).

Patent Owner presents evidence and arguments to show commercial success, long-felt but unmet need, and failure of others. PO Resp. 54–58. On these, Patent Owner relies on Latuda. *Id.* According to Patent Owner, "[l]ack of weight gain is a key reason" for Lutada's commercial success. *Id.* at 55–56. Similarly, Patent Owner contends that Latuda met the long-felt but unmet need "because it has a highly favorable profile as to weight gain." *Id.* at 57.

Petitioner contends that "Patent Owner's evidence [on objective indicia] is unavailing because neither of Patent Owner's two experts was

able to articulate anything that was novel in the claims." Reply 28. We are not persuaded by this argument.

Patent Owner asserts, and Petitioner does not dispute, that "claims 1–75 cover the FDA-approved Latuda® dosing regimen for treating schizophrenia and bipolar depression." PO Resp. 54. Thus, we agree with Patent Owner that a nexus is presumed. *See* Sur-reply 17 (quoting *Brown & Williamson Tobacco Corp.*, 229 F.3d at 1130).

Petitioner does not present sufficient evidence or arguments to rebut the presumption of nexus. Thus, we accord proper weight to Patent Owner's evidence that Latuda enjoyed commercial success and met a long-felt need. *See* PO Resp. 54–58.

Patent Owner also contends that industry skepticism shows non-obviousness of the challenged claims. PO Resp. 58. According to Patent Owner, other antipsychotic drugs, such as ziprasidone, "may lead to QT prolongation—a cardiac side effect that can end in sudden death." *Id.* at 6. Patent Owner argues that one of its collaborators terminated the relationship on suspicion of "lurasidone's impact on QTc." *Id.* at 58. Ultimately, it was shown that lurasidone does not carry the risks of QT prolongation or other serious side effects. *Id.* at 57, 59. This safety profile, although desirable, is not a claimed limitation, and thus, is irrelevant to our obviousness analysis.

In view of the foregoing, we determine that some, but not all, of Patent Owner's evidence of objective indicia tend to show non-obviousness of the challenged claims.

7. Summary

Having considered each of the *Graham* factors individually, we now weigh them collectively. We find the first three factors, including the scope and content of the prior art, the differences between the prior art and the challenged claims, and the level of skill in the art, weigh heavily in favor of Petitioner's contention that claims 1–75 would have been obvious. Some of Patent Owner's evidence on objective indicia, however, weigh in favor of finding non-obviousness.

As explained above, we agree with Petitioner that lack of weight gain, the basis of Latuda's commercial success and meeting the long-felt need, is inherent and suggested by the teachings of Horisawa. *See supra* at Section II.E.1.iv. Thus, although the record shows a successful product, on the whole, we determine that the first three *Graham* factors are so strong that they outweigh the evidence on objective indicia. *See Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 769 (Fed. Cir. 1988); *see also Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (affirming the district court's obviousness finding "given the strength of the prima facie obviousness showing," even though patentee "had provided substantial evidence of commercial success, praise, and long-felt need").

In sum, upon review of the record as a whole, including Patent Owner's evidence of objective indicia, and for the reasons discussed above, we determine that Petitioner has shown, by a preponderance of the evidence, that the subject matter of claims 1–75 would have been obvious over Saji.

F. Other Grounds

Petitioner argues that claims 8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, and 75 are (1) anticipated by Latuda Information, and (2) rendered obvious over the combination of Latuda Information and Loebel. Pet. 31–49. As explained above, we determine the subject matter of claims 1–75 would have been obvious over Saji. *See supra* at Section II.E. Thus, we need not and do not reach these additional challenges. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

III. MOTIONS TO SEAL

There is a strong public policy for making all information filed in an *inter partes* review open to the public, especially because the proceeding determines the patentability of claims in an issued patent and, therefore, affects the rights of the public. Generally, all papers filed in an *inter partes* review shall be made available to the public. *See* 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14. Our rules, however, "aim to strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." Consolidated Patent Trial Practice Guide 19. Thus, a party may move to seal

certain information (37 C.F.R. § 42.14); but only "confidential information" is protected from disclosure (35 U.S.C. § 326(a)(7)). Confidential information means trade secret or other confidential research, development, or commercial information. 37 C.F.R. § 42.2.

The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a). The party moving to seal bears the burden of proof and must explain why the information sought to be sealed constitutes confidential information. 37 C.F.R. § 42.20(c).

1. Patent Owner's Motion to Seal

Patent Owner filed a Motion to Seal and for entry of a Protective Order. Paper 13. Patent Owner represents that the parties have agreed to use the default protective order set forth in the Office Patent Trial Practice Guide. *Id.* at 6–7, Appendix A. The Protective Order (Appendix A to Paper 13) is hereby entered. It shall govern the conduct of the proceeding unless otherwise modified.

Patent Owner seeks to seal in their entirety Exhibits 2058–2060, 2069, 2074–2076, 2078, 2080, 2082, 2083, 2089, 2090, 2092–2095, 2132, and 2138, as well as portions of Exhibit 2131 and the Patent Owner Response that rely on those Exhibits (Paper 15). *Id.* at 2–6. According to Patent Owner, these Exhibits contain its sensitive financial and competitive commercial information, proprietary data and analysis related to the use of Latuda, proprietary scientific protocols and data, and other confidential communications and information. *Id.* Patent Owner has filed a redacted version of the Patent Owner Response (Paper 14) and Exhibit 2131.

Upon considering the content of the Papers and Exhibits the parties seek to seal, along with Patent Owner's representations as to the confidentiality of the information, we determine that there is good cause for sealing in their entirety Exhibits 2058–2060, 2069, 2074–2076, 2078, 2080, 2082, 2083, 2089, 2090, 2092–2095, 2132, and 2138, as well as the redacted portions of Exhibit 2131 and the Patent Owner Response that rely on those Exhibits (Paper 15).

The parties may, within 14 days of this Decision, jointly propose redactions for this Final Written Decision. In the absence of such proposal, at the expiration of 14 days from the date of this Decision, the entirety of the Final Written Decision will be made available to the public.

Confidential information that is subject to a protective order ordinarily becomes public 45 days after final judgment in a trial. Consolidated Trial Practice Guide 21–22. Patent Owner may file a motion to expunge the information from the record prior to the information becoming public. 37 C.F.R. § 42.56.

2. Petitioner's Motion to Seal

Petitioner filed a Motion to Seal its Reply to Patent Owner's Response as well as Exhibits 1054 and 1055 "at the request of Patent Owner." Paper 19, 2. In an email dated June 23, 2021, Petitioner explained that it was informed by Patent Owner that these documents do not contain confidential information. Ex. 3001. We granted Petitioner's request to file unredacted public versions of documents. *Id.* as a result, we dismiss Petitioner's Motion to Seal as moot.

IV. CONCLUSION[11]

After reviewing the entire record and weighing evidence offered by both parties, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–75 of the '827 patent would have been obvious over Saji.

In summary:

Claims	35 U.S.C. §	Reference(s)	Claims Shown Unpatentable	Claims Not shown Unpatentable
8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, 75	102	Latuda Information		
8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, 75	103	Latuda Information, Loebel		
1–75	103	Saji	1–75	
Overall Outcome			1–75	

[11] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–75 are unpatentable;

FURTHER ORDERED that the Protective Order (Paper 13, Appendix A) is hereby entered;

FURTHER ORDERED that Patent Owner's Motion to Seal is granted;

FURTHER ORDERED that Petitioner's Motion to Seal is dismissed; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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