

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.

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 $17.5^{\circ}2\theta \pm 0.1^{\circ}2\theta$ 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 $17.5^{\circ}2\theta \pm 0.1^{\circ}2\theta$ is absent or substantially absent in Polymorph A'). Moreover, Polymorph A' is distinguishable from Polymorph A by the presence of a peak appearing at $10.1^{\circ}2\theta \pm 0.1^{\circ}2\theta$. *Id.* at 7:43–46; *see also id.* at 5:14–19 (stating a peak at $10.1^{\circ}2\theta$ is absent or substantially absent in Polymorph A).

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:

crystalline psilocybin in the form Polymorph A characterized by peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and $19.7^{\circ}2\theta \pm 0.1^{\circ}2\theta$, 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} Nichols⁴ or Carhart-Harris,⁵ and Guo.⁶

Petitioner also relies on the Declarations of Drs. Poncho Mosenheimer and Alex Sherwood (Ex. 1008⁷), Dr. Jordan Slosower (Ex. 1017⁸), and Dr. Charles Raison (Ex. 1018⁹).

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](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.”

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.