

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FREEDOM TO OPERATE, INC.
Petitioner

v.

COMPASS PATHFINDER LIMITED
Patent Owner

Case No. PGR2022-00018

U.S. PATENT NO. 10,954,259

PATENT OWNER'S PRELIMINARY RESPONSE

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I. INTRODUCTION

Patent Owner COMPASS Pathfinder Limited (“Patent Owner”) hereby respectfully submits this Preliminary Response pursuant to 35 U.S.C. § 323 and 37 C.F.R. § 42.207 in response to the Petition for Post-Grant Review (“PGR”) of U.S. Patent No. 10,954,259 (“’259 Patent”) filed by Freedom to Operate, Inc. (“FTO” or “Petitioner”).

Patent Owner is a world-leading mental health care company that has developed a synthesized formulation of psilocybin for the treatment of various disorders, including treatment-resistant depression. To properly formulate these treatments, Patent Owner developed methods of synthesizing and purifying psilocybin that would meet FDA’s rigorous standards for product purity. The ’259 Patent’s claims recite a crystalline structure of psilocybin identified by Patent Owner as “Polymorph A,” which is defined by peaks in its corresponding X-ray powder diffraction (“XRPD”) diffractogram, as well as pharmaceutical compositions containing “Polymorph A” and methods of treating major depressive disorder by administering a therapeutically effective amount of “Polymorph A.”

The Board should deny institution because the Petition fails to demonstrate that it is more likely than not that at least 1 of the challenged claims is unpatentable under 35 U.S.C. § 324(a). First, the Petition’s § 101 and first enablement grounds

(*see* Pet. at 33-37) are based on an erroneous construction of “crystalline Polymorph A of psilocybin” that improperly reads non-existent limitations into the claims and is inconsistent with the intrinsic evidence. The '259 Patent's claims, specification, and prosecution history, and the prosecution history of its parent—U.S. Patent No. 10,947,257 (“’257 Patent”)—consistently describe the term “Polymorph A” to refer to a crystalline form of psilocybin having certain recited X-ray powder diffraction (XRPD) peaks. Under this proper interpretation of the claimed “crystalline Polymorph A of psilocybin,” Petitioner's § 101 and first enablement grounds fail.

Second, Petitioner has failed to show that it is more likely than not that any of the challenged claims is obvious (*see* Pet. at 38-52). As an initial matter, Petitioner failed to identify its obviousness ground(s) with the particularity required by 35 U.S.C. § 322(a)(3). To the extent that aspects of Petitioner's theories of obviousness can be discerned and understood, they are legally incorrect because they are premised on a claim construction that improperly seeks to enlarge the scope of the claims to satisfy Petitioner's flawed obviousness arguments.

In doing so, Petitioner impermissibly seeks to rewrite the claims to introduce an “experimental error” range of $\pm 0.2^\circ 2\theta$, which contradicts the $\pm 0.1^\circ 2\theta$ value recited in the claims and throughout the specification. Under a correct interpretation of the claims, the cited references do not disclose the claimed XRPD peaks. In

addition, the Petition provides only conclusory allegations regarding a motivation to combine the cited references to implement the claimed invention with the recited chemical purity and provides no substantive argument or evidence for a reasonable expectation of success in achieving the claimed invention.

Third, Petitioner's second enablement ground (*see* Pet. at 52-56) fails because it is based on a misinterpretation of the law of enablement. When analyzed under the proper legal standard, the claims of the '259 Patent are enabled, including by actual examples of the claimed subject matter.

Finally, 35 U.S.C. § 322(a)(2) mandates that a Petition "may be considered only if . . . the petition identifies all real parties in interest[.]" The real parties in interest ("RPI") identified in the Petition are FTO, Ceruvia Lifesciences LLC, and B.More Inc. Petitioner has intentionally concealed other, unnamed RPIs (including the Usona Institute and Carey Turnbull, Petitioner's Founder/Director).

II. THE PETITION SHOULD BE DENIED FOR FAILING TO DEMONSTRATE A LIKELIHOOD OF SUCCESS

For the reasons below, Petitioner has failed to demonstrate that it is more likely than not that any of the claims challenged in the Petition are unpatentable. Petitioner's arguments rely on incorrect interpretations of the claims and cannot carry Petitioner's burden of showing why the patent it challenges is allegedly unpatentable *with particularity*. *See* 35 U.S.C. § 322(a)(3) (requiring PGR petitions

to identify “with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim”); 37 C.F.R. § 42.204(b)(4) (“Where the grounds for unpatentability are based on prior art, the petition must specify where each element of the claim is found in the prior art.”).

A. Claim Construction

1. “crystalline Polymorph A of psilocybin”

Petitioner’s proposed construction of “crystalline Polymorph A of psilocybin” is incorrect because it is inconsistent with the intrinsic record of the ’259 Patent. *See, e.g., Immunex Corp. v. Sanofi-Aventis U.S. LLC*, 977 F.3d 1212, 1221 (Fed. Cir. 2020) (“[W]e give the intrinsic evidence priority . . . over extrinsic evidence with which it is inconsistent[.]”) (internal citation and quotation marks omitted).

The term “crystalline Polymorph A of psilocybin” (or “Polymorph A”) in the ’259 Patent means “a crystal form of psilocybin having the X-ray powder diffraction (XRPD) peaks listed in independent claims 1, 8, and 16.” The claim language supports this construction. Independent claim 1 of the ’259 Patent recites “[a] pharmaceutical composition, comprising crystalline Polymorph A of psilocybin and a pharmaceutically acceptable excipient, wherein the Polymorph A is *characterized by* X-ray powder diffraction (XRPD) peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1,

17.5±0.1, and 19.7±0.1 °2θ[.]” (Ex. 1101, claim 1 (emphasis added).)¹ “Polymorph A” had no plain and ordinary meaning in the art as of the effective filing date of the ’259 Patent. But even if it had, the inventors’ express definition of “Polymorph A” in independent claims 1, 8, and 16 would control. *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007) (“When a patentee defines a claim term, the patentee’s definition governs, even if it is contrary to the conventional meaning of the term.”); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003) (“Because 3M expressly acted as its own lexicographer by providing a definition of [the term] in the specification, the definition in the specification controls the meaning of [the term], regardless of any potential conflict with the term’s ordinary meaning as reflected in technical dictionaries.”).

The specification also supports Patent Owner’s construction. The inventors used various terms to distinguish between different pharmaceutical formulations of crystalline psilocybin. For example, the specification defines “Polymorph A,” “Polymorph A’,” “Polymorph B,” and “Hydrate A” by reference to different sets of

¹ Independent claims 8 and 16 also recite “wherein the Polymorph A is **characterized by** X-ray powder diffraction (XRPD) peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1, and 19.7±0.1 °2θ[.]” The arguments herein about this limitation therefore apply equally to claims 8 and 16 and, by extension, all claims of the ’259 Patent.

XRPD peaks associated with each respective crystalline form. (Ex. 1101, 4:4-5:36 (Polymorph A); *id.*, 6:35-8:12 (Polymorph A'); *id.*, 11:41-12:37 (Polymorph B); *id.*, 10:7-11:7 (Hydrate A)). Nothing in the specification defines or requires any of these formulations to comprise a single “polymorph,” as argued by Petitioner, regardless of the plain and ordinary meaning of “polymorph.” *Honeywell*, 493 F.3d at 1361 (“When a patentee defines a claim term, the patentee’s definition governs, even if it is contrary to the conventional meaning of the term.”) Instead, the terms were defined by the inventors with respect to certain XRPD peaks that distinguish them. Petitioner has also acknowledged that “[t]he specification teaches that XRPD is used to characterize the crystalline form of psilocybin[,]” (Pet. at 27), consistent with Patent Owner’s construction.

