IP's Developing Role In Cannabis Business Strategy

By **Pauline Pelletier, Deborah Sterling and Monica Talley** (June 11, 2019)

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Rapidly growing interest in therapies and consumer products that include cannabis-derived compounds, including cannabidiol, recently spurred the U.S. Food and Drug Administration to hold its first public hearing on cannabis regulation in May. The FDA's hearing comes in the wake of the 2018 Farm Bill, which declassified "hemp" as a controlled substance. While the contours of what is now federally legal under the Farm Bill continue to evolve, the arms race for cannabis intellectual property is already underway and is likely to intensify as the regulatory landscape matures and federally approved pathways are defined.

As one example, cannabis patent portfolios have been at the center of several acquisitions in this space, and cannabis is quickly becoming an industry where cutting-edge biotechnology, informatics and branding are driving competition and valuation.[1] Indeed, several recent legal developments have thrust cannabis intellectual property into the spotlight, all of which suggest that, properly secured, federally protected intellectual property is both available and enforceable.

Here we provide an overview of these legal developments, some takeaways from the FDA's cannabis hearing, and an assessment of how both are expected to impact the cannabis industry.

Overview of the Cannabis IP Landscape

A frequently asked question when it comes to cannabis intellectual property is whether the legal status of cannabis matters. The short answer is that it varies depending on the type of intellectual property and whether it is state or federal. Here we focus on federal intellectual property, which is typically viewed as the most commercially valuable given its national scope.

Patents

The illegal status of cannabis does not matter when it comes to patents (utility, design and plant). Courts have largely rejected the notion that inventions are unpatentable or invalid on the basis that "they are principally designed to serve immoral or illegal purposes."[2] Consistent with this, the U.S. Patent and Trademark Office has already issued hundreds of patents covering cannabis products, their derivatives, production processes and methods of use. The USPTO has done so without regard to whether making, using, or selling that subject matter would violate federal laws.[3] Thus, patents offer a legal-status-independent avenue for protecting cannabis inventions despite federal laws criminalizing possession of most cannabis products.

Two recent legal developments have reinforced the viability of cannabis patents. First, in January 2019, the USPTO upheld the patentability of several claims following an inter partes review of GW Pharmaceuticals PLC's patent relating to the drug Epidiolex, which is the first (and is still presently the only) FDA-approved cannabis-derived pharmaceutical.[4] Second, in April 2019, Judge William Martinez in the U.S. District Court for the District of Colorado

upheld UCANN's patent claims covering liquid cannabinoid formulations in a patent infringement suit.[5] The survival of these patent claims supports that cannabis inventions are patentable and enforceable in federal venues.

Trademarks

Federal trademarks are different in that the USPTO has generally refused to register trademarks on products and services that lack a "legal use" of the mark in commerce, which — at least historically — has included many cannabis-related products and services.[6] The question raised by passage of the 2018 Farm Bill, however, is whether removal of "hemp" from the Controlled Substances Act allows for trademark protection of products and services using CBD that is derived from "hemp," i.e., cannabis that contains less than 0.3% THC.

In May 2019, in response to the Farm Bill, the USPTO released new examination guidelines for marks for cannabis and cannabis-related goods and services.[7] The new guidelines explain that "cannabis plants and derivatives such as CBD that contain no more than 0.3% THC on a dry-weight basis are no longer controlled substances under the CSA" and may therefore be eligible for trademark protection.[8] For applications involving hemp cultivation or production, it states that the examining attorney will inquire into the applicant's authorization to produce hemp.

This inquiry extends to whether the product or service requires approval from some other federal agency, including the FDA. Thus, hemp-derived CBD products (for humans or animals) must be "legal" under any applicable regulatory statutes, including the Food, Drug and Cosmetic Act. As a result, a product requiring premarketing approval from the FDA may not be considered "legal" unless approved (e.g., a drug, food additive not generally recognized as safe, dietary supplement). Products that do not require FDA approval may be in a different boat.

In sum, federal trademarks are substantially intertwined with the legal status of cannabis. While this aspect of trademark protection presents some challenges, it also presents competitive advantages for those who are only aiming to market products in compliance with federal law.

Copyrights

While trademarks are generally preferred for protecting a brand, copyrights can be a stopgap for protecting logos and other marketing materials having sufficient originality and creativity to account for the exclusivity copyright protection provides. And unlike federally registered trademarks, their availability and enforceability is not contingent on the legal status of the subject matter. Copyright registration is also a substantially less costly undertaking.

Trade Secrets

The 2016 Defend Trade Secrets Act created federal recourse and remedies for trade secret misappropriation. While the requirements for trade secret protection are substantially different from other forms of intellectual property, they are particularly well-suited for competitively important aspects of a business that are (for lack of a better word) secret. Trade secrets can have significant value for protecting subject matter that is not typically eligible for patent protection (e.g., naturally occurring cultivars, confidential customer and pricing data).

Takeaways From the FDA's Hearing

On May 31, 2019, the FDA held its first public comment session on potential regulation of hemp-derived CBD, a compound typically extracted from cannabis that has recently become virally popular and is projected to reach nearly $1.3 billion in U.S. sales by 2022.[9] The hearing, which was conducted before a panel of FDA officials, lasted more than nine hours and included 100 speakers ranging from small business owners, manufacturers, lab operators and drugmakers to state officials, lawyers, patients, anti-marijuana groups, and agricultural stakeholders.

