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Navigating the psychedelic patent landscape: Trends, challenges and future directions

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The resurgence of interest in psychedelics for therapeutic use has driven remarkable growth in the global psychedelic industry. This booming market reflects renewed focus on the potential of psychoactive substances to treat various mental health conditions, such as depression and post-traumatic stress disorder.

As researchers and companies navigate the complexities of patenting these powerful substances, they must understand the trends, challenges, and strategies for securing patents effectively.

This article explores the dynamics of the psychedelic patent landscape, highlights recent developments in patent filings, examines the role of the United States Patent and Trademark Office ("USPTO"), and outlines best practices that stakeholders can adopt to protect their innovations in an ever-changing regulatory and competitive environment.

A resurgence in psychedelics

The global psychedelic industry is flourishing, with analysts projecting that it will grow from $2.9 billion in 2023 to $8.7 billion by 2033.[1] This projected growth likely stems from a renewed focus on the therapeutic potential of psychedelics, which are powerful psychoactive substances that alter perception, mood, and numerous cognitive processes.

Psychedelic use predates written history, as early cultures employed them in various sociocultural and ritual contexts.

After the discovery of lysergic acid diethylamide ("LSD") and the identification of serotonin in the brain, early research intensively explored the possibility that LSD and other psychedelics had a serotonergic basis for their effects.[2] This research soon came to a halt, partly due to the enactment of the Controlled Substances Act in 1970, which classified psychedelics as Schedule I controlled substances, making research difficult.

Fast-forwarding several decades, there has been a resurgence of interest in psychedelic research and progress toward approval of psychedelics in the United States. In 2019, the U.S. Food and Drug Administration ("FDA") approved a drug derived from a psychedelic, esketamine, for use in patients with treatment-resistant depression. This marked only the second time the FDA approved a psychedelic-based drug, following ketamine's approval as a general anesthetic in 1970.

Continuing to recognize the potential benefit of psychedelic therapies, the FDA awarded breakthrough therapy designation to psilocybin for treatment resistant depression in 2018 and major depressive disorder in 2019, and to CYB003 (Cybin), a deuterated psilocybin, for major depressive disorder in 2024.[3]

MDMA (3,4-Methylenedioxymethamphetamine) received breakthrough designation in 2017, and Lykos Therapeutics filed a New Drug Application at the FDA seeking approval for post-traumatic stress disorder in adults.[4]

In 2021, the results of two landmark Phase 2 clinical trials indicated that psilocybin can effectively reduce symptoms of moderate-to-severe and treatment-resistant depression.[5] Also in 2021, the U.S. National Institute of Health began funding research into psychedelics as therapeutic agents for the first time in approximately fifty years. As researchers continue to explore these substances, we expect the development of new psychedelic therapies to accelerate.

Recent trends in the psychedelic patent landscape reveal a significant surge in patent publications in the U.S., coinciding with a renewed interest in psychedelic research. In 2021 alone, nearly 500 psychedelic-related patent applications were published globally, and as of September 30, 2024, there are currently over 1,000 published patent applications and issued patents in the U.S. related to psychedelics.

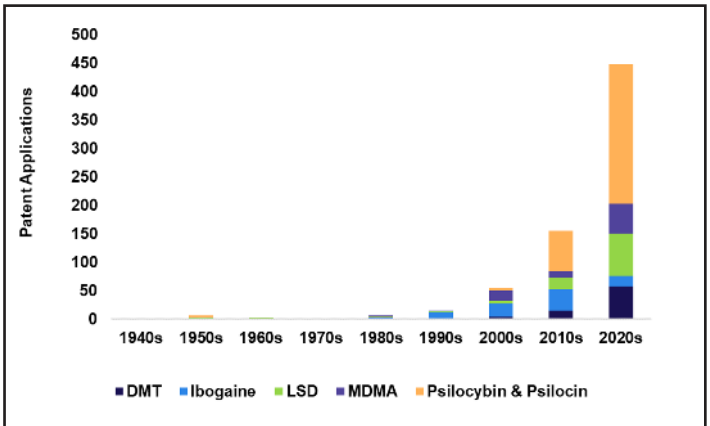

Figure 1. Number of psychedelic patent applications filed in the United States from 1940s to 2020s.