The prosecution history of the parent ’257 Patent provides further support for Patent Owner’s construction of the claims of the child ’259 Patent. The prosecution history of the ’257 Patent is relevant to the interpretation of terms of not only the ’257 Patent but the ’259 Patent given that the ’259 Patent is a continuation of the ’257 Patent. *Iridescent Networks, Inc. v. AT&T Mobility, LLC*, 933 F. 3d 1345, 1350 (Fed. Cir. 2019) (“Statements made during prosecution of a parent application are relevant to construing terms in a patent resulting from a continuation application if such statements relate to the subject matter of the claims being construed.”) (citing

Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1314 (Fed. Cir. 2007); *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1070 (Fed. Cir. 2019) (“When a parent application includes statements involving ‘common subject matter’ with the terms at issue, those statements are relevant to construction of the terms in the child patent.”); *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999) (applying statements from prosecution of a parent application where subject matter was common to the continuation-in-part application); *see also Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1371 (Fed. Cir. 2014) (“[W]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.”) (quoting *Elkay Manufacturing Co. v. EBCO Manufacturing Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999)).²

During prosecution of the parent '257 Patent, the Patent Office rejected original claim 1, in the form below, under 35 U.S.C. § 112(b) as indefinite:³

31. An oral dosage form comprising:

a therapeutically effective amount of crystalline psilocybin in the form of Polymorph A, wherein the crystalline psilocybin has a chemical

² The '259 Patent claims priority to the application that issued as the '257 Patent, which, in turn, is a continuation of U.S. Patent Application No. 16/679,009. The '009 application claims priority to U.S. Patent Application No. 16/155,386, filed October 9, 2018, which is now U.S. Patent No. 10,519,175.

³ Claim 31 from Preliminary Amendment dated July 2, 2020 ultimately issued as claim 1 in the '257 Patent.

purity of greater than 97% by HPLC, and no single impurity greater than 1%; and

silicified microcrystalline cellulose.

(Ex. 2124, Preliminary Amendment dated July 2, 2020 at 2.) The Patent Office considered the claim to be indefinite because it “refer[red] to crystalline psilocybin in the form Polymorph A without any identifying characteristics (*i.e.*, x-ray diffraction pattern data)” and thus required that “one must refer to the specification to determine what is Polymorph A.” (Ex. 2133, Non-Final Rejection dated August 13, 2020 at 7.) In response, Patent Owner amended the claims to define the claimed form of crystalline psilocybin using the characteristic XRPD peaks that appear in claim 1 of the '257 Patent:

31. (Currently Amended) An oral dosage form comprising:
a therapeutically effective amount of 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, wherein the crystalline psilocybin has a chemical purity of greater than 97% by HPLC, and no single impurity greater than 1%; and

silicified microcrystalline cellulose.

(Ex. 2134, Claim Amendment and Applicant Arguments/Remarks dated November 13, 2020 at 2.) Patent Owner explained: “As amended, claim 31 specifies that Polymorph A is characterized by peaks in an XRPD diffractogram at **11.5, 12.0, 14.5, 17.5, and 19.7 °2θ ± 0.1 °2θ**.” (*Id.* at 6 (emphasis added).) Thus, Patent Owner expressly defined the claimed form of crystalline psilocybin referred to as

“Polymorph A” using the five XRPD peaks recited in claim 1 of the parent '257 Patent. *Ajinomoto Co. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1351-52 (Fed. Cir. 2019) (“A patentee must ‘be held to what he declares during the prosecution of his patent,’ because a contrary rule would undermine ‘[t]he public notice function of a patent.’”) (quoting *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003)). Accordingly, the claimed “crystalline Polymorph A of psilocybin” of the claims of the child '259 Patent should also be defined using the recited XRPD peaks.

Patent Owner's claim construction of the parent '257 Patent and child '259 Patent is further consistent with various claim construction decisions interpreting similar claim language that, as here, expressly recite XRPD peak positions. First, in *In re Armodafinil Patent Litigation*, the court was presented with a claim construction dispute relating to the following claim from U.S. Patent No. 7,132,570 reciting a “polymorphic form” with recited XRPD peaks:

1. A laevorotatory enantiomer of modafinil in a polymorphic form that produces a powder X-ray diffraction spectrum comprising intensity peaks at the interplanar spacings: 8.54, 4.27, 4.02, 3.98 (Å).⁴

In re Armodafinil Patent Litigation, MDL No. 10-md-2200-GMS, 2011 WL 9158436, at *1 (D. Del. July 25, 2011) (construing claim terms from U.S. Patent No.

⁴ Claim 1 of U.S. Patent No. 7,132,570.

7,132,570) (Ex. 2101). For this claim, the court construed the term “[a] laevorotatory enantiomer of modafinil in a polymorphic form that produces a powder X-ray diffraction spectrum comprising,” to mean “a crystal form of Armodafinil having the claimed powder X-ray diffraction features.” In doing so, the court explicitly “decline[d] to include any reference to Form 1 in [the] construction because *precise limitations are set forth in the body of the claim.*”—*i.e.*, the XRPD peaks. *Id.* at 1 n.1 (emphasis added). The same is true in the claims of the '259 Patent.

Second, in *Willowood USA, LLC. V. BASF SE*, No. IPR2018-01096, Paper 10 (P.T.A.B. Nov. 29, 2018) (Ex. 2102), the Board construed the term “crystalline form of modification IV of pyraclostrobin” to mean “a crystalline structure of pyraclostrobin having a specific X-ray diffraction pattern at 25°C showing at least three of the following reflexes: $d=6.02 \pm 0.01 \text{ \AA}$, $d=4.78 \pm 0.01 \text{ \AA}$, $d=4.01 \pm 0.01 \text{ \AA}$, $d=3.55 \pm 0.01 \text{ \AA}$, $d=3.01 \pm 0.01 \text{ \AA}$ and a heat of fusion of about 72 to 78 J/g.” *Id.* at 8. Again, consistent with the Patent Owner's construction here, the Board in *Willowood* construed the recited crystalline structure by reference to the defining characteristic of the recited XRPD peaks.

Petitioner nevertheless proposes to construe “crystalline Polymorph A of psilocybin” as “a crystalline form of a single polymorphic phase of psilocybin

defined by the patentee as Polymorph A.” (*See* Pet. at 7.) This construction improperly seeks to supplant the inventors’ express definition with a construction based on the “ordinary and customary meaning that a person of skill in the art would give to the term ‘polymorph,’” contrary to the Federal Circuit’s instruction in both *Honeywell* and *3M*. (*Id.* at 9.) Petitioner’s proposed construction is unsupported by the intrinsic record, which defines “Polymorph A” according to the XRPD peaks recited in independent claims 1, 8, and 16 and does not require Polymorph A to be a “single polymorphic phase of psilocybin.” The phrase “single polymorphic phase” appears nowhere in the claims, specification, or prosecution history, and neither does the concept of limiting Polymorph A to a “single polymorphic phase.” Even if this concept appeared in the specification, it would nevertheless be improper to redefine the term as Petitioner suggests. *See Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (“We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that.”).

