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Paper 25
Date: August 20, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KOHN & ASSOCIATES PLLC,
Petitioner,

v.

COMPASS PATHWAYS LIMITED,
Patent Owner.

PGR2020-00030
Patent 10,519,175 B2

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and RICHARD J. SMITH, *Administrative Patent Judges.*

HULSE, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

Kohn & Associates PLLC ("Petitioner") filed a Corrected Petition requesting a post-grant review of claims 1–21 of U.S. Patent No. 10,519,175 B2 (Ex. 2003, "the '175 patent"). Paper 13 ("Pet."). COMPASS Pathways Limited ("Patent Owner") filed a Preliminary Response. Paper 15 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 17, "Reply"), and Patent Owner filed a Sur-Reply (Paper 23).

We have authority under 35 U.S.C. § 324(a), which provides that a post-grant review may not be instituted "unless . . . the information presented in the petition . . ., if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Upon considering the arguments and evidence presented by the parties, we determine Petitioner has not demonstrated that it is more likely than not that any of the claims challenged in the Petition are unpatentable.

A. Real Parties-in-Interest

In the Petition, Petitioner identifies only itself as the real party-in-interest to this proceeding.[1] Pet. 2. Patent Owner also identifies itself as the real party-in-interest. Paper 8, 1.

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[1] In its Reply, Petitioner requests leave to file an Amended Mandatory Notice to identify Freedom to Operate, Inc. ("FTO"), B. More Incorporated, and Carey Turnbull as the real parties-in-interest. Reply 1. Petitioner also requests leave to file a motion to change the identity of the Petition to replace Kohn & Associates PLLC with FTO. *Id.* at 2. Without prior authorization, Petitioner filed an Amended Mandatory Notice identifying the additional real parties-in-interest. Paper 21, 1. Because we deny the Petition on other grounds, we need not reach these requests (or the propriety of filing

B. Related Proceedings

Petitioner identifies U.S. Application No. 16/679,009 as related to the '175 patent. Pet. 2–3.

C. The '175 Patent

The '175 patent relates to the "large-scale production of psilocybin for use in medicine." Ex. 2003, 1:6–7. According to the Specification, psilocybin is a plant-based psychedelic that has been used to treat mood disorders and alcoholic disorders, including three clinical trials for treating depressive symptoms. *Id.* at 1:26–29. The '175 patent states an object of the invention is to provide chemically pure psilocybin of consistent polymorphic form for administration to humans. *Id.* at 3:21–23.

The '175 patent describes different psilocybin embodiments, including Polymorph A, Polymorph A′, Hydrate A, and Polymorph B. Each embodiment displays different peak positions at varying relative intensities on an X-Ray Powder Diffraction ("XRPD") diffractogram. *Id.* at Table 1 (XRPD for Polymorph A), Table 2 (XRPD for Polymorph A′), Table 3 (XRPD for Hydrate A), Table 4 (XRPD for Polymorph B). For example, a peak at about 17.5°2θ ±0.1°2θ distinguishes Polymorph A from Polymorph A′, in which the peak is absent or substantially absent. *Id.* at 4:32–37; *see also id.* at 6:21–24 (stating a peak at 17.5°2θ ±0.1°2θ is absent or substantially absent in Polymorph A′). Moreover, Polymorph A′ is distinguishable from Polymorph A by the presence of a peak appearing at 10.1°2θ ±0.1°2θ. *Id.* at 7:43–46; *see also id.* at 5:14–19 (stating a peak at 10.1°2θ is absent or substantially absent in Polymorph A).

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the Amended Mandatory Notice and amending the real parties-in-interest without prior authorization).

According to the '175 patent, psilocybin is a "difficult active to formulate" because it has poor flow characteristics and is used in relatively low doses, which makes it difficult to ensure content uniformity and tableting. *Id.* at 19:44–48. Accordingly, the inventors found that in formulating psilocybin tablets, a non-standard filler—specifically a silicified microcrystalline cellulose—was preferred to achieve a satisfactory product. *Id.* at 19:56–62.