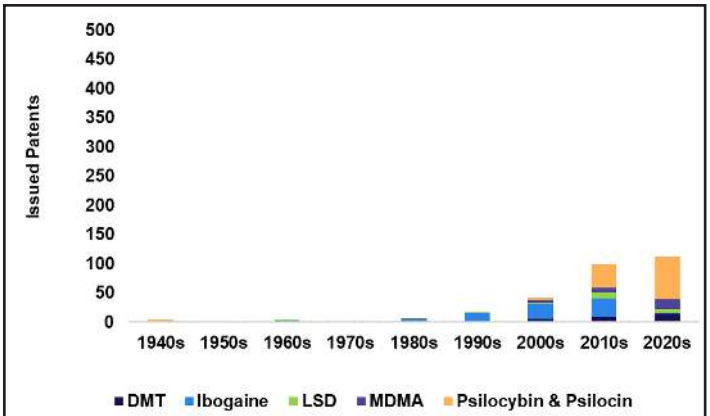

Figure 2. Number of psychedelic patents issued in the United States from 1940s to 2020s.

Companies like Compass Pathways, MindMed, and Atai Life Sciences, along with universities such as Johns Hopkins University, continue to secure patents for psychedelic-based innovations. And while patents directed to psilocybin and psilocin account for the majority of patent filings in the U.S., patent protections for other psychedelics, including dimethyltryptamine ("DMT"), ibogaine, LSD and MDMA, are being sought as well.

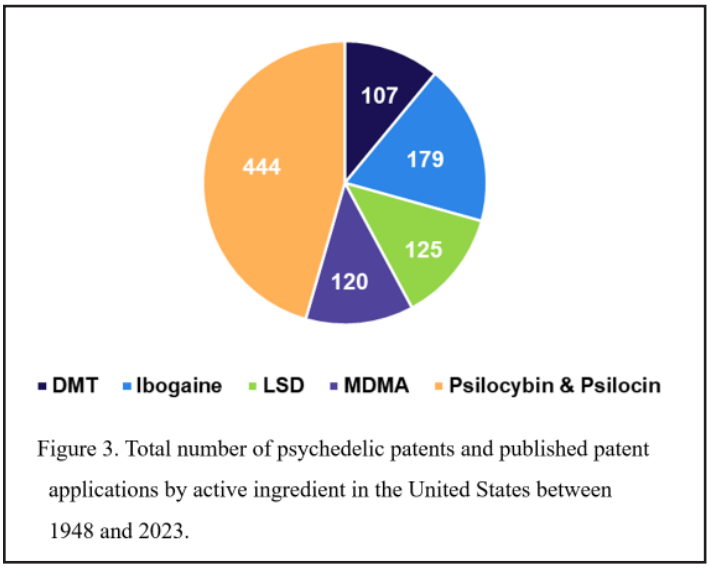

Figure 3. Total number of psychedelic patents and published patent applications by active ingredient in the United States between 1948 and 2023.

Challenges and strategies in securing psychedelic patents

The USPTO Technology Center 1600 ("TC 1600") serves as a pivotal hub for life science patent applications, covering areas such as organic compounds, organic chemistry, molecular biology, and plant sciences. TC 1600 plays a crucial role in the reemerging field of psychedelics, where innovators focus on novel compounds and their therapeutic applications.

The examination processes in TC 1600 align with broader biopharmaceutical patent practices, emphasizing rigorous scrutiny for novelty, utility, and non-obviousness, and as a result, many principles and strategies that have proven successful in traditional biopharma prosecution can guide psychedelic patent applicants.

For example, patent applicants can apply claim-drafting strategies commonly used in the biopharmaceutical space to psychedelic therapies, such as initially claiming formulations, dosage forms, delivery systems, and potential indications. As products progress through clinical trials and further investigations, second- and third-generation patents can protect new indications, specific subpopulations, and combination therapies.

The unique aspects that arise in psychedelic applications are explored below.

Subject matter eligibility: 35 U.S.C. § 101

Section 101 of the U.S. Patent Act states that a patent may be obtained for new and useful processes, machines, manufactures, and compositions of matter. The U.S. Supreme Court has held that there are certain exceptions to subject matter eligibility, including "natural phenomena," and thus, are not patentable. In the biopharma sector, many products involve naturally occurring substances or their derivatives, and psychedelics are no exception.

Patent applicants can apply claim-drafting strategies commonly used in the biopharmaceutical space to psychedelic therapies.

Many psychedelics are derived from natural products that have been used in traditional medicine for centuries.

For example, mescaline has long been used in northern Mexico and Peru, psilocybin in Central Mexico, DMT in Northeast Brazil, and ayahuasca in several countries including Brazil, Peru, Ecuador, and Colombia.[6] As a result, psychedelic patent applications often face rejections based on subject matter ineligibility under Section 101, particularly due to claims being considered "natural phenomena."

Thus, applicants must craft patent claims that avoid being categorized as patent-ineligible natural phenomena. One effective strategy to overcome this is to ensure that the composition in the claim is sufficiently distinct from its naturally occurring counterpart. This can be done by showing that the claimed composition has unique properties not found in nature.