Petitioner argues that its construction is supported by claim 1’s use of the definite article “the” to describe “Polymorph A” and by the specification distinguishing “Polymorph A” from other crystalline psilocybin described in the patent. (Pet. at 7-8.) But the claim’s use of “the Polymorph A” merely identifies the claimed crystalline psilocybin as “Polymorph A,” which is defined by the claim-

recited XRPD peak positions. And while the term “Polymorph A” distinguishes the claimed crystalline psilocybin from others described in the patent (such as Hydrate A), Polymorph A is not defined in the '259 Patent as a “single polymorphic phase.” Instead, Polymorph A is consistently used in the claims and specification to identify the claimed crystalline psilocybin as Polymorph A, which is defined by its characteristic XRPD peak positions.⁵

Further, Petitioner ignores the prosecution history of the '259 Patent's parent '257 Patent, which runs counter to Petitioner's proposed construction. During prosecution of the '259 Patent's parent, as noted above, Patent Owner amended the claims to define the claim-recited crystalline psilocybin by the XRPD peaks recited in the claims. The Patent Owner did not define, and the Patent Office did not understand, the claims to require a “single polymorphic phase” as Petitioner suggests.

⁵ The specification further expressly teaches how the characteristic XRPD peak positions for “Polymorph A” differentiate it from the peaks observed in “Polymorph A’”: “A peak at about 17.5, $^{\circ}2\theta \pm 0.1^{\circ}2\theta$ distinguishes psilocybin Polymorph A from Polymorph A', in which the peak is absent or substantially absent (*i.e.* has a relative intensity compared to the peak at $14.5^{\circ}2\theta \pm 0.1^{\circ}2\theta$ of less than 2%, more preferably less than 1%).” (Ex. 1101, 4:42-47.)

For the foregoing reasons, the Board should construe “crystalline Polymorph A of psilocybin” to mean “a crystal form of psilocybin having the X-ray powder diffraction (XRPD) peaks listed in independent claims 1, 8, and 16.”

2. “characterized by X-ray powder diffraction (XRPD) peaks at 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and $19.7\pm 0.1^\circ 2\theta$ ”

The Board should construe “characterized by X-ray powder diffraction (XRPD) peaks at 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and $19.7\pm 0.1^\circ 2\theta$ ” to take on its plain and ordinary meaning without further construction. Petitioner provides no justification for departing from the recited claim language. The XRPD peaks are expressly recited with a standard precision accepted within the art of “ $\pm 0.1^\circ 2\theta$ ” and do not require further construction.

Petitioner points to nothing in the intrinsic record to support deviating from the plain claim language. To the contrary, the intrinsic record supports Patent Owner's plain meaning construction. As discussed in the preceding section, the claims were amended during prosecution of the '259 Patent's parent to recite characteristic peaks with a variance of “ $\pm 0.1^\circ 2\theta$.” This amendment defined the variance, or experimental error, as “ $\pm 0.1^\circ 2\theta$.” As such, the Board should construe the claims to require peaks in an XRPD diffractogram at 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and $19.7\pm 0.1^\circ 2\theta$. *Honeywell*, 493 F.3d at 1361 (“When a patentee defines a claim term, the patentee's definition governs[.]”); *3M*, 350 F.3d

at 1374 (“Because 3M expressly acted as its own lexicographer by providing a definition of [the term] in the specification, the definition in the specification controls the meaning of [the term.]”).

The specification supports the plain meaning of XRPD peaks at “ $\pm 0.1^\circ 2\theta$.” In this regard, “ $\pm 0.1^\circ 2\theta$ ” is the only variance from the specified XRPD peak positions described or disclosed in the '259 Patent. If Patent Owner had desired broader claim scope with an experimental error exceeding “ $\pm 0.1^\circ 2\theta$,” it could have used the term “about” to modify the XRPD peak values recited in the claims. But Patent Owner did not do so, and the Board should not deviate from the claim language Patent Owner purposely chose to describe the invention. *See, e.g., U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1376 (Fed. Cir. 2007) (construing the term “between 10^{-6} and 10^{-4} ” to cover only the specified range and rejecting U.S. Philips’ argument that “one of ordinary skill in the art” would understand the range “to mean something different and less precise”).

Courts have consistently construed claims reciting XRPD peaks with a variance of “ $\pm 0.1^\circ 2\theta$ ” to include only the claim-recited variance of “ $\pm 0.1^\circ 2\theta$,” and not a broader range to account for additional “experimental error” as proposed by Petitioner. *See, e.g., Pharmacyclics LLC et al v. Fresenius Kabi USA, LLC*, No. 1:18-cv-00192-CFC-CJB, D.I. 346 at 3-4 (D. Del. Feb. 3, 2020) (Ex. 2103)

(construing claims reciting variance of $\pm 0.1^\circ 2\theta$ to cover only a variance of $\pm 0.1^\circ 2\theta$); *Forest Lab's, LLC v. Accord Healthcare Inc.*, No. 15-272-GMS, 2016 WL 6892094, at *1 n.7 (D. Del. Nov. 21, 2016) (“The XRD instrument is controlled for $2\theta \pm 0.1^\circ$.”) (Ex. 2104).

The claims' recited variance of “ $\pm 0.1^\circ 2\theta$ ” is recognized in the art as the established experimental error for XRPD peaks. The U.S. Pharmacopeia (USP), an authoritative source of industry standards for medicinal products, notes that variances in XRPD 2θ values “should typically be reproducible to ± 0.10 ” or a total variance of 0.20 degrees. (Ex. 2105 [USP], Page 2007.) Thus, the Patent Owner's use of ± 0.10 conforms to the industry standard.

Indeed, courts have regularly relied on the USP when construing claims directed to the XRPD peaks to have a variance of “ $\pm 0.1^\circ 2\theta$ ” while rejecting proposed claim constructions that seek to impermissibly expand claim scope under the guise of “normal experimental error.” For instance, in *GlaxoSmithKline Intellectual Property Management Ltd. v. Sandoz, Inc.*, No. 11-1284-RGA, 2013 WL 1163759 (D. Del. Mar. 20, 2013) (“*GSK*”) (Ex. 2106), claims reciting an XRPD peak “at around 18.9 degrees 2θ ” were construed to mean 18.9 degrees “within a range of $\pm[0].1$ degrees 2θ .” *Id.* at *2, *4. Similar to Petitioner's proposed construction in the present case, the plaintiff in *GSK* argued that the claims should

be construed to “account for the acceptable margin of error intrinsic to the XRPD measuring process” and that a margin of error of $\pm .10^\circ 2\theta$ was too restrictive. *Id.* at **2-4. The court rejected this argument, holding that the USP, in conjunction with the intrinsic record, “strongly suggests that an XRPD margin of error is no greater than $\pm .10$ degrees 2θ .” *Id.* at *2. In reaching this conclusion, the court found the USP to be an authoritative scientific treatise which set “ $\pm .10$ ” as the level of XRPD peak variance that would have been known and accepted by one of ordinary skill in the art as the experimental “margin of error.” *Id.* at *3-4. The plaintiff in *GSK*, like Petitioner, “was unable to cite a single technical treatise or publication indicating an XRPD margin of error greater than $\pm .10$ degrees.” *Id.* at *4; *see also Abbott Lab'ys v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 772-73 (N.D. Ill. 2007) (relying on USP to apply a variance of ± 0.1 degrees).

