UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FREEDOM TO OPERATE, INC., Petitioner,
v.
COMPASS PATHFINDER LIMITED, Patent Owner.

PGR2022-00012
Patent 10,947,257 B2

PETITIONER'S REQUEST FOR REHEARING UNDER 37 C.F.R. § 42.71

I. INTRODUCTION

In response to the Decision Denying Institution of *Post Grant* Review of U.S. Patent No. 10,947,257 ("the '257 Patent"), entered June 22, 2022 (Paper 18, hereinafter "Decision" or "Dec."), and pursuant to 37 C.F.R. § 42.71(c) and (d), Freedom to Operate, Inc. ("Petitioner") hereby respectfully requests that the Patent Trial and Appeal Board ("Board") reconsider institution on the grounds that claims 1-23 are invalid pursuant to 35 U.S.C. § 101 and 112, and that claims 1-6, 8-9, 15-16, and 21 are obvious pursuant to 35 U.S.C. § 103.

II. LEGAL STANDARD

Pursuant to 37 C.F.R. § 42.71(d), a party may request rehearing of a decision by the Board whether to institute a trial. "The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." 37 C.F.R. § 42.71(d). The Board will review the previous decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be indicated if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005).

III. Summary of Argument

As issued, the '257 Patent attempted to claim a purportedly novel polymorph of crystalline psilocybin the inventors believed they had discovered in the process of scaling up the manufacture of synthetic psilocybin. Paper 2 ("Pet.") at 25. However, peer-reviewed scientific analysis (Ex. 1085) as explained by one of the authors of that research, Dr. James Kaduk (Ex. 1008), establishes that the claimed polymorph is not a single polymorph at all, but rather a mixture of two polymorphs known in the prior art. Pet. at 33; Ex. 1008 at ¶4. The Petition explained how the claims, specification and understanding of the skilled artisan all supported a claim construction that fit the inventors' belief—that the claimed "form Polymorph A" characterized by five XRPD peaks must be a single polymorphic form. Pet. at 7. In response, Patent Owner contended that the inventors of the '257 Patent defined "Polymorph A" only by the five XRPD peaks, so that it was not limited to a single polymorph as a matter of claim construction. Prelim. Resp. at 10-11. The Board erroneously adopted this argument, overlooking the separate and singular phrase "the form" in the claims and misapplying the law that allows applicants to be their own lexicographers. Dec. at 9-10. The Board should reconsider its claim construction, adopt the construction proposed by Petitioners, and institute review of all claims under 35 U.S.C. §§ 101 and 112.

The Board also erred in failing to follow its statutory mandate under 35 U.S.C. § 324 to institute proceedings if the "information presented" suggested that at least one claim is invalid. It also failed to give sufficient weight to Petitioners' experts' testimony regarding how a skilled artisan would read *Folen*, one of the more than 500 references submitted by the Patent Owner during prosecution. Pet. at 26-27. Petitioner submitted detailed testimony from a leading expert in crystallography, Dr. Sven Lidin, that a person of ordinary skill would read *Folen* to disclose the five peaks claimed as characteristic of Polymorph A. Pet. at 40. Three of the peaks identified in *Folen* are identical to the claimed peaks, and the other two are within 0.1°2θ of the claimed peaks, and Dr. Lidin concluded that a skilled artisan would interpret those peaks to be the same as those claimed to be characteristic of Polymorph A. *Id.*; Ex 1006 at ¶58-66.

Dr. Lidin's testimony is based on his lifetime of experience investigating polymorphic phenomena, including interpreting XRPD data, and his knowledge of what a person of skill would know about how to interpret XRPD data in older papers like *Folen*. *See* Pet. at 56. He provided detailed, reasoned evidence based on that experience and identified the existence of other evidence that supported his reading. Pet. at 40 (citing Ex. 1006 at ¶ 38-42, 61-66 and 71-75.). The Board erred in failing to give weight to this experience and detailed testimony as sufficient to meet the statutory institution standard. At the institution stage, Petition is not

required to come forward with every piece of evidence that supports its position. The Board should credit the clear, detailed and unequivocal testimony of a recognized expert such as Dr. Lidin, institute proceedings, and allow the fact-intensive question of obviousness to be made on a full record.

