Hope on the Horizon for Psychedelic Drug Treatment?

September 29, 2025 Sharon Crane

PRACTICES Patents, Patent Prosecution and Counseling, Biotechnology

Decades of stifled research into the therapeutic effects of psychedelics followed the “War on Drugs” that was codified in the Controlled Substances Act of 1970. However, over the past two decades, there has been renewed interest in the use of psychedelics for otherwise intractable syndromes such as depression, addiction and post-traumatic stress disorder (PTSD). As a result, hundreds of psychedelic-related patent applications covering psilocybin, lysergic acid diethylamide (LSD), 3,4-methylenedioxymethamphetamine (MDMA; also known as ecstasy), dimethyltryptamine (DMT), ketamine analogs and various formulations and methods have been filed in the U.S.

Patents issuing on these compounds often face significant post-grant challenges based on lack of subject matter eligibility under 35 U.S.C. 101 as products of nature and under 35 U.S.C. 102 as lacking novelty. Potential invalidity over prior art is due in large part to the limited landscape of prior art available to examiners – much relevant prior art exists as traditional knowledge and may be completely undocumented other than being handed down in oral tradition.

However, while patents are issuing, significant barriers to approval and marketing exist. Most of these psychedelic compounds are still listed as Schedule I drugs, defined as having a high potential for abuse and no currently accepted medical use in treatment in the United States. Hence, the manufacture, distribution and possession of Schedule I substances are prohibited unless specifically permitted by law for research purposes, with the only exceptions being for research studies approved by the federal government in which registration with the Drug Enforcement Agency (DEA) is required.

The Johns Hopkins Center for Psychedelic and Consciousness Research has been a leader in the resurgence of psychedelics research, becoming the first dedicated academic psychedelic research center in 2000, with research demonstrating the positive effects of psilocybin to treat various disorders, including cigarette addiction, alcohol abuse, depression and reducing existential anxiety in people with life-threatening cancer. While this research shows promise, there needs to be regulatory change for patients to benefit from these findings.

Such change may not be far along on the horizon. The Trump administration, including Secretary of the Department of Health and Human Services (HHS), Robert F. Kennedy, Jr., seems to support psychedelic medicine**,** suggesting there could be rapid regulatory change and federal investment, especially for psilocybin and other psychedelics such as MDMA and ibogaine. Secretary Kennedy has publicly criticized prior FDA decisions on psychedelics and has prioritized reversing federal restrictions. Likewise, FDA Commissioner Martin Makary explicitly designated psychedelics (including psilocybin and ibogaine) as a “top priority” for review, citing potential for treating PTSD and other mental health conditions, especially for veterans and trauma survivors. Surgeon General nominee Casey Means has personally advocated for psilocybin therapy, describing powerful personal outcomes in her book and policy writings. Staff hires at the FDA and HHS include individuals with direct ties to the psychedelic research community.

While psilocybin is still listed as a Schedule I drug, a petition requesting the reclassification of psilocybin to the less restrictive Schedule II has recently been submitted to the DEA and forwarded

to the U.S. Department of Health and Human Services, a hopeful sign for patients seeking these life-changing treatments.