Petitioner relies on *Astrazeneca AB v. Reddy's Laboratories, Inc.*, No. 11-2317, 2013 U.S. Dist. LEXIS 62149 (D.N.J. May 1, 2013) (Ex. 1132) and *Astrazeneca AB v. Andrx Labs, LLC*, No. 14-8030 (MLC)(DEA), 2017 U.S. Dist. LEXIS 3990 (D.N.J. Jan. 11. 2017) (Ex. 2107), as allegedly supporting its argument that the claims in the '259 Patent should be construed to “allow[] for experimental error and variation that would be expected by a person of ordinary skill” in the art. (Pet. at 10-12.) But these cases do not support such a construction of the terms

within the '259 Patent. As discussed above, the USP and cases that rely on the USP use the claim-recited " $\pm 0.1^\circ 2\theta$ " as the *industry standard* for normal experimental error in XRPD peaks, and therefore the claims of the '259 Patent already recite the experimental error that a person of ordinary skill in the art would expect to apply. Moreover, the *Astrazeneca* cases are factually distinct from the instant dispute because the claims at issue in those cases referred to either an XRPD pattern from a figure or a listing of peaks, neither of which expressly recited a specific variance. Nor did the intrinsic evidence describe a specific variance due to experimental error in either of the cases. In contrast, independent claims 1, 8, and 16 recite a variance of $\pm 0.1^\circ 2\theta$, as does the specification. (*See, e.g.*, Ex. 1101, claim 1, 4:5-13.)

For the foregoing reasons, the Board should construe "characterized by X-ray powder diffraction (XRPD) peaks at 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and $19.7\pm 0.1^\circ 2\theta$ " to have its plain and ordinary meaning without further construction.

B. The Board Should Deny Institution of Petitioner's § 101 and First Enablement Grounds

Petitioner's § 101 and first enablement grounds fail because they are premised on an incorrect interpretation of "crystalline Polymorph A of psilocybin." Specifically, Petitioner argues that the claims of the '259 Patent are (1) invalid under 35 U.S.C. § 101 because they are directed to an inoperative invention and (2) invalid for lack of enablement because they claim an invention that is "impossible to

practice.” (Pet. at 37.) These grounds are based on Petitioner’s argument that “[t]he ’259 Patent claims a *single* polymorphic form of psilocybin characterized by an XRPD diffractogram with five particular peaks[.]” (*Id.* (emphasis added).) Petitioner argues that no such polymorph exists, because the five XRPD peaks recited in the claims (*i.e.*, 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and 19.7 ± 0.1 °2 θ) derive from a *mixture* of polymorphic forms of psilocybin. (Pet. at 34, 37.) The presence of a mixture of polymorphic forms only matters, however, if the Board adopts Petitioner’s flawed claim construction for “crystalline Polymorph A of psilocybin,” under which Polymorph A would need to be a “single polymorphic phase.” As discussed in Section II.A.1, the Board should reject Petitioner’s proposed construction for “crystalline Polymorph A of psilocybin” and, in turn, deny institution on its § 101 and first enablement grounds.

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (alteration in original) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). The ’259 Patent includes extensive teachings as well as specific examples regarding how to make and use the recited crystalline Polymorph A with the claim-recited XRPD peaks and chemical purity. *See In re Wands*, 858 F.2d 731,

737 (1988) (“Factors to be considered in determining whether a disclosure would require undue experimentation . . . include [] the presence or absence of working examples[.]”).

Example 1 of the '259 Patent exemplifies the production of Polymorph A at about a 100-gram scale. (Ex. 1101, 31:40-35:32.) The XRPD pattern of the Polymorph A provided by the process of Example 1 is shown in Figure 7a and includes peaks at 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and 19.7 ± 0.1 °2 θ . The chemical purity of Polymorph A from Example 1 was determined to be 99.3%. (*Id.*, 32:28-29.) Accordingly, Example 1 of the '259 Patent teaches a method for obtaining the claimed “Polymorph A [that] is characterized by X-ray powder diffraction (XRPD) peaks at 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and 19.7 ± 0.1 °2 θ , wherein the psilocybin has a chemical purity of greater than 97% and no single impurity greater than 1% as determined by HPLC analysis.” (No impurity could be greater than 1%, given the 99.3% purity.)

The '259 Patent discloses how to make the claimed pharmaceutical compositions by combining the crystalline psilocybin with a pharmaceutically acceptable excipient. (Ex. 1101, 19:28-20:30, 66:45-69:20.) The '259 Patent also teaches how to use the pharmaceutical compositions by administering them to patients to treat central nervous system disorders, including major depressive

disorder. (*Id.*, 21:25-22:15.) Because the ’259 Patent teaches how to make and use the claimed inventions, the enablement requirement under § 112 is satisfied.

Because the claimed inventions are useful for treating, *e.g.*, major depressive disorder, they meet the utility requirement of § 101 and are not “inoperative,” as argued by Petitioner. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (“The threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.”).

For these reasons, the Board should deny institution based on Petitioner’s § 101 and first enablement grounds, because the Petitioner has no likelihood of succeeding on them.

C. The Board Should Deny Institution of Petitioner’s Obviousness Grounds

1. The Obviousness Grounds Are Not Identified in the Petition with the Required Particularity

Petitioner has the burden to show *with particularity* why the patent it challenges is unpatentable as obvious. *See* 35 U.S.C. § 322(a)(3) (requiring PGR petitions to identify “with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim”); *Philip Morris Prods., S.A. v. Rai Strategic Holdings, Inc.*, No. PGR2020-00071, 2022 WL 129099, at *4 (P.T.A.B. Jan. 10, 2022) (“In a post-grant

review, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable, and this burden of persuasion never shifts to the patent owner.”) (citing *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)) (Ex. 2108); *Schlumberger Tech. Corp. v. DynaEnergetics Europe GmbH*, No. PGR2021-00089, 2021 WL 6338268, at *1 (P.T.A.B. Dec. 14, 2021) (“[W]e deny post-grant review, for example, where a petition fails to identify ‘with particularity’ the challenges or evidence supporting them.”) (Ex. 2109). The obviousness combination(s) presented in the Petition have not come close to meeting this requirement.

The Petition first sets out its proposed obviousness combinations on pages 4 and 5:

- Claims 1-10 and 16-23 claim, *inter alia*, a single crystalline polymorph defined by the inventors as “Polymorph A.” If, however, claims 1-10 and 16-23 are construed to allow “Polymorph A” to comprise a mixture of polymorphs of psilocybin, then they are unpatentable as obvious under U.S.C. § 103 based on V.A. Folen, *X-Ray Powder Diffraction Data for Some Drugs, Excipients, and Adulterants in Illicit Samples*, 20 J. FORENSIC SCI. 348-72 (1975) (Ex. 1102) in view of D.E. Nichols, *Psychedelics*, 68 PHARMACOL. REV. 264-355 (2016) (Ex. 1103) or, alternatively, R. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment-Resistant Depression: an Open-Label Feasibility Study*, LANCET PSYCHIATRY, available at [https://doi.org/10.1016/S2215-0366\(16\)30065-7](https://doi.org/10.1016/S2215-0366(16)30065-7) (Published online May 17, 2015) (Ex. 1104), together with R.R. Griffiths, *Psilocybin Produces Substantial and Sustained Decreases in Depression*, 30 J. PSYCHOPHARMACOL. Journal of Psychopharmacology 1181 –

1197 (Ex. 1127), in view of Roy, J., *An Introduction to Pharmaceutical Sciences* (2011) (Ex. 1113), and the other prior art cited in the claim chart in Section IV.C.3 below, and the general knowledge of one of ordinary skill in the art described in the Declarations submitted herewith.

- Claims 11-12 and 16 are unpatentable as obvious under U.S.C. § 103 for the same reasons as Claims 1-10 and 16-23 above, in further view of the publicly available JHU Batch (as defined *infra*, Section IV.B.5.vi).

