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The October 2021 issue of Sterne Kessler's MarkIt to Market® newsletter discusses a precedential TTAB decision regarding fraud; the DEA's proposal to increase production quotas for several schedule I controlled substances, including cannabis; and the open gTLD sunrise periods.

Sterne Kessler's <u>Trademark & Brand Protection practice</u> is designed to help meet the intellectual property needs of companies interested in developing and maintaining strong brands around the world. For more information, please contact Monica Riva Talley or Tracy-Gene G. Durkin.

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IGNORANCE IS NOT BLISS: RECKLESS DISREGARD FOR THE

TRUTH SUPPORTS A FINDING OF FRAUD

By: Shana L. Olson

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WATCHING THE POT™

DEA Calls for Increased Production Quotas for Research-Grade Cannabis and Psychedelics in 2022

By: Pauline M. Pelletier

While it may come as a surprise to some, the U.S. Drug Enforcement Administration (DEA) has called for significantly increasing the production quotas for research-grade cannabis and other psychedelic controlled substances in 2022. In a notice published in the Federal Register on October 18, 2021, the DEA has proposed increasing production quotas for several schedule I controlled substances, citing increased demand for federal research and clinical trials.¹

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In this case, counsel for Great Concepts, LLC, the owner of US Trademark Reg. No. 2929764 for the mark **DANTANNA'S** for restaurant services, signed a Combined Declaration of Use and Incontestability, making a representation that "no proceeding involving said rights pending and not disposed of in either the U.S. Patent and Trademark Office or the courts exists." See Combined Declaration of Use and Incontestability under Sections 8 & 15 filed March 8, 2010 in Reg. No. 2929764. This statement was, in fact, false, because at the time of filing the Declaration, both a Board proceeding and civil action involving the Registrant's right to register and use the mark DANTANNA'S were pending. Counsel for Great Concepts, LLC testified that he did not review the Declaration carefully enough before signing to see that the statement was incorrect. The record also demonstrated that when this falsity was brought to counsel's attention (evidently more than once), he took no action to notify the USPTO about the false statement.

The Board found that counsel's actions amounted to reckless disregard for the truth, which supported a finding of fraud upon the USPTO. This is an important precedential finding because in the fundamental fraud case *In Re Bose Corporation*, 772 F.2d 866 (Fed. Cir. 1985), the Court ruled that the intent to deceive must be "willful," and few TTAB fraud cases have been found to meet this standard. In applying case law from the Supreme Court and various other circuits, the Board in this case found that counsel's reckless behavior was, in fact, willful, and therefore the record supported the "intent to deceive" requirement to prove fraud. Ultimately, the Board granted the petition to cancel this registration on the basis of fraud.

Trademark practitioners and trademark owners should take notice of this case. Documents need to be closely read and carefully considered before they are submitted to the USPTO—both by the client and the attorney. Simply claiming that you did not read a Declaration closely enough is *not* enough to circumvent a fraud claim, and fraud may jeopardize the validity of an application or registration, as it did in this case.

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Specifically, for 2022 quotas, the agency has proposed increasing cannabis extract production to 1,000,000 grams (doubling the current quota), increasing cannabis flower production by 1,200,000 grams (yielding a total of 3,200,000 grams), increasing production of psilocybin to 3,000 grams (doubling the current quota), and increasing production of MDMA from 50 to 3,200 grams (a 6,300% increase). Additionally, the notice states: "DEA supports regulated research with schedule I controlled substances, as evidenced by increases proposed for 2022 as compared with aggregate production quotas for these substances in 2021."²

While it is not unusual for the DEA to increase production quotas for controlled substances, the agency's expression of support for regulated research and clinical trials is notable. The DEA made a similar, if not stronger, statement in September—expressing in a Federal Register notice on the same subject: "DEA firmly believes in supporting regulated research of schedule I controlled substances. Therefore, the [Aggregate Production Quota] increases reflect the need to fulfill research and development requirements in the production of new drug products, and the study of marijuana effects in particular, as necessary steps toward potential Food and Drug Administration (FDA) approval of new drug products." These statements by the DEA are consistent with a broader trend among federal authorities, including the FDA, to recognize the therapeutic potential of cannabis and psychedelics.