D. Illustrative Claim

Petitioner challenges claims 1–21 of the '175 patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and is reproduced below:

> 1. A method of treating drug resistant depression comprising orally administering to a subject in need thereof a therapeutically effective amount of an oral dosage form, wherein, the oral dosage form comprises:
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> 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 of greater than 1%; and
>
> silicified microcrystalline cellulose.

Ex. 2003, 69:47–58.

E. The Asserted Ground of Unpatentability

Petitioner asserts that claims 1–21 are unpatentable as obvious over Folen,[2,3] Nichols[4] or Carhart-Harris,[5] and Guo.[6]

Petitioner also relies on the Declarations of Drs. Poncho Mosenheimer and Alex Sherwood (Ex. 1008[7]), Dr. Jordan Sloshower (Ex. 1017[8]), and Dr. Charles Raison (Ex. 1018[9]).

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[2] We note Petitioner refers to its exhibits by letter. Because our rules state that Petitioner's exhibits must be uniquely numbered sequentially in the range of 1001–1999, we cite to the exhibits by their exhibit number, as filed. *See* 37 C.F.R. § 42.63(c).

[3] V.A. Folen, *X-Ray Powder Diffraction Data for Some Drugs, Excipients, and Adulterants in Illicit Samples*, 20 J. FORENSIC SCI. 348–72 (1975) ("Folen," Ex. 1001). Referred to by Petitioner as "Exhibit A."

[4] D.E. Nichols, *Psychedelics*, 68 PHARMACOL. REV. 264–355 (2016) ("Nichols," Ex. 1002). Referred to by Petitioner as "Exhibit B."

[5] R. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment-Resistant Depression: an Open-Label Feasibility Study*, LANCET PSYCHIATRY, *available at* http://dx.doi.org/10.1016/S2215-0366(16)30065-7 (published online May 17, 2016) ("Carhart-Harris," Ex. 1003). Referred to by Petitioner as "Exhibit C."

[6] M. Guo et al., *Potential Application of Silicified Microcrystalline Cellulose in Direct-Fit Formulations for Automatic Capsule-Filling Machines*, 8 PHARM. DEV. AND TECH. 47–59 (2003) ("Guo," Ex. 1004). Referred to by Petitioner as "Exhibit D."

[7] Referred to by Petitioner as "Exhibit H."

[8] Referred to by Petitioner as "Exhibit Q."

[9] Referred to by Petitioner as "Exhibit R."

II. ANALYSIS

A. Post-Grant Eligibility

We must first determine whether the '175 patent is eligible for post-grant review. Section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-20, 125 Stat. 284 (2011) ("AIA") sets forth the post-grant review provisions, which apply only to patents subject to the first-inventor-to-file provisions of the AIA. AIA § 6(f)(2)(A) (stating the provisions of Section 6(d) "shall apply only to patents described in section 3(n)(1)"). Post-grant reviews are only available for patents that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . on or after" March 16, 2013. AIA § 3(n)(1). Moreover, "[a] petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be)." 35 U.S.C. § 321(c).

Other than certifying that the '175 patent is available for post-grant review, Petitioner does not address post-grant review eligibility. *See* Pet. 2. Patent Owner, however, does not challenge eligibility in the Preliminary Response. *See generally* Prelim. Resp.

The '175 patent issued on December 31, 2019, from U.S. Application No. 16/155,386, which was filed on October 9, 2018. Ex. 2003, codes (45), (22). The '175 patent does not expressly claim priority to any earlier applications. The earliest effective filing date for the '175 patent claims is, therefore, October 9, 2018, which is after March 16, 2013. Moreover, the original Petition was filed February 21, 2020, which is within the nine-month statutory window after issuance to file a petition for post-grant review. *See* Paper 1; 35 U.S.C. § 321(c).

We, therefore, determine the '175 patent is eligible for post-grant review and the Petition was timely filed.