(Pet. at 4-5.) This litany of prior art references fails to identify any particular combination(s) of prior art references, as required under 35 U.S.C. § 322(a)(3). For example, the ground(s) appear to assert **any** combination of **any** of the references “cited in the claim chart in Section IV.C.3” with **any** of the other references listed above and elsewhere in the Petition, including at least 11 different references (“Folen,” “Carhart-Harris,” “Nichols,” “Griffiths,” “Roy,” “JHU Sample,” “Techceuticals,” “ICH Guidance,” “USP Standards,” “Triclinic’s report,” and “Martin’s reports”). (See Pet. at 39, 42-52.) Later in the Petition, Petitioner states:

As set forth in the claim chart below, if claims 1-12, 15, and 16-23 of the ‘259 Patent are not considered invalid under Section 101 and 112, they are rendered obvious by Folen (Ex. 1102) and/or the JHU Sample, in view of Nichols (Ex. 1103), or alternatively Carhart-Harris (Ex. 1104), together with Roy (Ex. 1113), Martin’s (Ex. 1166) and/or Techceuticals (Ex. 1178), and ICH Guidance (Ex. 1164) and/or USP Standards (Ex. 1170).

(Pet. at 38-39.)

This recitation is ambiguous as to whether the asserted combination(s) is based on Folen and JHU Sample as a combination, Folen alone, JHU alone, or some combination of Folen, JHU Sample, and other references such as Nichols. Similarly, it is unclear whether the Folen/JHU Sample/Nichols alternative combination is intended to be a standalone combination, with another combination beginning with Carhart-Harris as a primary reference, or whether Carhart-Harris is yet another reference to be included in the Folen/JHU Sample/Nichols alternative combination. Likewise, it is unclear whether Carhart-Harris is to be combined with one or more of Roy, Martin's, and/or Techceuticals or whether Techceuticals must also be combined with ICH Guidance and/or USP Standards. Similarly, it is unclear whether Roy and Martin's may be replaced by Techceuticals and ICH Guidance or whether Techceuticals and ICH Guidance are being asserted solely as an alternative for Martin's. Numerous other permutations are also possible, and it is unclear which of them Petitioner is asserting. Thus, even though the chart on pages 42-52 of the Petition purports to identify prior art disclosures associated with the various claim limitations, it is unclear from the Petition what particular *combinations* of the references (both those referenced in the chart and those referenced elsewhere in the Petition) are being combined for obviousness purposes.

Because it is impossible to discern which obviousness combinations are at issue in the Petition, the Petition should be denied for failure to comply with the statutory requirement of 35 U.S.C. § 322(a)(3). *Agarwal v. Jhunjhunwala*, No. PGR2021-00071, 2021 WL 4812937, at *2 (P.T.A.B. Sept. 17, 2021) (denying institution because “[t]he exact grounds and support relied on by Petitioner are neither clear nor set out with particularity” and “[t]he Petition includes many contradictions between various statements as to the grounds that are individually ambiguous themselves”) (Ex. 2110); *see also id.* at *7 (“[W]e are unable to reasonably determine exactly what grounds Petitioner is asserting. For the prior art grounds, this includes what references are relied on, and in what combinations, as well as how these references (or combinations) are to be mapped to the claims.”).

2. The Cited References Fail to Teach or Suggest XRPD Peaks at “ 17.5 ± 0.1 ” and “ 19.7 ± 0.1 ” °2 θ .

If the Board determines that Petitioner has presented some identifiable obviousness combination(s), Petitioner's obviousness arguments nevertheless fail as a matter of law. No combination of the cited references discloses the claim-recited XRPD peaks of “ 11.5 ± 0.1 , 12.0 ± 0.1 , 14.5 ± 0.1 , 17.5 ± 0.1 , and 19.7 ± 0.1 °2 θ .” A claim is unpatentable under § 103 if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quotations omitted). To establish that a claim is obvious, the cited prior art must disclose all challenged claim limitations. *Ferring B.V. v. Watson Lab’ys, Inc.-Fla.*, 764 F.3d 1401, 1407 (Fed. Cir. 2014).

Petitioner relies on Folen (Ex. 1102), as interpreted in the Lidin Declaration (Ex. 1106), as allegedly disclosing the XRPD peaks recited in the claims of the ’259 Patent. (Pet. at 39.) This is incorrect. Folen does *not* disclose XRPD peaks at 17.5 and 19.7°2θ “± **0.1°2θ**.” To the contrary, and as Petitioner acknowledges, Folen discloses XRPD peaks of 17.7 and 19.5 °2θ. (Pet. at 39 (“As further explained in the Lidin Declaration, Folen’s peaks convert to 11.5, 12.0, 14.5, **17.7 and 19.5°2θ**.”) (emphasis added); Ex. 1106 ¶ 65 (“As seen above, Folen’s peaks convert to 11.5, 12.0, 14.5, **17.7 and 19.5°2θ**.”) (emphasis added).) As such, Folen does not disclose the XRPD peaks recited in the claims of the ’259 Patent. Indeed, Petitioner admits this in their Petition: “The second two peaks are within ±0.2°2θ.” (Pet. at 39 (emphasis added).) However, the ’259 Patent’s claims require that the XRPD peaks be within ±0.1°2θ of the recited peak position, which Folen does not satisfy.

Petitioner attempts to explain away this discrepancy by arguing that Folen “used older equipment and manual methods of assigning d-values, which might create some variability in measuring exact peak locations.” (Pet. at 39.) However,

Petitioner has provided absolutely no evidence to support this assertion, and Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (“The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.”).

Although it is unclear, Petitioner also seems to be relying on the “JHU Sample” material to somehow support its arguments for obviousness. (Pet. at 19-23, 46-47.) Like Folen, the JHU Sample cannot render the claimed inventions obvious because it also fails to include all the recited limitations of the claims challenged using the JHU Sample. For example, the JHU Sample does *not* contain a peak at $17.5 \pm 0.1^\circ 2\theta$. Therefore, the JHU Sample does not cure the deficiencies in Folen to arrive at the claimed inventions, and the Board should reject the grounds based on the JHU Sample.

3. Petitioner Failed to Establish Obviousness of Crystalline Psilocybin with “a Chemical Purity of Greater than 97% and No Single Impurity of Greater Than 1% as Determined by HPLC Analysis.”

Obviousness requires an “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Petitioner failed to meet its burden because it has not articulated “with particularity” a legally sufficient

rationale that would lead a skilled artisan from the prior art references to the claims of the '259 Patent, including the claim-recited crystalline psilocybin having a chemical purity of greater than 97% and no single impurity greater than 1% as determined by HPLC analysis.

Instead of making the particularized findings necessary to support its obviousness grounds, Petitioner provides unsupported and conclusory statements, such as a “POSA also would know that impurities in a drug product should be minimized[.]” (Pet. at 41.) *See KSR*, 550 U.S. at 418 (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”) (quoting *Kahn*, 441 F.3d at 988).

Petitioner has not met its burden to identify “with particularity” the evidence that supports its obviousness grounds because it has failed to: (1) identify which alleged prior art crystalline psilocybin (*e.g.*, Folen or the JHU Sample) should be purified; (2) establish why a POSA would select that particular crystalline psilocybin out of other options; (3) identify what impurities should be removed from the prior art sample in order to arrive at the claimed invention in the '259 Patent; or (4) identify a prior art method to achieve the claimed invention with the claim-recited chemical purity. Instead of providing particularized evidence, Petitioner

relies on the general guidance from USP standards, which are not specifically related to psilocybin, to assert that a “POSA also would know that impurities in a drug product should be minimized[.]” (Pet. at 41.) These conclusory statements are insufficient as a matter of law to satisfy Petitioner’s burden of proving obviousness. *In re Magnum Oil*, 829 F.3d at 1380 (“The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.”).