This strategy is exemplified by one case in which a patent applicant initially claimed an aqueous or solid fraction of *Fomitopsis officinalis* mycelium, a fermented substrate thereof, or a combination, along with one or more buffering agents, ethanol, and water.[7]

After receiving a rejection based on "natural phenomena" subject matter ineligibility under § 101, the applicant was able to overcome the rejection by amending the claims to cover a specific concentration of *Fomitopsis officinalis* mycelium combined with a concentration of *Trametes versicolor* mycelium.

The applicant filed a declaration under 37 C.F.R. § 1.132, providing data to demonstrate that: (i) the two types of mycelium do not co-exist naturally, and (ii) the combination of mycelium in the

specified dose ranges exhibited significantly different characteristics compared to the individual components.

Additionally, when psychedelic compositions are used in methods or processes that involve natural substances, applicants can avoid subject matter ineligibility by specifying how the natural composition is utilized in a non-natural or novel way. By carefully drafting claims that emphasize these distinctions, applicants can strengthen their chances of obtaining psychedelic-related patents despite the challenges posed by the natural origin of these substances.

Novelty and non-obviousness: 35 U.S.C. §§ 102 and 103

Patented subject matter must be novel and not obvious. While there are a number of sources of prior art, including prior public use, due to practical constraints, USPTO examiners typically rely upon patents and printed publications when examining patent applications.

The decades-long prohibition on psychedelic substances has significantly complicated these prior art searches, as many traditional users and practitioners of psychedelics did not document their practices or methods in a way that would be easily accessible to patent examiners. This lack of formal documentation poses a challenge in establishing a lack of novelty or obviousness of psychedelic inventions.

To address this gap, one patent attorney founded Porta Sophia ("Doorway to Wisdom"), a company dedicated to building a comprehensive library of research on psychedelics.[8] This initiative has enabled the creation of a curated collection of existing research papers and historical information related to psychedelics, which can be submitted to the USPTO to assist patent examiners in assessing the novelty of psychedelic-related inventions.

Moreover, Porta Sophia provides a valuable resource for psychedelic patent applicants and practitioners, offering them an accessible platform to review the existing prior art landscape relevant to their inventions. By leveraging this resource, applicants can better navigate the complexities of prior art and ensure that their innovations are appropriately distinguished from prior discoveries.

Written description and enablement: 35 U.S.C. § 112

Psychedelic patent applications face challenges similar to those encountered in biopharma, particularly with regard to rejections based on lack of written description or enablement under 35 U.S.C. § 112(a).

However, unlike biopharma, psychedelic patent applications typically disclose less associated clinical, animal model, or even pharmacokinetic data for the claimed drug or dosage form than is seen in biopharma patent applications. This is likely attributable to the challenges associated with obtaining the necessary permission to conduct research and clinical trials with psychedelic compounds.

This absence of data and clinical evidence may further complicate the task of overcoming Section 112 rejections, as it could be difficult to demonstrate that the invention is sufficiently described or enabled without data.

In our analysis, we found that most Section 112 rejections are typically addressed through claim amendments. Given the increase in research and growing number of clinical trials for psychedelic therapies underway across North America, however, which will provide additional data to include in patent applications, we expect to see more robust data-driven arguments for overcoming Section 112 rejections and strengthening the patentability of psychedelic-based therapies.

Post-grant challenges

Even once a patent has been granted, it can be the target of post-grant challenges. Freedom to Operate, Inc., for example, filed petitions for post-grant review of two patents owned by Compass Pathways, asserting that the patented crystalline psilocybin was unpatentable because the inventions were purportedly obvious.[9]

The Patent Trial and Appeal Board declined to institute the proceeding, finding that the cited prior art did not teach all five x-ray powder diffraction peaks recited in the claims.

We expect that psychedelic-based patents may be subject to post-grant challenges in the future, especially if the industry continues to expand at its current rate.

Applicants should adopt a staggered scope in claim coverage to provide fallback positions in case of litigation or post-grant challenges. This multilayered claiming approach also creates a thicket that is difficult to navigate from a freedom-to-operate perspective. As interest in psychedelics for mental health treatment grows, stakeholders must understand how these nuances impact the patenting process.

Regulatory exclusivity

In addition to patent exclusivity, companies pursuing FDA approval for psychedelics can obtain regulatory exclusivity to protect their products.

One type of regulatory exclusivity is new chemical entity ("NCE") exclusivity, which is granted to a drug that contains no active moiety that has been approved by FDA in any other application.

