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Thank you for reading the September 2022 issue of Sterne Kessler's Markt to Market® newsletter. This month, we discuss the how the growing psychedelic industry can learn from the cannabis and biopharma industries regarding intellectual property protection.

I am giving the trademarks year in review presentation during the [2022 AIPLA Annual Meeting](#)'s closing plenary session on Saturday, October 29. Please reach out to me if you'd like to connect during the event at National Harbor!

Our [Trademark & Brand Protection practice](#) here at Sterne Kessler is devoted to guiding companies of all sizes in developing and maintaining strong brands around the world. There is always something new and exciting happening in our unique IP niche, and we bring you updates each month to help you keep on top of it all. Thanks for your readership. If there is something you would like us to cover, please don't hesitate to reach out to us and let us know!

Kind Regards,

[Monica Riva Talley](#)
Editor

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IP for Psychedelics: Lessons From Biopharma

By: [Deborah Sterling, Ph.D.](#)



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IP for Psychedelics: Lessons From Biopharma

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From a quick survey of published patents and applications on the USPTO's website, psychedelic innovation touches on a wide range of disciplines, from pharmaceutical formulations and methods of treatments, to extraction and purification, genetic engineering, and agriculture. Given the biological origins and chemical properties of this class of compounds, psychedelic-related applications are examined primarily in Technology Center 1600. TC 1600 focuses on applications relating to biotechnology and organic chemistry.

Applications directed to pharmaceutical compositions and methods of treatment using psychedelics are, for the most part, being claimed in the same manner as one would expect to see in a traditional biopharma application, except that the active ingredient is a psychedelic. One notable difference, however, is the relative infrequency with which applicants appear to be disclosing associated clinical, or even pharmacokinetic, data for the claimed drug or dosage form. This may be attributable to the challenges associated with obtaining the necessary permission to conduct clinical trials using Schedule I drug substances, at least in the United States.

Given the significant overlap between claiming strategies between psychedelic applicants and biopharma applicants alike, many of the principles and strategies that have proven successful in traditional biopharma prosecution should serve as logical guideposts for psychedelic applicants. For example, claim drafting strategies commonly applied in the biopharmaceutical space translate readily to psychedelic therapies. These include initially claiming formulations, dosage forms, delivery systems, and potential indications. As products move through clinical trials and are further investigated, second- and third-generation patents protect new indications and subpopulations; combination therapies; etc. In any given claim set, applicants are also advised to obtain claim coverage that is staggered in scope to provide fallback positions in

litigation or post-grant challenges. A secondary benefit of employing a multilayered approach to claiming is that it creates a thicket that is difficult to design around or clear from a freedom to operate perspective.

In the biopharma space, many products and their corresponding claims involve a naturally occurring product or variant thereof. Psychedelics are no exception. Drafting claims so that they are not directed to a patent-ineligible natural phenomenon is important. One way to achieve this objective is by ensuring that the composition recited in the claim is markedly different from the naturally occurring counterpart. In cases where the composition used is a natural product, method, or process, claims employing the natural composition in a non-natural or specific way may also avoid the issue. Also, from an infringement perspective, method claims should be carefully drafted with divided infringement defenses in mind.

In sum, while the psychedelic patent landscape is still maturing, an initial review suggests that in the therapeutic space, it is closely tracking that of biopharma. As traditional industries that understand the value of intellectual property (biopharma and food/beverage, for example) turn their attention to psychedelics, patent issues are likely to shape the business landscape. Whether for purposes of competition or valuation (or both), protecting psychedelic-related innovation starts with creating an intellectual property strategy centered on strong, diversified protection for core technologies and potential commercial applications.

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