Similarly, Petitioner has failed to articulate a reasonable expectation of success in purifying prior art psilocybin and arriving at the limitations of the ’259 Patent’s claims, including the claim-recited XRPD peaks with a variance of $\pm 0.1^\circ 2\theta$. “[T]o have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365 (Fed. Cir. 2007) (citation omitted).

Because Petitioner’s obviousness grounds are conclusory, legally deficient, and do not teach all elements of the ’259 Patent’s claims, the Board should deny institution based on the Petition’s obviousness grounds.

D. The Board Should Deny Institution of Petitioner's Second Enablement Ground

Petitioner's second enablement ground fails because Petitioner's arguments are premised on an incorrect interpretation of the law of enablement. When the proper enablement standard is applied, the Petition has no likelihood of success with respect to this ground.

Petitioner asserts that claims 1-7 and 21-22 of the '259 Patent lack enablement because the patent allegedly "does not teach how to analyze the claimed pharmaceutical composition to determine whether the claimed characteristics of Polymorph A or its purity limitations are present." (Pet. at 53.) Whether a claim is enabled has nothing to do with whether a particular claim element may be "analyzed" or have its presence "determined" as Petitioner alleges.⁶ Instead, "[t]o be enabling, the specification of a patent must teach those skilled in the art *how to make and use* the full scope of the claimed invention without 'undue experimentation.'" *Genentech*, 108 F.3d at 1365 (emphasis added) (citation omitted).

⁶ To support its enablement position, Petitioner cites *Ferring B.V. V. Watson Labs, Inc.* 764 F.3d 1382, 1388 (Fed. Cir. 2014), though it is not clear why. The opinion provides no analysis of the enablement requirement (the word "enablement" does not even appear in the opinion). Instead, Petitioner quotes the legal standard the *Ferring* court applied when analyzing whether a patentee has proven infringement by an ANDA filing, which has no bearing on enablement analysis. (See Pet. at 52-53.)

Claim 1 of the '259 Patent is directed to pharmaceutical compositions containing "crystalline Polymorph A of psilocybin" and a pharmaceutically acceptable excipient, where the crystalline psilocybin has a chemical purity of greater than 97% and no single impurity greater than 1% as determined by HPLC analysis. Dependent claims further recite, among other things, characteristics of the crystalline psilocybin (claim 4). Similarly, claim 16 recites a method for treating major depressive disorder by administering a therapeutically effective amount of crystalline Polymorph A of psilocybin having the same purity and XRPD-peak characteristics recited in claim 1. Claim 16's dependent claims further recite, among other things, that the claimed crystalline psilocybin may be administered in capsule (claim 21) or tablet (claim 22) forms.

The '259 Patent discloses (including actual examples) *how to make* crystalline Polymorph A with the claim-recited XRPD peaks, DSC thermogram, residual solvent content, loss on drying, and chemical purity (*e.g.*, Ex. 1101, 17:16-18:67, 32:1-32, Fig. 7a, Fig. 8a) and *how to make* the claimed pharmaceutical compositions by combining the crystalline psilocybin with a pharmaceutically acceptable excipient, such as SMCC (*id.*, 19:28-20:30, 66:45-69:20). The '259 Patent further teaches *how to use* the pharmaceutical composition by administering it to patients to treat central nervous system disorders, including major depressive

disorder (*id.*, 21:25-22:13). For instance, the '259 Patent teaches that a preferred pharmaceutical formulation is an oral dosage form that “may be a tablet or a capsule.” (*Id.*, 21:1-3.) Thus, the '259 Patent teaches how to *make and use* the inventions claimed in claims 1-7 and 21-22 and, as such, Petitioner has no likelihood of success on its second enablement ground.

III. THE PETITION SHOULD BE DENIED FOR FAILING TO IDENTIFY ALL REAL PARTIES-IN-INTEREST

The Petition fails to identify all RPIs and, as a result, the Petition should not be instituted. Under 35 U.S.C. § 322(a)(2), a petition for post-grant review can only be considered by the Board if the petitioner identifies *all* real parties-in-interest. *See Worlds Inc. v. Bungie, Inc.*, 903 F.3d 1237, 1240 (Fed. Cir. 2018) (“Correctly identifying all real parties in interest with respect to each IPR petition is important, as the determination may impact whether a petition may be instituted.”).⁷ A petitioner bears the burden of persuasion to demonstrate that it has identified all of the real parties in interest and that burden never shifts to the patent owner. *See id.* at 1242-44.

⁷ The requirement to identify all RPIs is worded identically in the IPR (35 U.S.C. § 312(a)(2)) and PGR (35 U.S.C. § 322(a)(2)) statutes, and the Board uses the same description of an RPI for both IPRs and PGRs (*see Patent Trial and Appeal Board Consolidated Trial Practice Guide* (Nov. 2019) at 12-18). Hence the RPI standards and requirements in the context of IPRs also apply to PGRs, including the present Petition.

The Federal Circuit has recognized that “Congress intended that the term ‘real party in interest’ have its expansive common-law meaning.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018); *see also RPX Corp. v. Applications in Internet Time, LLC*, No. IPR2015-01750, Paper 128 at 2 (P.T.A.B. October 2, 2020) (precedential) (Ex. 2112).⁸ As such, “[d]etermining whether a non-party is a ‘real party in interest’ demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward **determining whether the non-party is a clear beneficiary that has a preexisting, established relationship with the petitioner.**” *Applications in Internet Time*, 897 F.3d at 1351 (emphasis added). The purpose of this inquiry is to: “(1) ensur[e] that third parties who have sufficiently close relationships with IPR petitioners are bound by the outcome of instituted IPRs in final written decisions under 35 U.S.C. § 315(e), the IPR estoppel provision; and (2) safeguard[] patent owners from having to defend their patents against belated administrative attacks by related parties via 35 U.S.C. § 315(b).” *RPX Corp.*, IPR2015-01750, Paper 128 at 2 (Ex. 2112).

While there is no bright line test, the Board has set forth factors to be considered in determining whether an unnamed party is a real party in interest, including: (1) the petitioner’s business model, (2) the petitioner’s explanation of its

⁸ *See supra*, n.7.

own interest in the IPR, (3) whether the petitioner takes the unnamed party's interests into account when determining whether to file the IPR petition, (4) the unnamed party's relationship with petitioner, (5) the unnamed party's interest in and benefit from the IPR, (6) whether the petitioner can be said to be representing that interest, (7) whether the unnamed party actually desired review of the challenged patent, (8) the relevance of any overlap in board members between the petitioner and the unnamed party, and (9) evidence of communications between the petitioner and the unnamed party. *Volkswagen Group of America, Inc. v. Arigna Technology Ltd.*, No. IPR2021-01263, Paper 16 at 5-7 (P.T.A.B. Jan. 21, 2022) (citing *RPX Corp.*, IPR2015-01750, Paper 128 at 10–11).⁹

Here, the Board's factors demonstrate that Petitioner did not disclose the identity of all RPIs. Petitioner has provided no explanation for why clearly involved entities and individuals to the present Petition, including the Usona Institute ("Usona") and Mr. Carey Turnbull, were not identified as real parties in interest. Petitioner appears to be trying to intentionally conceal the identity of other RPIs in contravention of 35 U.S.C. § 322(a)(2) to shield unnamed RPIs from the statutory estoppel provisions of 35 U.S.C. § 325(e). "[R]equiring a petition to identify all RPIs serves 'to assist members of the Board in identifying potential conflicts, and to

⁹ See *supra*, n.7.

assure proper application of the statutory estoppel provisions.”” *Adello Biologics LLC v. Amgen Inc.*, No. PGR2019-00001, 2019 WL 1750943, at *2 (P.T.A.B. Feb. 14, 2019) (Precedential) (quoting Office Patent Trial Practice Guide (“Trial Practice Guide”), 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (Ex. 2111)).