The DEA's October notice also recognizes the need for additional licensed cultivators and producers. Historically, DEA-registered cannabis researchers could receive supplies from just one federally-authorized marijuana grower, the University of Mississippi, under the auspices of the National Institute on Drug Abuse Drug Supply Program.⁵ Following a long-running public campaign to expand the pool of licensed growers—including lawsuits filed against the DEA by scientists and other stakeholders—DEA announced in 2019 that it would undertake a process

to act on applications for licensure to cultivate marijuana for research purposes. In May 2021, the DEA announced that it was making progress on its review, with approvals likely for a number of manufacturers who had applied. Consistent with the May update, the October notice explains that "the agency is working diligently" to review and approve applications to make marijuana for research purposes, and has "approved new applications for registration from manufacturers and corresponding quota applications to grow, synthesize, extract, and manufacture dosage forms containing specific schedule I hallucinogenic substances for clinical trial purposes."

The DEA's commitment to research involving cannabis and psychedelics signifies a major shift in the regulatory landscape. While much remains to be done, the hurdles to federal approval—particularly in the therapeutic arena—are being lowered. As this policy plays out in the months and years ahead, those operating in this fast-evolving technology space should consider the importance of intellectual property to their business objectives. Intellectual property plays a uniquely important role in regulated industries, where a period of exclusivity is crucial for recouping initial investments made to develop, test, and secure regulatory approval.⁹

[1] Department of Justice, Drug Enforcement Administration, *Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2022*, 86 Fed. Reg. 198, 57690–57699 (Oct. 18, 2021).

[2] *Id.* at 57692.

[3] Department of Justice, Drug Enforcement Administration, *Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021*, 86 Fed. Reg. 168, 49346–49354 (Sept. 2, 2021).

[4] IP Hot Topic: FDA Expedites its Efforts to Release CBD Regulations (July 31, 2019), https://www.sternekessler.com/news-insights/client-alerts/ip-hot-topic-fda-expedites-its-efforts-release-cbd-regulations.

[5] Vanessa K. Burrows, *Cannabis Considerations for Health Care Entities*, 24 J. Health Care L. & Pol'y 89, 105–06 (2021), *available at*

https://digitalcommons.law.umaryland.edu/jhclp/vol24/iss1/5/.

[6] Melissa Schiller, Federal Court Orders DEA to Explain Why It Has Ignored Cannabis Cultivation Applications, Cannabis Business Times (Aug. 6, 2019), available at https://www.cannabisbusinesstimes.com/article/federal-court-orders-dea-to-explain-why-it-has-ignored-cannabis-cultivation-applications/.

[7] DEA Continues to Prioritize Efforts to Expand Access to Marijuana for Research in the United States (May 14, 2021), https://www.dea.gov/stories/2021/2021-05/2021-05-14/dea-continues-prioritize-efforts-expand-access-marijuana-research.

[8] 86 Fed. Reg. 198, 57690-57699 at 57692.

[9] Pauline Pelletier, Deborah Sterling, Monica Riva Talley, IP's Developing Role In Cannabis Business Strategy, Law360 (June 2019), *available at* https://www.sternekessler.com/news-insights/publications/ips-developing-role-cannabis-business-strategy.

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As of October 26, 2021, ICANN lists new Sunrise periods as open for the following new gTLDs that may be of interest to our clients. A full list can be viewed here.

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ICANN maintains an up-to-date list of all open Sunrise periods <u>here</u>. This list also provides the closing dates of the Sunrise periods. We will endeavor to provide information regarding new gTLD launches via this monthly newsletter, but please refer to the list on ICANN's website for the most up-to-date information – as the list of approved/launched domains can change daily.

Because new gTLD options will be coming on the market over the next year, brand owners should review the list of new gTLDs (a full list can be found here) to identify those that are of interest.

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