B. Person of Ordinary Skill in the Art

Petitioner does not address the level of ordinary skill in the art in the Petition. *See generally* Pet. Nor does Patent Owner in the Preliminary Response. *See generally* Prelim. Resp.

We note Petitioner's experts Drs. Meisenheimer and Sherwood both have a Ph.D. in organic synthesis with experience in small molecule characterization. Ex. 1008 ¶ 1. Absent further guidance from the parties, we rely on the experience of the declarants and the prior art itself as sufficient to demonstrate the relatively high level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Claim Construction

Where, as here, a Petition is filed on or after November 13, 2018, the Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 200(b) (2019); *see* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

We determine that it is unnecessary to expressly construe any claim terms for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Obviousness of the Challenged Claims

Petitioner asserts claims 1–21 of the '175 patent are unpatentable as obvious over Folen in view of Nichols or Carhart-Harris, and further in view of Guo. Pet. 3–47. Patent Owner does not address the merits of Petitioner's challenge in the Preliminary Response. *See generally* Prelim. Resp.

Nevertheless, having considered the evidence and argument presented in the Petition, we determine Petitioner has not shown it is more likely than not that any of the challenged claims are unpatentable as obvious over the cited art.

1. Folen (Ex. 1001)

Folen is an article entitled, "X-Ray Powder Diffraction Data for Some Drugs, Excipients, and Adulterants in Illicit Samples," published in the *Journal of Forensic Science*. Ex. 1001, 1. According to Folen, "[t]he development of new compounds with the potential for drug abuse necessitates a continuous accumulation of analytical data in the forensic laboratory." *Id.* Moreover, identifying excipients and adulterants in drug samples provides a database that can be used for intelligence purposes. *Id.* Accordingly, Folen states that "[t]he purpose of the present paper is to present X-ray powder diffraction data not available in the literature." *Id.*

Table 2 of Folen provides complete X-ray diffraction data and relative intensities of the peaks for 73 different compounds, including psilocybin (*id.* at 366). *Id.* at 353–69.

2. Nichols (Ex. 1002)

Nichols is a review article on psychedelics. Ex. 1002, 264. Nichols describes the use of psilocybin in several double-blind placebo-controlled phase 2 studies to treat anxiety and depression caused by cancer-related psychosocial distress. *Id.* at 266, 323.

3. Carhart-Harris (Ex. 1003)

Carhart-Harris describes an open-label feasibility trial of psilocybin to treat treatment-resistant depression. Ex. 1003, 1. The Carhart-Harris study included 12 patients with moderate-to-severe unipolar treatment-resistant major depression who received two oral doses of psilocybin. *Id.* The study found depressive symptoms were markedly reduced one week and three months after high-dose treatment. *Id.*

4. Guo (Ex. 1004)

Guo teaches that silicified microcrystalline cellulose ("SMCC") has physico-mechanical properties that may be advantageous in hard gelatin capsule formulations. Ex. 1004, 47. Guo found that products formulated with SMCC exhibited relatively high compactibility under low compression force and faster dissolution rates than those formulated with pregelatinized starch and anyhydrous lactose when loaded with 5% piroxicam, 30% acetaminophen, and 50% acetaminophen. *Id.* at 58. The higher compactibility and fast dissolution rates "suggest that SMCC could be a suitable alternative excipient for direct-fill formulations for hard shell capsules." *Id.*

5. Analysis

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* Moreover, a person of ordinary skill in the art must have had a reasonable expectation of success of doing so. *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

Although Patent Owner does not address the substance of Petitioner's challenge, after considering the arguments and evidence presented in the Petition, we find Petitioner has failed to show sufficiently that the combination of references teaches or suggests each limitation of claim 1. Specifically, claim 1 recites "peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2θ ±0.1°2θ." Ex. 2003, 69:52–53. Petitioner relies on

the teachings of Folen for the recited XRPD peaks of Polymorph A.[10] Pet. 3–4, 30–41. Petitioner provides a side-by-side comparison of the psilocybin XRPD peaks taught by Table 2 of Folen and the XRPD peak positions for Polymorph A disclosed in Table 1 of the '175 patent:

Intensity (I/I_1) [1]	d-spacing (Å) [1]	Calculated Position (°2Θ) [A]
7	14.20	6.2
33	10.00	8.8
12	8.85	10.0
41	7.74	11.4
43	7.40	11.9
11	7.08	12.5
23	6.42	13.8
100	6.13	14.4
11	5.96	14.9
11	5.52	16.0
9	5.00	17.7
5	4.73	18.7
43	4.56	19.45
27	4.38	20.3
9	4.30	20.6
11	4.24	20.9
16	4.14	21.4
22	4.02	22.1
25	3.86	23.0
20	3.81	23.3
32	3.67	24.2
20	3.46	25.7
7	3.34	26.7
11	3.21	27.8
14	3.02	29.6
4	2.77	32.3
6	2.73	32.8
3	2.67	33.6
4	2.62	34.2
4	2.58	34.8

(Positions Not determined past 35 °2Θ in US2019/0119310 A1)

TABLE 1

XRPD peak positions for Polymorph A

Position [°2Th.]	Relative Intensity [%]
5.6	8.42
11.5	13.05
12.0	26.45
14.5	100
17.5	10.71
19.7	37.29
20.4	20.06
22.2	17.83
23.2	6.99
24.3	17.93
25.7	16.4
26.8	3.15
27.8	4.54
29.7	9.53
31.2	6.51
32.6	2.45
33.7	1.75

US Patent No. 10,519,175 Table 1 found on pages 2-3 listing peak positions for claimed invention Polymorph A.
Green highlighted positions correlated to calculated values in prior art (Folen, 1975) within ±0.1 °2Θ. Yellow highlighted values correlated to calculated values in prior art within ±0.2 – 0.25 °2Θ.

[10] As Petitioner notes, Folen provides d-spacing values for the XRPD peaks, which can be converted to their corresponding degrees 2θ values using Bragg's Equation, which allows for direct comparison to the claims of the '175 patent. Pet. 31–32.

Pet. 34. Petitioner's comparison highlights in green the peaks of Folen that correspond to the peaks of Table 1 of the '175 patent within ±0.1°2θ. *Id.* Petitioner highlights in yellow the peaks of Folen that correspond to the peaks of Table 1 within ±0.2–0.25°2θ. *Id.* Thus, for the claimed peaks of 11.5, 12.0, and 14.5°2θ ±0.1°2θ, Petitioner asserts that Folen teaches corresponding peaks at 11.4, 11.9, and 14.4°2θ, which are each within the ±0.1°2θ range recited in claim 1.

For the claimed peaks at 17.5 and 19.7°2θ ±0.1°2θ, however, Petitioner admits that Folen does not teach XRPD peaks within the ±0.1°2θ range. *Id.* at 37–38. Rather, Petitioner asserts that Folen teaches peaks at 17.7 and 19.45°2θ, which are ±0.2°2θ and ±0.25°2θ of the claimed peak position, respectively. Ex. 1001, 366; *see also* Pet. 34 (converting d-spacing values to degrees 2θ).

To satisfy the claim limitations, Petitioner asserts that Folen's peaks are "equivalent" to the claimed peaks because the peaks of Folen are "within the expectations of instrumental precision as claimed in claim 1." Pet. 4, 37–38. According to Petitioner, "[i]rrespective of the attempt in [the '175 patent] to claim a narrow uncertainty of ±0.1° in measurement tolerance, USP standards reflect that even current conventions accept tolerances of ±0.2° 2θ [citing Ex. 1005] let alone the tolerances found in instrumentation of 1975." *Id.* at 30.