A. Carey Turnbull is an Unnamed Real Party-In-Interest

Petitioner has failed to identify RPI Carey Turnbull in its Petition. Petitioner previously filed a petition for post-grant review against a related patent owned by Patent Owner in PGR2020-00030. In that proceeding, Patent Owner challenged the petitioners' identification of the filing attorneys as the only RPIs. (*See* Ex. 2121 at 1.) The petition was subsequently amended to identify Freedom to Operate, Inc., B.More Incorporated, and Carey Turnbull as additional RPIs. (*Id.*) Although Freedom to Operate, Inc. and B.More Incorporated—as well as Ceruvia Life Sciences LLC—were identified as RPIs in the present Petition, Mr. Turnbull and other RPIs (such as Usona) were not.

Mr. Turnbull has filed challenges to Patent Owner's psilocybin patents since he first became aware of their existence, including third-party observations in Great Britain and a petition for post-grant review in PGR2020-00030. (*See* Ex. 2117 at 2 (“I already had a patent attorney, and one day he told me, ‘Somebody just filed a patent on psilocybin.’ It was COMPASS So I thought it was worth filing some

observations to the patent prosecutor in Great Britain.”); Ex. 2113 (Petition in PGR2020-00030).) The petition in PGR2020-00030 was filed in the name of Mr. Turnbull's attorneys, Kohn & Associates PLLC, who were identified as the sole “Parties of Interest.” (Ex. 2113 at 1.) Mr. Turnbull then formed FTO based on Patent Owner's questioning of Kohn & Associates regarding the actual real in party of interest to PGR2020-00030. (Ex. 2117 at 3 (“My patent attorney had just put his own name down as filing, and now [Patent Owner] wanted to know who was paying for all this. I formed FTO right after that”))

After forming FTO, Mr. Turnbull's patent attorneys filed Amended Mandatory Notices identifying FTO, B.More Incorporated, and Carey Turnbull as the real parties-in-interest to the petition in PGR2020-00030. (Ex. 2121 at 1.) Thus, FTO was created by Mr. Turnbull as the entity through which he would challenge Patent Owner's patents. (*See* Ex. 2117 at 3 (“after [Patent Owner] hired a patent litigator, which scared me, frankly, I started a corporation [FTO] and got 501(c)(3) status”); Ex. 2125 at 4 (referencing “the observations critical of Compass's patents filed in patent offices by a nonprofit that I recently formed and funded, Freedom to Operate”).)

Mr. Turnbull is the CEO and Director of FTO. (*See* Ex. 2120 at 4; Ex. 2125 at 5.) According to Mr. Turnbull, “FTO has taken the first step in seeking to

invalidate Compass's" patents in the present PGR. (Ex. 2123.) Mr. Turnbull personally covered approximately half of the costs for the challenge, which "cost[] close to a million dollars," with the rest coming from donors. (Ex. 2126 at 3.)

FTO has been set up as a non-profit 501(c)(3) corporation. (*See* Ex. 2117 at 3.) One of FTO's stated missions is "to challenge patents that would have the effect of deterring, and potentially preventing, other individuals and organizations from engaging in research and innovation" and that in doing so FTO "enable[s] research and development of medicines" based on psilocybin. (Ex. 2120 at 5-7 ("How We are Defending and Employing Psilocybin Research and Development").) Accordingly, the challenges of Patent Owner's patents undertaken by Mr. Turnbull through FTO inure to the benefit of entities and individuals that are engaged in developing psilocybin-based drug products. These entities include not only the companies with which Mr. Turnbull is the founder and CEO—Ceruvia Lifesciences LLC and B.More Inc.—but also includes any other entity that is engaged in psilocybin drug development and has a relationship and/or collaborates with Mr. Turnbull (or any of the entities under his control). (*See* Ex. 2127 (Mr. Turnbull is founder and CEO of Ceruvia); Ex. 2128 (Mr. Turnbull is founder and CEO of B.More).)

Based on the foregoing, and upon information and belief, Mr. Turnbull is funding and controlling FTO's conduct during these proceedings and is clearly an RPI who should have been identified in the Petition.

B. The Usona Institute is an Unnamed Real-Party-In-Interest

The Petition identifies companies that were founded by Mr. Turnbull and for which Mr. Turnbull is the CEO as RPIs—Freedom to Operate, Inc. (“FTO”), Ceruvia Lifesciences LLC and B.More Inc. (Pet. at 1-2.) However, the Petition fails to identify other RPIs, including the Usona Institute (“Usona”), which is an RPI under the Board's factors set forth in *RPX Corp.*, IPR2015-01750, Paper 128 at 10–11.

Usona has a long-established relationship with Petitioner with respect to challenging the validity of Patent Owner's patents directed to crystalline psilocybin. Mr. Turnbull is a Board member of Usona together with Usona's co-founder, Executive Director, and President of the Board of Directors Mr. Bill Linton. (Ex. 2129 at 1-3.) Indeed, Mr. Linton has been identified as a key donor to FTO's present Petition, without which the Petitions “would not have been possible.” (Ex. 2126 at 3 (“Turnbull footed around half of the bill for the research that underpins the challenge The rest came from *donors like Bill Linton*[.]”) (emphasis added); Ex. 2115 at 3-4 (FTO's PGR Petition Filing Milestone: “we owe a debt to the vision,

patience, and generosity of Bill Linton . . . and others without whose gifts . . . this important work would not have been possible.”.)

In addition to Mr. Turnbull's membership on the Board of Usona and Usona's founder and president providing funding for the filing of the present Petition, Usona is also an active collaboration partner with Mr. Turnbull's commercial entities and identified RPIs Ceruvia Lifesciences and B.More. (*See, e.g.*, Ex. 2127 at 7 (Ceruvia's "Meet Our Collaborators and Partnerships" page identifying Usona Institute); Ex. 2128 at 5 (B.More's "Partners and Collaborators" page identifying Usona Institute.) Ceruvia and B.More state on their websites that "Usona has manufactured pharmaceutical-grade psilocybin and is currently conducting the necessary comprehensive pre-clinical toxicology work for prescription medication, enabling Ceruvia Lifesciences' FDA clinical trials." (Ex. 2127 at 7; Ex. 2128 at 5.) The RPIs' deep relationship with Usona is further evidenced on B.More's website: "Our research, *along with Usona* and clinical trials at NYU, aims to support the FDA approval of psilocybin as a prescription medication." (Ex. 2130 at 24. (emphasis added))

Indeed, based on his deep relationship with Usona, Mr. Turnbull has relied on Usona's direct participation in filing challenges to Patent Owner's patents, including the present Petition. In this regard, employees of Usona have a long history of

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directly participating in patent challenges of Patent Owner's patents. First, in 2020, PGR2020-00030 was filed under the direction of Mr. Turnbull, as mentioned above, against Patent Owner's U.S. Patent No. 10,519,175, which is in the same patent family as the '259 Patent for which review is currently being sought. (Ex. 2113.) In that previous filing, Petitioner submitted and relied on a declaration from Dr. Alex Sherwood and Dr. Poncho Meisenheimer, who both work for Usona. (*See* Ex. 2114; *see also* Ex. 1185 at 1 of 20.) Dr. Sherwood previously testified that he is a "Medicinal Chemist for Usona Institute," and both he and Dr. Meisenheimer are identified as presently working for Usona Institute. (*See* Ex. 2114; Ex. 1185 at 1 of 20.)