Granting rehearing is particularly important for this patent in light of the burden it could impose in blocking access to low-cost psilocybin medicines that have shown great promise in treating a wide range of unmet medical needs. The PTO has a unique and vital role in ensuring that improperly granted patents do not unjustifiably make life-saving drugs cost prohibitive for those they would benefit, or unduly delay the availability of lower-cost generic and biosimilar products. *See, e.g.*, USPTO Corrected Pet. for Panel Rehearing at 1, *ImmunoGen Inc. v. Hirshfeld*, No. 21-1939, Doc. 51 (Fed. Cir.) (In which the PTO observed its "mission" to include ensuring that "patent laws are not misused to delay getting generic, biosimilar, and more affordable versions of those drugs into the hands of Americans who need them."). Petitioners have incurred significant cost and submitted substantial evidence from world-renowned experts in crystallography that the '257 Patent discloses no innovation deserving of patent protection. Respectfully, the Board should grant Petitioner's request for rehearing and upon rehearing institute review on the first through fourth grounds identified by Petitioner. *See* Dec. at 4-5.

IV. Argument

A. The Board Erred In Construing "Polymorph A" To Permit More Than One Polymorph

The Board's interpretation of claim 1 violates several principles of claim construction. When properly applied, those principles unanimously indicate that the claim term "the form" should be interpreted to require that "Polymorph A", a term the inventors defined as having five particular XRPD peaks, be only be a single polymorphic form of crystalline psilocybin.

First, the Board's construction of claim 1 conflicts with the ordinary meaning of the term "the form", which should control absent a contrary meaning clearly, precisely, and deliberately given by the inventor and which was not accomplished here. The terms of a claim must be given the meaning they would have to a person of ordinary skill at the time of the invention. *See Innova/Pura Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). "There is a heavy presumption that a claim term carries its ordinary and customary meaning." *U.S. Bancorp v. Ret. Cap. Access Mgmt.*, 2014 Pat. App. LEXIS 9035, CBM2013-00014, Paper 34 at 6 (PTAB Aug. 22, 2014) (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (internal quotation omitted). The Decision does not address explicitly how one of ordinary skill would have understood the phrase "the form." Petitioner presented

unrebutted expert testimony that one of skill would understand a "form" to refer to only one of two or more polymorphic phases of a compound. Ex. 1006 at ¶18 (observing that the generally agreed definition of "polymorph" is "*a* solid crystalline *phase* of a given compound resulting from the possibility of at least two different arrangements of the molecules of that compound in the solid state.") (quoting Ex. 1015 at 2-4, emphasis added); *see also* Ex. 1008 at ¶5 (concurring with Dr. Lidin's opinions).

The Board, however, applied an exception to the principle that a claim term's ordinary meaning should govern, finding that the inventors of the '257 Patent defined the term "Polymorph A" only with reference to five peaks in a XRPD diffractogram. That conclusion was erroneous because the specification does not define Polymorph A in the manner required by the Federal Circuit in order for the inventor to act as lexicographer. To act as a lexicographer, the inventor must provide a clear, deliberate, and precise definition of a term in the patent specification or file history. *Laryngeal Mask Co. v Ambu A/S*, 618 F.3d 1367, 1372 (Fed. Cir. 2010) ("To be his own lexicographer, a patentee must use a 'special definition of the term [that] is clearly stated in the patent specification or file history.'") (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996)) (alteration in original); *see also Regions Fin. Corp. v. Ret. Cap. Access Mgmt.*, 2015 Pat. App. LEXIS 2507, CBM2014-00012, Paper 28 (PTAB

Mar. 23, 2015) ("If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification 'with reasonable clarity, deliberateness, and precision.'") (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). "It is not enough for a patentee to simply . . . use a word in the same manner in all embodiments, [rather] the patentee must 'clearly express an intent' to redefine the term." *Thorner v. Sony Computer Entertainment Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008). This precision is particularly important when the inventor's definition of a term conflicts with the term's ordinary meaning as understood by a person of ordinary skill. *See, e.g.*, *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364, 1368-69 (Fed. Cir. 2003) ("Although it is firmly settled that an applicant may act as a lexicographer in the specification [] the specification cannot support a definition that is contrary to the ordinary meaning of a claim term unless it communicates a deliberate and clear preference for this alternative definition.") (citing *Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 21 n.5 (Fed. Cir. 2000) and *Renishaw PLC*, 158 F.3d at 1249) (internal citation omitted).

In construing claim 1, the Board focused on the term "Polymorph A" but failed to appropriately consider the adjacent and separate claim term "the form." The Board's construction does not account for the many places in the specification

where the inventors referred to "the form Polymorph A" as a single polymorphic form of psilocybin. Whereas the Board's construction permits claim 1 to include a mixture of Polymorph A-prime and Polymorph B, the '257 Patent explicitly teaches that Polymorph A *excludes* and is distinct from Polymorph A-prime: "A peak at about 17.5, °2θ±0.1°2θ distinguishes psilocybin Polymorph A from Polymorph A-prime." Ex. 1001 at 4:43-45. If the inventors had acted as their own lexicographer, as the Board states, in light of this statement in the specification they should have stated that Polymorph A could be a mixture of Polymorph A-prime and Polymorph B, contrary to the ordinary meaning of "form" and "polymorph". Additionally, to interpret "the *form*"—i.e., a singular form— in the claims to encompass plural "forms" is inconsistent with the specification's repeated use of "forms" to mean more than one form. *See.*, *e.g.*, Ex. 1001 at 2:54-57; 3:15-17; 9:33-37. The specification also identifies Polymorph A as a unique crystalline form, not a mixture of forms. Ex. 1001 at 62:66-63:1 and Fig. 17 (showing "[a] summary of the solid forms").

