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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

[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

institute," "it cannot be the case that the general statements [the petitioner] relies upon provided sufficient notice that [those prior art references] could be applied to all claims." *Id.*

In contrast, here, Petitioner discussed Horisawa (Ex. 1028) in detail in the Petition.[3] *See* Pet. 51–53. Specifically, when asserting *all* challenged claims would have been obvious over Saji, Petitioner cited Horisawa to show that an ordinarily skilled artisan would not have expected weight gain. *Id.* at 51–53, 55–57, 59.

Moreover, in *EmeraChem*, "neither party addressed in briefing or argument" the application of the reference-at-issue to the claims-at-issue. 859 F.3d at 1351. According to the court, this fact "helps make the point that neither party was on notice that [the reference-at-issue] was at issue as to those challenged claims." *Id.* at 1351–52.

In contrast, here, both parties thoroughly addressed issues related to Horisawa throughout trial. Indeed, in its Preliminary Response, when arguing that the challenged claims are patentable over Saji, Patent Owner contended that "Horisawa does not establish that lack of weight gain was expected." Prelim. Resp. 25–27. In our decision to institute, when discussing obviousness over Saji, we specifically noted the parties' disagreement over the significance of Horisawa with regard to expectation of no weight gain. Inst. Dec. 20–21 (citing Pet. 21; Paper 6, 25–27). We encouraged the parties to "fully develop the record during trial" on this issue. *Id.* at 22.

[3] The fact that Horisawa was introduced in the Petition also makes our case stronger than *Genzyme* and *Anacor*, where the references-at-issue were introduced after the respective petitions. *See Genzyme*, 825 F.3d at 1367; *Anacor*, 889 F.3d at 1381.

The parties did exactly that. In fact, Patent Owner disputed the accuracy of the translated Horisawa submitted by Petitioner (Ex. 1028), and submitted its own version (Ex. 2040).[4] PO Resp. 44 n.144. In its Response, Patent Owner again argued that "Horisawa does not establish that lack of weight gain was expected." *Id.* at 41–44; *see also* Ex. 2131 ¶¶ 127–139 (Patent Owner's expert testifying the same).

In the Reply, Petitioner again pointed to Horisawa for supporting "the conclusion that lurasidone's allegedly favorable profile for cardiac and weight gain side effects was not unexpected." Paper 21, 26–27 (citing Ex. 1002 ¶ 118). In the Sur-reply, Patent Owner argued that Petitioner and its expert "tacitly admitt[ed] that [Patent Owner] is correct" on the implication of Horisawa's teaching. Paper 25, 15–16. Finally, during the oral hearing, counsel for both Petitioner and Patent Owner argued at length about Horisawa's teachings as related to the expectation of no weight gain. *See* Paper 28, 12:7–14, 14:20, 32:22–35:8.

Considering the record as a whole, we find that Patent Owner had actual notice of Petitioner's reliance on Horisawa for showing lack of weight gain is not unexpected. Patent Owner also had ample opportunities to respond, and indeed, had repeatedly countered Petitioner's arguments as related to Horisawa. Accordingly, we are not persuaded that we erred in relying on Horisawa in our Decision to determine whether an ordinarily skilled artisan would have expected a lack of weight gain.

[4] In our Decision, we relied on Exhibit 2040, the alleged "correct translation" that "the parties agreed to." Dec. 20 n.6 (quoting PO Resp. 44 n.144).

B. The Board Is Not Obligated to Address All the Grounds in the Final Written Decision

In its Request for Rehearing of the Final Written Decision, Patent Owner asks us to dismiss Grounds 1 and 2 for lack of jurisdiction. Reh'g Req. 9–10. For the reasons explained below, we decline this invitation.

In the Petition, Petitioner asserted under Grounds 1 and 2 that a subset of the challenged claims ("the manic depressive claims") are unpatentable as anticipated by or obvious over certain references, including Latuda Information.[5] Pet. 23–49. The central issue for Grounds 1 and 2 is the prior-art status of Latuda Information. Petitioner argued the claims-at-issue cannot claim priority before the August 28, 2014, filing date of the '827 patent application, because the priority application does not provide sufficient written-description support for using lurasidone to treat manic depressive psychosis. *Id.* at 23–31. Thus, Petitioner concluded that Latuda Information qualifies as prior art. *Id.* at 31, 38.

In our decision to institute, based on the then-current record, we agreed with Petitioner on this issue. Inst. Dec. 13–14. In the Final Written Decision, however, we did not reach the challenges raised in Grounds 1 and 2 because we determined all challenged claims would have been obvious over Saji. Dec. 36. We explained that the Board "need not address issues that are not necessary to the resolution of the proceeding." *Id.* (quoting *Bos. Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020)).

Patent Owner argues that our "analysis of priority was contrary to law." Reh'g Req. 3. According to Patent Owner, the Board lacked

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

jurisdiction to consider Grounds 1 and 2 of the Petition, and thus, should dismiss those grounds. *Id.* We are not persuaded.

As Patent Owner recognizes, in our Decision, we did not rule on the merits of Grounds 1 and 2. Dec. 36. Decisions from both the Supreme Court and the Federal Circuit permit this approach. *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"); *Bos. Sci. Scimed*, 809 F. App'x at 990 (stating the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims"); *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) (holding that once a dispositive issue is decided, there is no need to decide other issues).

In addition, "the Board is not bound by any findings made in its Institution Decision" and "[t]he Board is free to change its view of the merits after further development of the record." *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016). Indeed, because the decision to institute and the final written decision involve "very different analyses," the Board has an obligation to assess the unpatentability question anew after trial based on the totality of the record. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1377 (Fed. Cir. 2016). Thus, even though we analyzed the priority issue at the institution stage, we do not have to revisit that issue in the Final Written Decision.

Patent Owner does not argue that we misapprehended or overlooked any matter in the Decision, or otherwise abused our discretion in disposing the case based on Ground 3. We declined to revisit the priority issue in the Decision, and we continue to do so now that the trial has ended.

IV. CONCLUSION

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

Outcome of Decision on Rehearing:

Claims	35 U.S.C. §	Reference(s)	Denied	Granted
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	
8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, 75	103	Latuda Information, Loebel	8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, 75	
1–75	103	Saji	1–75	
Overall Outcome			1–75	

Final Outcome of Final Written Decision after Rehearing:

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	

V. ORDER

Accordingly, it is

ORDERED that Patent Owner's Request for Rehearing is *denied*.

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