Based on the hearing, there appears to be consensus that, for better or worse, "the genie is out of the bottle" with CBD and it is not going back in, as one presenter memorably put it. A speaker from Consumer Reports noted that CBD products are popular in nearly every age group (from teenagers to baby boomers) and for a variety of reasons (from recreation and anxiety relief to general health and joint pain). Consumers are giving CBD to their children and pets and some in the livestock industry are advocating that CBD be liberally permitted in animal feed.

That is not to mention the impact that legal hemp is expected to have on U.S. agriculture. Several agricultural stakeholders, including state officials, noted that farmers enjoy significantly wider profit margins on hemp crops useful for CBD as compared to fiber alone. One stakeholder estimated averages of $30,000 per acre for CBD cultivation versus $7,000 per acre for fiber.[10] In other words, farmers in Colorado, Kentucky and Oregon want to cultivate hemp for CBD content and want the FDA to set forth pathways for their customers to market CBD products legally.

On the other hand, numerous speakers highlighted the prevalence of consumer fraud. Many cited significant evidence of misleading marketing and mislabeling of CBD products. For example, many commercially available products contain less than the advertised amount of CBD (e.g., 0% CBD) while other were found to contain more than seven times the advertised amount, sometimes with the presence of THC, the well-known cousin of CBD that can have acute psychotropic effects and was not declassified under the Farm Bill.

While the FDA stated that it would not be announcing any new policies or taking any positions at the hearing, what transpired provides a road map for where the policy debate currently stands and where the FDA is being asked to focus its regulatory efforts in the near-term. For example, several speakers highlighted the need for labeling, testing and dosing requirements in light of (1) the documented prevalence of consumer fraud and (2) the chemical profile of CBD as biologically active with the potential for drug interactions and hepatotoxicity.

Implications of FDA Regulation

As matters stand, it seems inevitable that the FDA will regulate CBD, but how swiftly and comprehensively remains unclear. Beyond its formal approval of Epidiolex as a "drug," the FDA has not endorsed any other pathways for approval. Presently the agency has stated only that CBD cannot be used as a food additive or dietary supplement and that it will be exercising its enforcement authority against companies making misleading health claims.[11] Beyond that limited guidance, the regulatory landscape for CBD remains in flux and may be for some time.

The business implications of this uncertainty are significant, with many stakeholders left wondering whether and when they can legally market their products. This makes intellectual property all the more important. Uncertainty is something many regulated industries face,

and cannabis will likely be no different. Perhaps this explains why intellectual property that does not depend on the legal status of cannabis has been surging.

Indeed, the period from 2015 to 2017 saw the greatest increase in U.S. cannabis patent application filings, reaching an all-time high of 118 applications filed in 2017 alone.[12] And the number of cannabis-related patent applications filed under the Patent Cooperation Treaty has more than doubled in the past decade, with over 10,000 such applications filed since 1978, roughly 6,000 of which were filed after 2008.[13]

Given the precedent of Epidiolex, it would not be surprising for the cannabis industry to end up following the model of biopharma, which presently appears to be the industry's closest analog. Cannabis innovation is diverse, touching on disciplines ranging from genetic engineering and biochemistry to commercial agriculture and manufacturing. And in an industry as nascent, diverse and commoditized as cannabis is, intellectual property plays key role.

As legalization trends continue and traditional industries that value intellectual property (biopharma, tobacco, food/beverage, alcohol, cosmetics) turn their attention to cannabis, intellectual property issues are likely to shape the business landscape. Whether for purposes of competition or valuation (or both), cannabis business strategy should include a conversation about intellectual property.

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[1] See, e.g., https://www.newcannabisventures.com/canopy-growth-invests-c429-million-to-acquire-ebbu-hemp-intellectual-property/; https://mjbizdaily.com/aurora-canopy-are-canadas-most-reputable-cannabis-firms-survey-finds-others-rank-far-behind/?utm_medium=email&utm_source=international&utm_campaign=INTL_20190607_NEWS_Weekly_06052019

[2] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999) ("Congress is free to declare particular types of inventions unpatentable for a variety of reasons . . . . Cf. 42 U.S.C. § 2181(a) (exempting from patent protection inventions useful solely in connection with special nuclear material or atomic weapons). Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable . . . .").

[3] https://www.law360.com/articles/1119184/what-cannabis-patent-applicants-can-learn-from-biopharma (noting that some of the patents within this technology class are even owned by or licensed to federal agencies including the U.S. Department of Health and Human Services).

[4] https://www.law360.com/articles/1116813/3-takeaways-from-the-ptab-s-cannabis-experience

[5] https://www.law360.com/articles/1153163/colo-ruling-could-provide-road-map-for-cannabis-inventors; https://www.law360.com/articles/1151252.

[6] Exemplary language in such a rejection is: "In addition, applicant must submit a written statement indicating whether the goods and/or services identified in the application comply with the Controlled Substances Act (CSA), 21 U.S.C. §§801-971. See 37 C.F.R. §2.69; TMEP §907."

[7] https://www.law360.com/articles/1156381/uspto-will-allow-registration-of-some-hemp-based-tms

[8] https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%201-19.pdf

[9] https://newfrontierdata.com/marijuana-insights/stakeholders-await-the-fdas-first-public-hearing-about-cannabis-and-cbd/

[10] Oral Comments of Cameron Cane (Deutsche Process, non-government).

[11] See https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys; https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers

[12] https://www.law360.com/articles/1119184/what-cannabis-patent-applicants-can-learn-from-biopharma

[13] https://cannabislaw.report/cannabis-ip-patents-top-10k-double-in-last-decade-figures-reveal/