NCE exclusivity lasts for five years and prevents the submission of an Abbreviated New Drug Applications ("ANDAs") for drugs containing the same active moiety until one year before the NCE exclusivity expires. Given the dearth of psychedelic drugs that have been approved by the FDA, NCE exclusivity will likely be available to most psychedelics as they are approved.

Another type of exclusivity is orphan drug exclusivity ("ODE"), which is granted to a drug that is intended to diagnose, prevent, or treat a disease or condition that affects fewer than 200,000 people.

The FDA can grant orphan drug designation ("ODD") to a drug before it is fully approved, which provides tax advantages and reduced filing fees for drugs with ODD. ODE exclusivity lasts for seven years and prevents the submission of ANDAs for drugs with the same indication.

Psychedelic-based therapies have already taken advantage of regulatory exclusivity. For instance, in addition to having its patents listed in the OrangeBook, esketamine was granted NCE status.

Ketamine was granted ODD for the treatment of Amyotrophic Lateral Sclerosis, as well as for the treatment of complex regional pain syndrome. Thus, psychedelic-based therapies will likely benefit from NCE or ODE exclusivity, which can provide further hurdles to market entry for competitor and generic companies.

Opportunities and future directions in the psychedelic patent and regulatory landscape

The psychedelic patent landscape evolves rapidly, driven by emerging trends in research and innovation. Anticipated developments in psychedelic therapies, such as new formulations and delivery methods, as well as the potential enactment of new legislation promise to expand the therapeutic potential of these substances.

Ongoing clinical trials throughout the U.S. and Canada, including those conducted by large healthcare systems like NYU Langong Health and Johns Hopkins, support this momentum (https://bit.ly/3CE1b4a).

As novel applications of psychedelic compounds for conditions like depression, anxiety, and post-traumatic stress disorder are developed, patent applicants must adopt strategic approaches to navigate the patent process effectively.

Additionally, building robust intellectual property and regulatory strategies is essential for applicants, allowing applicants to protect their innovations and capitalize on the growing market for psychedelic therapies. By proactively addressing these considerations, stakeholders can position themselves advantageously in a competitive and rapidly changing field.

Notes:

[1] Spherical Insights LLP, *Global Psychedelic Drugs Market Size to Worth USD 8.7 Billion by 2033 | CAGR of 11.61%*, Yahoo! Finance (Mar. 13, 2024), https://yhoo.it/40V73A2.

[2] D.E. Nichols & E.L. Barker, *Psychedelics*, 68 Pharmacological Rev. 264-355 (2016).

[3] Megan Brooks, *FDA Grants Psilocybin Second Breakthrough Therapy Designation for Resistant Depression*, Medscape (Nov. 25, 2019), https://wb.md/3AQ01SF; Alana Hippensteele, *FDA Breakthrough Therapy Designation Granted to Novel Psychedelic Molecule CYB003 for Major Depressive Disorder*, Pharmacy Times (March 14, 2024), https://bit.ly/3B3tdpc.

[4] *Lykos Therapeutics Announces Complete Response Letter for Midomafetamine Capsules for PTSD*, Lykos Therapeutics (Aug. 9, 2024), https://bit.ly/3V1JTEi.

[5] Robin Carhart-Harris et al., *Trial of Psilocybin Versus Escitalopram for Depression*, 384 New Eng. J. Med. 1402, 1402, 1408 (2021) (reporting that two doses of psilocybin spaced three weeks apart treated depression as effectively as six weeks of daily escitalopram, an SSRI); see also Olivia Goldhill, *Largest Psilocybin Trial Finds the Psychedelic Is Effective in Treating Serious Depression*, STAT (Nov. 9, 2021), https://bit.ly/4eGIREM.

[6] Rafael Guimarães dos Santos, *The Use of Classic Hallucinogens/Psychedelics in a Therapeutic Context: Healthcare Policy Opportunities and Challenges*, 14 Risk Mgmt. & Healthcare Pol'y 901, 902 (2021); Mason Marks & I. Glenn Cohen, *Psychedelic Therapy: A Roadmap for Wider Acceptance and Utilization*, 27 Nature Med. 1669, 1670 (2021).

[7] 17/221,437 Patent Center File History.

[8] *Porta Sophia Achieves Landmark Milestone: 50 Third-Party Interventions Filed*, Porta Sophia (July 3, 2023), https://bit.ly/48Ybc8i.

[9] *Freedom to Operate, Inc. v. Compass Pathfinder Ltd.*, No. PGR2022-00018, 2022 WL 2251062, Paper 16 (P.T.A.B. June 22, 2022); *Freedom to Operate, Inc. v. Compass Pathfinder Ltd.*, No. PGR2022-00012, 2022 WL 2251030, Paper 18 (June 22, 2022).

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