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Assessing USDA Hemp Rule's Impact On Cannabis IP

By **Pauline Pelletier** (November 1, 2019, 4:50 PM EDT)

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The long-awaited rules for authorizing hemp cultivation under the 2018 Farm Bill are finally out. On Oct. 29, the U.S. Department of Agriculture released its interim final rule establishing a national regulatory framework for domestic hemp production, referred to as the U.S. Domestic Hemp Production Program.

Aside from passage of the Farm Bill itself, the USDA's rule is one of the most significant steps to date towards the legal sourcing of hemp and hemp derivatives, including CBD. Hemp is defined in the 2018 Farm Bill as cannabis containing no more than 0.3% THC.

While the USDA's new program will impact many aspects of the hemp supply chain, beginning at the ground level (i.e., agriculture), here we focus on the impact that this rule is likely to have on cannabis intellectual property.

Where Things Currently Stand on Legal Hemp

The 2018 Farm Bill directed the USDA to establish a national regulatory framework for domestic hemp production.

The USDA has now established that framework through an interim final rule that sets forth how the USDA will approve plans submitted by states and tribes for authorizing the domestic production of hemp. The rule also establishes a federal plan for hemp producers in states or territories of tribes that do not have their own USDA-approved plan.

The USDA rolled out its new regulatory framework in the form of an interim final rule, which means that the regulation takes effect immediately upon publication in the Federal Register. Publication of the interim rule in the Federal Register triggers a 60-day public comment period. Once the rules are finalized, the USDA will begin to evaluate any hemp production plans submitted by states and tribes.

Twenty state or tribal hemp production plans have been submitted to the USDA for review, as of Oct. 31., among them plans submitted by Arizona, Georgia, Kentucky, Montana, North Dakota, Oregon, Pennsylvania, Tennessee, Texas and Wyoming.

In terms of substance, the USDA's interim rules provide detailed guidance to states and tribes on how to

craft hemp production programs, including specifying the necessary procedures for, among other things, tracking the land where hemp is grown, testing for the concentration levels of THC, disposing of noncompliant plants, crafting compliance provisions for handling violations (including farm inspections), and sharing information with law enforcement.

Whether operating under a state or the federal plan, the interim rules provide guidance to hemp producers, processors and transporters on what activities are necessary for compliance with federal law.

What This Will Mean for the Cannabis Industry

What does this mean for the hemp industry and those invested in the burgeoning market for CBD-containing products? It means that the road to legally sourced hemp and its derivatives, including CBD, is being paved. The CBD market has been booming, despite the lack of federally legal CBD sourcing options to date.

In 2018, even before Farm Bill implementation, that market totaled $1.45 billion. With the availability of legally sourced CBD on the horizon, those numbers are projected to multiply by a factor of 10 or more over the next decade. Indeed, a recent report by Fior Markets estimates that the global CBD market is expected to reach $17 billion by 2026.

Despite continued uncertainty about how CBD-containing products marketed directly to consumers will be regulated, namely by the U.S. Food and Drug Administration and the Federal Trade Commission, many in the cannabis sector are plowing forward with business plans premised on the imminent availability of federally legal and domestically sourced hemp.

The USDA's interim rules are a big step closer to reaching that milestone. In addition, the FDA is expected to provide an update soon regarding its parallel efforts to establish a cannabis regulatory scheme. The FDA has been asked to clarify what approval, if any, will be required for CBD-containing products, including pharmaceuticals, dietary supplements, foods, cosmetics or smokables.

Once federal guidelines are in hand, the industry will be poised for dramatic growth. The potential for legal CBD in the near future has some major commercial and business implications.

While traditional industries, including food, beverage, alcohol, tobacco, cosmetics and pharmaceuticals, have been eyeing the burgeoning cannabis industry (if not investing in it or dabbling in jurisdictions where marijuana is not illegal under state law), many have been reluctant to dive in head first. This is due, in large part, to the federal classification of marijuana as a controlled substance, as well as the lack of clarity regarding how CBD can be marketed.

With the legalization of hemp and USDA's implementation of its Farm Bill mandate, all that remains is for the FDA to clarify how it intends to regulate the CBD-containing products that fall within its purview (e.g., drugs, dietary supplements, food/beverages, cosmetics).

And once the FDA begins to specify regulatory pathways and standards for the industry to follow, the race for market dominance will begin in earnest — potentially with the involvement of traditional industry players who may start by acquiring recognized brands and innovative cannabis firms.

In this regard, current players in the industry are increasingly seeking to fortify their business plans with intellectual property, whether to secure a competitive edge or increase company valuation.[1]

The Impact on Cannabis Intellectual Property

Cannabis laws and regulations impact different types of intellectual property differently. For example, whether or not a product is lawful under federal law is largely irrelevant in the context of patent, copyright and trade secret protection.[2]

But in the case of federally registered trademarks, lawful use in commerce is a basic requirement, and one that makes securing such protection uniquely challenging for cannabis businesses (even those with famous brands).

Here we focus on how the USDA's interim rule could impact federal trademark registration as well as how the leeway given for satisfying the 0.3% THC threshold could impact patenting strategy.

Federally Registered Trademarks

With respect to trademarks, in May, following enactment of the 2018 Farm Bill, the U.S. Patent and Trademark Office issued new guidelines for the examination of trademarks for cannabis and cannabis-related goods and services.

In particular, the guidelines provided for the federal registration of marks for federally lawful hemp-derived CBD goods and services, in light of the fact that the 2018 Farm Bill removed hemp from the Controlled Substances Act, or CSA. The guidelines make clear that "lawful" means that the product or service must be in compliance with any applicable federal regulatory scheme, including those imposed by the USDA and FDA.

