

What's Going On with Patents and Psychedelics?



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In the last few months, the topic of patents and psychedelic medicine has turned up several times in the news and social media. Let's look at why, what it means for the future of psychedelics in medicine, and what can be done about patent applications that appear to cover existing, known psychedelic treatments.

What's a patent?

First, some background. A patent is a type of intellectual property (IP) right that protects an inventor's newly created technologies – including devices, methods, and processes. Patents are different from other types of intellectual property that you may have heard of, like copyrights or trademarks or trade secrets.

A key feature is that a patent is a “negative right” – it does not entitle the owner to make, use, or sell the invention, but rather confers the right to exclude others from making, using, or selling the invention.

How do you get a patent?

Patent rights do not arise in new inventions automatically. To obtain a patent in the US, an inventor must submit a patent application describing the invention in detail to the United States Patent and Trademark Office (USPTO). The USPTO will then begin the process of patent examination, in which a bureaucrat is assigned to study the “claims” of the patent (i.e., the specific elements the inventor is claiming to have invented) and determine whether the invention meets the legal requirements for patentability. It is typically several years after filing before a patent application is picked up by a patent examiner.

One of the important requirements an invention must meet to obtain patent protection is novelty, which requires that the invention be distinct from all other inventions that came before it. In other words, you can't get patent protection on technology that is already known to the world. The body of relevant existing knowledge is known in patent lingo as "prior art." When a patent examiner searches for prior art that could invalidate a patent claim, they primarily look for other patents or patent applications describing similar subject matter. However, prior art can also include printed publications, products on sale or in public use, and any other information otherwise available to the public.

If a patent examiner finds prior art that they believe describes the technology in one or more of the applicant's claims, the application will be rejected. To overcome the rejection, the applicant usually has to come back to the patent examiner with a detailed argument or an amendment to the claims that sufficiently narrows their scope to avoid claiming the identified prior art – a back-and-forth process that can go on for years. In fact, about 20-25% of the time, applicants simply give up and never receive their patents. The rest, who still want their patent rights to be granted, often must narrow the scope of their claims.

So, if you see a patent application that seems too broad in scope, it is likely the original application which includes the broadest claims the applicant thought were reasonable. (And while patent applicants are prohibited from acting with dishonesty or deceit, they can sometimes get pretty creative with what they think is reasonable!) The result of this back-and-forth between the applicant and the examiner is that a published patent application rarely reflects the final scope of a resulting issued patent.

What is MAPS doing?

It's not the first time the topic of patents and psychedelics has come up – Rick Doblin wrote about it in the *Bulletin* in 1992.

From the start, MAPS has opted for a strategy that does not entail filing for patent protection. Instead, MAPS is adding the body of prior art in the psychedelics space by continuously publishing research findings and other information about what is already known about psychedelic medicine. This accomplishes two goals.

First, it increases the body of knowledge about psychedelics available to the public and provides patent examiners with reliable information on the state of the art. One problem in patent examination for psychedelics is that psychedelic research is difficult for examiners to find, since a substantial amount of research has operated underground or is otherwise not available in traditional published form.

Second, publishing the results of research prevents others from obtaining patents on any product or practice described in them. Generally, the more prior art that is available in any given field – and the easier it is for patent examiners to find – the more likely it is that a patent application in that field will be narrowed (or abandoned entirely). In contrast, without comprehensive information about the state of the art, examiners might issue overly broad patents that cover existing products and practices.

MAPS also relies on alternatives to patent protection when appropriate. One alternative to patent protection is what the FDA calls "data exclusivity," in which a drug treatment developer can prevent others from relying on data the developer generated when a competitor seeks approval for use of the same drug. This gives the developer a limited period of opportunity to get a head start in the market by claiming exclusive ownership in exchange for their innovation.

What's next?

As more companies appear in the psychedelic space, expect to see more patent applications. Investors and executives typically expect startups to show that they have intellectual property on their balance sheets, and companies are usually incentivized to file patent applications as early as possible. Some patent applications with broad claims on psychedelic treatments have already appeared in the news. We'll be watching closely.

Frank Gerratana is an attorney in Boston specializing in the high tech industry. He advises MAPS on a pro bono basis with respect to patents and intellectual property. He received his juris doctor (J.D.) from American University, Washington College of Law, and his bachelor of science (B.S.) in electrical and computer engineering along with a master of science (M.S.) in computer science from Worcester Polytechnic Institute. Outside of work, Frank participated in the successful effort to advocate for decriminalization of psychedelics at the municipal level in Cambridge, MA. He has also served on the board of directors of Firefly Arts Collective, the New England regional Burning Man affiliate.