The '257 Patent nowhere teaches that the inventors *intended* "Polymorph A" to include a mixture of polymorphs, contrary to the usual meaning of "polymorph" in the singular and reinforced by the words "the form". It is apparent that the inventors never realized that what they believed was a novel single polymorph form was, in fact, a combination of two polymorphs. Patent Owner does not

contend to the contrary. The use of the phrase "the form" in claim 1 confirms that the inventors intended to claim a single polymorphic phase, contrary to Patent Owner and the Board's construction of "Polymorph A."

Second, the Board's construction is inherently inconsistent for several reasons. That construction defines claim 1 in a way that requires a mixture of polymorph forms, such as Polymorph A-prime and Polymorph B, but the '257 Patent teaches that its Polymorph A *excluded* Polymorph A-prime. The Board's construction also excludes one of the specification's preferred embodiments that teaches that Polymorph A "is a *highly pure crystalline form*" of psilocybin. In effect, the Board's construction renders superfluous the claim language "in the form Polymorph A," contrary to another essential claim construction principle. Individually and collectively, the intrinsic evidence supports the conclusion that claim 1 of the '257 Patent is properly interpreted to claim a *single* crystalline form of psilocybin, i.e., Polymorph A. However, Petitioner has submitted overwhelming evidence that no such polymorph exists, and so the Board should institute trial on all claims for invalidity under 35 U.S.C. 101 and 112.

Construing claim 1 to permit a mixture of crystalline forms renders superfluous the claim language "in the form Polymorph A." "A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir.

2005). If claim 1 is construed to encompass more than one crystalline form of psilocybin, then the claim phrase "in the form Polymorph A" is devoid of meaning. That is, if the claim encompasses more than one crystalline form, then the claim language "crystalline psilocybin . . . characterized by peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2θ±0.1°2θ" has the exact same scope as if the phrase were included, "crystalline psilocybin *in the form Polymorph A* characterized by peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2θ±0.1°2θ."

Defining Polymorph A to include a mixture of forms precludes one of the specification's preferred embodiments: "In one embodiment, crystalline psilocybin Polymorph A is *a highly pure crystalline form* of Polymorph A, for example, psilocybin comprises at least 90 % by weight, such as 95 % , such as 99 % , such as 99.5 % of Polymorph A." Ex. 1001 at 6:5-8 (emphasis added). If Polymorph A includes two polymorphs, as the Board's construction requires, it would not reach the very high level of purity envisioned in the embodiment. This embodiment also illustrates that the inventors mistakenly believed they had discovered a novel psilocybin polymorph, but a mixture of forms cannot be "a . . . form of," which the embodiment requires. "A claim construction that excludes a preferred embodiment . . . is 'rarely, if ever, correct.'" *SanDisk Corp.*, 415 F.3d at 1285 (quoting *Vitronics*, 90 F.3d at 1583).

The Board's construction is also contrary to the way other courts have construed the term "the form" to mean a particular polymorph having characteristics which distinguish that polymorph from other polymorphs. *See Celgene Corp. v. Natco Pharma Ltd.*, Civil Action No. 10-5197 (SDW), 2014 U.S. Dist. LEXIS 71646, at *13-14 (D.N.J. May 27, 2014); *see also Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997) and *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1297 (Fed. Cir. 2009) ("The '507 patent indisputably describes and claims Crystal A, and not Crystal B. The '507 patent, of course, could have claimed the known Crystal B formulation which was known to the inventors because it appeared in their priority JP '199 application. The applicants chose not to claim Crystal B. Thus Crystal B compounds, most relevantly cefdinir monohydrate, fall outside the scope, literal or equivalent, of claims 1-5 of the '507 patent"); Pat. No. 9,365,538 B2 ("The term 'substantially pure' when used to describe a polymorph of a compound means a solid form of the compound that comprises that polymorph and is substantially free of other polymorphs of the compound" (4:43-47). Moreover, "polymorph" is often defined as a discrete form of a compound that, akin to the word "form" conveys a particular polymorph having distinct characteristics from other polymorphs. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1348 (Fed. Cir. 2005) ("'Polymorphs' are distinct crystalline structures containing the same molecules.").