The new guidelines explain that for trademark applications that recite services involving the cultivation or production of cannabis that is hemp, the examining attorney will issue inquiries concerning the applicant's authorization to produce hemp.

Specifically, the applicant must state that their activities meet the requirements of the 2018 Farm Bill with respect to the production of hemp, including production pursuant to a license or authorization by a state, territory or tribal government in accordance with a plan approved by the USDA.

At the time the guidelines were released, the USDA had not yet promulgated regulations, created its own hemp-production plan, or approved any state or tribal plans. That is no longer the case and things are moving quickly.

As a practical matter, those who anticipate seeking federal trademark protection in this space should be prepared to provide the USPTO with the requisite assurances that the product or service involves only hemp that was cultivated pursuant to a federally-approved plan. Assuming that this is the case, there is now a clear pathway for securing federal trademark protection.

For the same reason that a lawful hemp product can be protected by a federally registered trademark, the mark should also be defensible from attacks based on the "unlawful use" doctrine, which has been raised in the context of cannabis trademark enforcement in recent years with mixed and confusing results.

For example, some jurisdiction have allowed accused infringers to undermine the enforceability of a

trademark based on the accused or prior use being unlawful (e.g., related to recreational marijuana use).[3] Other jurisdictions have come out the other way, holding that the doctrine is limited to the federal trademark examination process and does not deprive a trademark holder of standing to enforce the trademark right against infringers.[4]

Genetic Variation and Plant Patents

In the context of patent protection, the USDA's testing requirements may be of interest to those who were wondering if genetic variation and imprecision in sampling and testing would be fatal to satisfying the 0.3% THC threshold. As it turns out, the USDA plans to allow for a margin of error with respect to THC concentration, i.e., a measurement of uncertainty. This will allow for some variation in sampling and testing as well as in plant genetics.

As implemented in the rules, producers will not be considered to be in negligent violation unless their hemp crops test above 0.5% THC, although hemp that tests over the 0.3% THC threshold must still be destroyed. Thus, while farmers may be less worried about penalties, they may still worry about lost profits.

This October, many cannabis and investor news outlets reported that the Patent and Trademark Office had awarded the first plant patent for a hemp strain to Denver-based Charlotte's Web Holdings Inc.[5] The commercial interest in this development revolved around the strain's notable characteristic of producing up to 6.24% CBD and only 0.27% THC.

Plant patents afford protection for asexually propagated plants (i.e., clones having identical genetics to those of the patented plant). Thus, a plant patent is infringed when the infringer has cloned the accused plant from the plant protected by the patent.

The question then becomes, will the industry come to rely on cloning (e.g., to ensure consistent THC concentrations)? If so, a patented strain that is cloned to ensure consistency could have far-reaching implications. If, however, the standards for testing are not so exacting as to require cloning, seed farming may continue to be the dominant approach to hemp cultivation, making plant patents of more limited value within the industry.

In this regard, utility patents offer relatively broader protection than plant patents and can be advantageous where the innovation lies in the development of a plant or plant product that is cultivated to have previously unknown and non-naturally occurring properties.

One advantage of utility patents in this regard is that, if such protection is awarded, the claimed invention can be infringed even if the accused product is reproduced sexually (e.g., by seed farming, not cloning). Utility patents are routinely issued by the USPTO for plants and plant elements (e.g., buds, pollen, fruit, plant-derived chemicals, extracts, proteins, engineered genes).

Thus, while a plant patent for a commercially valuable strain could have great potential if the strain is likely to be cloned, its scope is bounded to its precise genetics and leaves room for seed farming. Depending on how THC testing operates in practice, and whether cloning becomes the de facto standard, those in the industry may shift from one form of patent protection to the other.

In sum, the USDA's interim rule marks an important milestone in cannabis legalization, one that brings the industry closer to reaching its promising potential.

As illustrated above, the regulatory landscape has a unique interplay with cannabis intellectual property. Thus, monitoring regulatory activity is crucial. Next up will be the FDA's eagerly anticipated update regarding its ongoing efforts to develop a comprehensive regulatory scheme for cannabis and its derivatives.

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[1] Matthew Bultman, Cannabis Patent Activity Surges Amid Industry Gold Rush, Law360 (Oct. 16, 2019), https://www.law360.com/articles/1203746/cannabis-patent-activity-surges-amid-industry-gold-rush; Malathi Nayak, Cannabis Companies Gamble on Patents to Lure Possible Suitors, Bloomberg News (Apr. 1, 2019), https://news.bloomberglaw.com/ip-law/cannabis-companies-gamble-on-patents-to-lure-possible-suitors.

[2] IP's Developing Role In Cannabis Business Strategy, Law360 (June 11, 2019), https://www.law360.com/articles/1167936/ip-s-developing-role-in-cannabis-business-strategy.

[3] See, e.g., Woodstock Ventures LC v. Woodstock Roots, LLC, Case No. 1:18-cv-01840, ECF No. 129 (S.D.N.Y. Jul. 29, 2019) (Gardephe, J.) (2nd Cir. Appeal No. 19-2720); Kiva Health brands LLC v. Kiva Brands Inc., Case No. 19-cv-03459-CRB (C.A.N.D. Sept. 6, 2019).

[4] See, e.g., Roor Int'l. BV v. Kinan Shouk, Inc., Case No. 3:19-cv-00027, ECF. No. 16 (M.D. Fl. Jul. 31, 2019) (Schlesinger, J.).

[5] Pauline Pelletier and Deborah Sterling, What Does a Plant Patent Covering the Charlotte's Web Strain Mean for the CBD Industry? Sterne Kessler Client Alert (Oct. 14, 2019), https://www.sternekessler.com/news-insights/client-alerts/what-does-plant-patent-covering-charlottes-web-strain-mean-cbd-industry.