We are not persuaded by Petitioner's argument. Even assuming the USP standard supports Petitioner's contention that "current conventions" accept tolerances of ±0.2°2θ, Folen's peak at 19.45°2θ is outside that range

at ±0.25°2θ of the claimed peak at 19.7°2θ.[11] Thus, even assuming acceptable instrument tolerances of ±0.2°2θ, Petitioner has not shown sufficiently that a person of ordinary skill in the art would have considered a peak at 19.45°2θ (or 19.4°2θ) to be equivalent to 19.7°2θ ±0.1°2θ. Indeed, the lack of a peak at 19.7°2θ ±0.1°2θ in Folen was one of the reasons identified by the examiner in her Notice of Allowance: "The closest prior art of record, Folen, fails to teach or suggest Applicant's instantly claimed invention as the psilocybin in Folen differs by having . . . a peak at 19.4 instead of 19.7 +/- 0.1, see page 366 Table II and Bragg's law." Ex. 3001, 8.

Moreover, to the extent Petitioner relies on the "tolerances found in instrumentation of 1975" as support for its argument, Petitioner provides no objective evidence for this statement other than the conclusory testimony of its experts, who also fail to provide objective evidence. *See* Pet. 30; Ex. 1008 ¶ 2. We give little to no weight to such unsupported expert testimony and therefore do not find this argument persuasive. *See* 37 C.F.R. § 42.65(a) (stating opinion testimony that does not disclose underlying facts or data "is entitled to little or no weight"); *see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (stating a lack of objective support for expert opinion "may render the testimony of little probative value in a validity determination").

Petitioner also argues that "Polymorph A as claimed in claim 1 would have been inherent in all historical isolations using the described method." Pet. 31. According to Petitioner, the '175 patent "discloses that Polymorph

[11] We further note that when solving for 2θ using Bragg's equation where d=4.56, 2θ = 19.449. When rounded to the tenths place—as the rest of the peak positions are in Petitioner's table (*see* Pet. 34)—19.449°2θ rounds down to 19.4°2θ, which is ±0.3°2θ of the claimed peak at 19.7°2θ.

A is consistently yielded from their method of isolating the final crystalline material by recrystallization from water and drying under vacuum, and their method is a historically taught method." *Id.* at 31 (citing Ex. 1002 (Nichols), Ex. 1006 (Shirota), and Ex. 1007 (Hofman)). Petitioner again cites its experts' declaration, which parrots the language of the Petition. Ex. 1008 ¶ 2.

To establish inherency in the context of obviousness, "the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329 (Fed. Cir. 2020). To the extent Petitioner argues that Polymorph A would have been inherent in the methods taught by Nichols, Shirota, or Hofman, Petitioner fails to provide any specific evidence or argument demonstrating that the claimed peak positions would have necessarily been present, or would have been the natural result of the methods taught by the cited references. Indeed, neither Petitioner nor its experts provide specific citations to the references identifying what methods are taught by the references or any explanation of how or why those methods necessarily result in the production of Polymorph A with the peaks disclosed by Folen. *See id.*; Ex. 1002 ¶ 2. That is, Petitioner fails to explain how the methods of Nichols, Shirota, or Hofman relate to the psilocybin analyzed by Folen, which Petitioner admits was "of undisclosed origin." Pet. 31. Without knowing where the psilocybin came from or how the psilocybin in Folen was produced, it is unclear why or how the methods of Nichols, Shirota, or Hofman are relevant to Petitioner's argument. Accordingly, we are not persuaded by Petitioner's argument.

Thus, having considered the arguments and evidence presented in the Petition, we find Petitioner has failed to demonstrate that Folen (or any of

the cited references) teaches or suggests the claimed peak at 19.7°2θ ±0.1°2θ, as required by each of the challenged claims. Accordingly, we determine Petitioner has not shown that it is more likely than not that any of the challenged claims of the '175 patent are unpatentable as obvious over the cited references.

E. Remaining Arguments

Patent Owner also argues we should deny the Petition under 35 U.S.C. § 325(d) and for failure to identify all real parties-in-interest in the Petition. *See generally* Prelim. Resp. Because we determine that Petitioner has not sufficiently established that any of the challenged claims are unpatentable as obvious over the cited references, we need not address those issues in this Decision.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has failed to show it is more likely than not that any of the challenged claims of the '175 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '175 patent and no trial is instituted.

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