Second, Dr. Sherwood and Dr. Meisenheimer have been identified by Petitioner as "research collaborators" and that these individuals "worked on this project and are named in the filings and publications" upon which the present Petition relies. (*See* Ex. 2115 at 4 ("FTO founder and Executive Director Carey Turnbull said 'I want to thank the chemists and crystallographers who worked on this project and who are named in the filings and publications for their perseverance and hard work.'").) Petitioner goes so far as to specifically thank Usona for its contributions to the present petition: "Congratulations and *thanks to the scientists at Usona* and the consulting scientists who were able to complete this very

specialized work, and to those who supported the project financially through Freedom to Operate.” (*Id.* at 3 (emphasis added); *see also* Ex. 2116 at 3 (“FTO paired up with chemists and crystallographers . . . all to claim in the petition that the form of psilocybin that Compass’ patents rest on is not actually novel[.]”).)

Mr. Turnbull further admitted to the news media that, as part of the present Petition, “Freedom to Operate used research from chemists and crystallographers to argue in a legal filing that Compass’ form of synthetic psilocybin is not a new invention.” (Ex. 2116 at 1.) The “research from chemists” refers specifically to the research conducted by at least Dr. Sherwood and Dr. Meisenheimer, indicating the key role played by Usona in the present Petition. (*See* Ex. 1185 at 1 of 20 (identifying both Dr. Sherwood and Dr. Meisenheimer as working for the Usona Institute).)

Third, the preexisting relationship between Petitioner and Usona is further demonstrated by the fact that Petitioner obtained an advanced copy of Exhibit 1185—a pre-published version of a research article—from Usona for submission with the Petition. As Mr. Turnbull admitted with respect to the present Petition, “we filed our post-grant review literally the day before our timeline was up, and the crystallography paper [Ex. 1185] didn’t come out until four or five days later.” (Ex. 2117 at 4 (Microdose Article).) Petitioner was only able to obtain an advance copy

of Ex. 1185 prior to its publication through its preexisting relationship with Usona and the authors who were engaged in research specifically directed to generating evidence in support of Petitioner's alleged grounds for invalidity in the present Petition.

Beyond the preexisting relationship between Petitioner and Usona, the evidence further establishes that Usona is a clear beneficiary of the present Petition. Usona has submitted numerous declarations in conjunction with Petitioner's challenges to Patent Owner's patents regarding crystalline psilocybin in the United States and throughout the world. (*See* Ex. 2114, Ex. 2118.) In addition to working in conjunction with Petitioner's challenges, Usona has also filed challenges against Patent Owner's patent applications. For example, on March 9, 2022, Shahin Shams filed third-party observations against the pending claims of U.S. Patent Application No. 17/604,610, which is owned by Patent Owner. (*See* Ex. 2131 at 1 ("Filer: Shahin Shams"), 16 (same).) Evidence shows that Shahin Shams works for Usona. (Ex. 2132 at page 3, (identifying "Shahin Shams, Usona Institute," as part of a panel concerning "Psychedelics for addiction treatment: enabling access and protecting innovation and opportunity through preserving the public domain").)

Additionally, Usona's research paper submitted as Ex. 1185 expressly challenges Patent Owner's '259 Patent by alleging that "revision is recommended

on characterizations in recently granted patents that include descriptions of crystalline psilocybin inappropriately reported as a single-phase ‘isostructural variant.’” (Ex. 1185 at 1 (Abstract).) Furthermore, Usona is pursuing FDA approval for its own clinical uses of psilocybin in direct competition with Patent Owner, and would clearly benefit from the invalidity challenges of the present Petition. (See Ex. 2119.) FTO itself admits that Usona is an entity that would be a direct beneficiary of institution of the current Petition with respect to its attempts to commercialize clinical treatments utilizing crystalline psilocybin. (See Ex. 2120 at 3 (Petitioner explaining that it aims to challenge patent rights that prevent entities like Usona from engaging in “research and innovation” related to psilocybin).)

Because Usona had preexisting, established relationships with other RPIs when the Petition was filed, and because it stands to benefit from institution of the Petition, it is an unnamed RPI.

C. The Persons and/or Entities who Donated to FTO are Unnamed Real Parties-In-Interest

Factors for determining whether an unnamed third party is an RPI include “whether a non-party ‘funds and directs and controls’ an IPR petition or proceeding; the non-party’s relationship with the petitioner; the non-party’s relationship to the petition itself, including the nature and/or degree of involvement in the filing; and the nature of the entity filing the petition.” *Cisco Sys., Inc. v. Hewlett Packard*

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Enters. Co., No. IPR2017-01933, 2018 WL 1364821, at *5 (P.T.A.B. Mar. 16, 2018) (citing Trial Practice Guide, 77 Fed. Reg. at 48,760) (Ex. 2122).

FTO's mission, as set forth in the Petition, is to "challenge mistakenly issued patents as an independent 501(c)(3) non-profit organization." (Pet. at 1.) To achieve its mission to undermine Patent Owner's intellectual property, FTO solicits donations via its website. (Ex. 2123.) FTO's website urges potential donors, "FTO needs your help in paying the cost of expert witnesses and patent lawyers. We anticipate *expenses directly related to our Petitions* challenging Compass's bad patents *to be at least \$500,000 or more this coming year.*" (*Id.* (emphasis added).) Although Patent Owner was able to find some public information concerning FTO's donors (*see* Ex. 2126 at 3; Ex. 2115 at 3-4), Patent Owner was not able to find a complete list of all donors to FTO.

Yet, by its own words, FTO is effectively a conduit through which unnamed third parties may fund litigation challenging patents that they deem to be inconvenient or "bad." (Ex. 2115 at 2.) These unnamed third parties are funding FTO's Petition and, depending on their identity, may directly benefit if the claims at issue are invalidated. (*Id.* at 3) *See Cisco Sys.*, IPR2017-01933, at *6 (denying institution where the petitioner acted as a "proxy" in filing the petition for an entity

not named as an RPI). Those funding FTO's Petition are RPIs who should be named and subject to the statutory estoppel provisions of 35 U.S.C. § 325(e).

Because Petitioner has failed to identify all RPIs as required by 35 U.S.C. § 322(a)(2), the Petition should be denied institution.

IV. CONCLUSION

The Board should deny institution of the Petition because (1) Petitioner has failed to demonstrate that it is more likely than not that any of the claims challenged in the Petition are unpatentable under 35 U.S.C. § 324(a) and (2) the Petition failed to name all RPIs as of the filing date of the Petition under 35 U.S.C. § 322(a)(2).

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Dated: April 11, 2022	Respectfully submitted, By: <u>/Michael Tuscan/</u> Michael Tuscan Reg. No. 43,210 <i>Counsel for Patent Owner</i> COMPASS Pathfinder Limited
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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this Preliminary Response complies with the type-volume limits of 37 C.F.R. § 42.24(b)(1). According to the word processing system used to prepare it, this Preliminary Response contains 9,661 words, excluding parts that are exempted by 37 C.F.R. § 42.24(b) and § 42.24(a)(1).

Dated: April 11, 2022

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CERTIFICATE OF SERVICE

The undersigned certifies, that on this 11th day of April, 2022, the foregoing Patent Owner's Preliminary Response is being served by electronic (e-mail) delivery to counsel of record for Petitioner as follows:

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