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Paper No. 35
Date: July 26, 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 JAMIE T. WISZ, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Patent Owner's Request on Rehearing of
Final Written Decision
37 C.F.R. § 42.71(d)

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. Sumitomo Dainippon Pharma Co., Ltd. ("Patent Owner") filed a Preliminary Response (Paper 6 ("Prelim. Resp.")). We instituted trial to review the challenged claims. Paper 7 ("Inst. Dec."). 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).

At the conclusion of the trial, we issued a Final Written Decision, determining that Petitioner has established the unpatentability of the challenged claims. Paper 29 ("Decision" or "Dec."). Patent Owner timely filed a Request for Rehearing of the Decision. Paper 30 ("Reh'g Req."). Patent Owner also timely filed a request for Precedential Opinion Panel (POP) review. Paper 31; Ex. 3002. The POP panel denied that request and instructed this panel to consider Patent Owner's rehearing request. Paper 33, 2.

For the reasons explained below, we deny Patent Owner's Request for Rehearing.

II. STANDARD OF REVIEW

The party challenging a decision in a request for rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). A request for rehearing "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed." *Id.*

III. ANALYSIS

In our Decision, we determined that Petitioner showed claims 1–75 were unpatentable as obvious over Saji[1], as asserted in Ground 3 of the Petition. Dec. 12–35. Because we determined that all of the claims were unpatentable as obvious over Saji, we did not reach Grounds 1 and 2 of the Petition. *Id.* at 36. In the Request for Rehearing, Patent Owner contends that (1) the Board relied on a new ground of unpatentability, and (2) the Board erred in its analysis of Grounds 1 and 2 in the Institution Decision. Reh'g Req. 2–3. We address each of Patent Owner's arguments below.

A. The Board Did Not Rely on A New Ground of Unpatentability

Patent Owner argues that the Board misapplied the law by finding the claims obvious based on a new ground of unpatentability. Reh'g Req. 2 (citing Pet. 14; Dec. 22, 25). Specifically, Patent Owner argues that the Petition alleged that claims 1–75 would have been obvious over Saji alone, but the Board relied on Saji and Horisawa[2] to conclude that the claims are unpatentable. *Id.* at 4–6 (citing Pet. 50–55; Dec. 20–22). Patent Owner argues that "[t]he Board's decision to rely on Horisawa, and to treat it as prior art in its obviousness analysis, represented an improper new ground of unpatentability." *Id.* at 6. Patent Owner further argues that it was deprived of a full and fair opportunity to address Horisawa. *See id.* at 6–7 (citing

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[1] U.S. Patent No. 5,532,372, issued July 2, 1996 (Ex. 1009, "Saji").
[2] 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.

EmeraChem Holdings, LLC v. Volkswagen Group of America, Inc., 859 F.3d 1341 (Fed. Cir. 2017)). We are not persuaded.

In our Decision, we determined that Petitioner has shown, by a preponderance of the evidence, that "Saji teaches or suggests each limitation of the challenged claims," and "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." Dec. 13. Specifically, we found that Saji teaches lurasidone as a preferred embodiment for treating schizophrenia and manic depressive psychosis and its preferred dosage range overlaps with the claimed dosage range. *Id.* at 13–20. We noted Patent Owner's argument that, despite the overlap, the claimed dosing regimen was unobvious because it unexpectedly "does not cause weight gain." *Id.* at 20 (citing PO Resp. 39–40). In addressing that argument, we considered the evidence of record, including Horisawa. *Id.* at 20–25. Thus, considering Horisawa to determine whether the lack of weight gain was unexpected does not deviate from the theory of obviousness set forth in the Petition.

The Federal Circuit has "made clear that the Board may consider a prior art reference to show the state of the art at the time of the invention, regardless of whether that reference was cited in the Board's institution decision." *Genzyme Therapeutic Prod. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1369 (Fed. Cir. 2016); *see also Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1381 (Fed. Cir. 2018) (stating the Board may consider additional references "as evidence of the knowledge that a skilled artisan would bring to bear in reading [the asserted references] even though those additional references were not cited in the petition").

In the instant case, our Decision was based on the ground set forth in the Petition, that is, the challenged claims would have been obviousness over Saji. *See Genzyme*, 825 F.3d at 1366 (affirming the Board's final written decisions because they were "based on the same combinations of references that were set forth in its institution decisions," and "the Board found the claims at issue unpatentable based on those same grounds and no others"). We considered Horisawa to determine whether an ordinarily skilled artisan would have expected a lack of weight gain. Dec. 20. Patent Owner has not shown it is improper for us to do so. *See Anacor*, 889 F.3d at 1381 (holding "it was not improper for the Board to rely on those [additional] references to show what a person of skill in the art would believe about" the effectiveness of a therapeutic compound).

We also are not persuaded by Patent Owner's argument that it did not receive adequate notice of Horisawa in our obviousness analysis. Reh'g Req. 2–3. According to Patent Owner, our treatment of Horisawa is contrary to the Federal Circuit case law holding that "broad, general statements regarding a reference in the Petition did not provide adequate notice for purposes of relying on the reference to support an obviousness ground." *Id.* (citing *EmeraChem*, 859 F.3d at 1348–49). The facts in our case, however, are distinguishable from those in *EmeraChem*.

In *EmeraChem*, the Federal Circuit emphasized "the specificity with which the petition's claim chart and the Institution Decision's list of claims expressly identified particular references' disclosures for some claims and not for others." 859 F.3d at 1349. It was in this context that the court stated that "[w]here the petitioner uses certain prior art references to target specific claims with precision, or the Board does the same in its decision to

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