Finally, the "objects" of the invention recited in the specification strongly support a construction of "the form Polymorph A" to require a single polymorph. The specification recites the following "objects" of the invention:

- "[T]o provide psilocybin, *of consistent polymorphic form*, for administration to human subjects." Ex. 1001 at 3:27-29.
- [T]o provide chemically pure psilocybin, *of consistent polymorphic form*, for administration to human subjects." *Id.* at 3:30-32.
- [T]o provide a method of crystallising psilocybin *in a desired polymorphic form*." *Id.* at 3:36-38.

A proper construction will allow the claims to achieve the objects of the invention. *See STX, Inc v. Brine, Inc.*, 37 F. Supp.2d 740, 766 (D. Md. 1999), *aff'd*, 211 F.3d 588 (Fed. Cir. 2000).

Individually and collectively, the Board's erroneous application of several claim construction principles support the conclusion that the Board's Decision was an abuse of discretion and that rehearing is warranted.

B. The Board Erred In Failing To Credit At The Institution Stage Petitioner's Expert Testimony Regarding How A Person Of Skill In The Art Would Understand *Folen*.

Petitioner's experts Dr. Lidin and Dr. Kaduk each offered unrebutted testimony that one of skill in the art would understand *Folen* to disclose Polymorph A-prime and Polymorph B, the components of the '257 Patent's Polymorph A. The Board discounted that expert testimony, finding that the testimony was not supported by objective evidence. Dec. at 20.

The Board's finding is contrary to its statutory mandate under 35 U.S.C. § 324 to institute proceedings if the "information presented" suggests that at least one claim is invalid. Dr. Kaduk's and Dr. Lidin's respective testimonies were based on their education and unparalleled experience in crystallography. Dr. Lidin testified that a person of skill would have interpreted the XRPD peaks of *Folen* to correspond to those claimed as characteristic of "Polymorph A." Pet. at 40 (citing Ex. 1006 at ¶ 38-42, 61-66 and 71-75). The Board acknowledges and quotes his testimony, Dec. at 20, but then discounts it as not "persuasive" because it says he does not provide "objective evidence" to support it. By this statement, it appears that the Board means copies of publications of the work by "other researchers" that he describes in his testimony. *Id.*

The Board exceeded its statutory mandate at the institution stage in failing to credit Dr. Lidin's testimony that a person of skill would read Folen as teaching the claimed "Polymorph A" peaks. His testimony was based on decades of exceptional experience in crystallography and described in detail in his Declaration. Petitioner respectfully submits that Dr. Lidin's testimony, in light of his experience and its detail, *is* "objective evidence" sufficient to carry Petitioner's burden at the institution stage. Petitioner is not required at the institution stage to demonstrate conclusively that the claims of the '257 Patent are invalid. Rather, as

the Board observed in *Sandoz Inc. v. Abbvie Biotechnology Ltd.*, 2018 Pat. App. LEXIS 5883, *18, IPR2018-00156, Paper 11 (PTAB June 5, 2018):

> The reasonable likelihood standard for instituting *inter partes* review is . . . not a *lower* standard of proof than a preponderance of the evidence, but instead asks whether the same preponderance standard is reasonably likely to be met *at a later time*. We must assess the persuasiveness of the petitioner's evidence while "recognizing that [we are] doing so without all evidence that may come out at trial." As such, we have required only a "threshold showing" of public availability in order to institute trial. *Sandoz*, Paper 11 at 12 (quoting *ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00707, Paper 12 (PTAB Aug. 26, 2015) (Crumbley, APJ, dissenting)).

In *Sandoz,* the Board relied on expert testimony based on an expert's experience to conclude a printed publication was publicly accessible and qualified as prior art. *Sandoz,* IPR2018-00156, Paper 11 at 8-13; *see also Google LLC v. Ji-Soo Lee*, 759 Fed. Appx. 992, 996-97 (Fed. Cir. 2019) (unrebutted expert testimony sufficient to demonstrate that reference taught particular limitation); *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 164 (Fed. Cir. 2021) (Board improperly gave no weight to expert testimony that relied on objective evidence).

V. CONCLUSION

Petitioner respectfully requests that its Request for Rehearing be granted and, upon rehearing, the Board find that Petitioner has demonstrated that the

challenged claims of the ‘257 Patent more likely than not are unpatentable and institute trial on all claims.

Dated: July 22, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies, that on this 22nd day of July, 2022, the foregoing PETITIONER'S REQUEST FOR REHEARING UNDER 37 C.F.R. § 42.71 is being served by electronic (e-mail) delivery to counsel of record for Petitioner as follows:

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