

# Global Patent Prosecution

June 2019



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Despite marijuana's illegal status in most countries, the patent arms race for cannabis has already begun. Indeed, analysts have projected that in North America alone the cannabis industry will grow from \$9.2 billion in 2017 to \$47.3 billion in 2027. The June issue of the Global Patent Prosecution Newsletter focuses on IP issues facing the cannabis industry.

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## CANNABIS PATENTING AT AN ALL-TIME HIGH DESPITE ILLEGAL STATUS

By: [Pauline M. Pelletier](#) and [Deborah Sterling, Ph.D.](#)

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## IP'S DEVELOPING ROLE IN CANNABIS BUSINESS STRATEGY

Directors Pauline M. Pelletier, Deborah Sterling, Ph.D., and Monica Riva Talley authored the article, "IP's Developing Role in Cannabis Business Strategy," published by *Law360* on June 11, 2019. The article outlines the cannabis IP landscape and provides takeaways from the FDA's recent hearing.

*Law360* -- 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.

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Legal or not, the cannabis industry is booming. Indeed, analysts have projected that in North America alone it will grow from \$9.2 billion in 2017 to \$47.3 billion in 2027. Despite marijuana's illegal status in most countries, the patent arms race for cannabis has already begun. The number of cannabis-related patent applications filed under the Patent Cooperation Treaty ("PCT") 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. And the U.S. Patent & Trademark Office has already issued hundreds of patents covering cannabis products, their derivatives, production processes, and methods of use. In fact, the period from 2015 to 2017 saw the greatest increase in cannabis application filings, reaching an all-time high of 118 applications filed in 2017 alone.<sup>[1]</sup>

Likewise, cannabis-related patents have been issued in other jurisdictions with promising markets, among them Canada (which legalized marijuana in 2018), the European Patent Office, and Israel. Interestingly, seven of Canada's top ten cannabis-patent holders are multi-national pharmaceutical companies, including Ciba-Geigy, Pfizer, GW Pharmaceuticals, and Merck. Parallel trends can be observed in Israel, which is a recognized center for cannabis biomedical research. Efforts by pharmaceutical firms to obtain patents in Canada preceded legalization and are likely to intensify as approval pathways and programs for conducting clinical trials mature. The same is expected in other jurisdictions.<sup>[2]</sup> Consistent with these global trends, in February of 2019, the World Health Organization recommended that the United Nations de-schedule hemp and reschedule marijuana to a lower level of control under international treaties.<sup>[3]</sup> If adopted, these recommendations could significantly reduce the international controls placed on cannabis.

Cannabis innovation touches on a wide range of disciplines, from genetic engineering and biochemistry to agriculture and manufacturing. Intellectual property, particularly patents, have been at the center of acquisitions and mergers in this nascent industry. For example, in 2018, Canopy Growth (the world's largest cannabis company as of April) acquired a small Colorado-based hemp research company called Ebbu LLC days before Canada legalized cannabis in a stock-and-cash deal worth \$425 million.<sup>[4]</sup> Ebbu had amassed a notable patent portfolio covering, among other things, ways to reduce the cost of CBD production and engineer cannabis-infused beverages. Other marijuana companies, including Aurora Cannabis (Canopy's main competitor), appear to be in the hunt to acquire intellectual property as well.<sup>[5]</sup> Smaller marijuana firms are, in turn, attempting to better position themselves for valuation by securing

patent protection.[6]

As traditional industries who understand the value of intellectual property (biopharma, tobacco, food/beverage, alcohol, cosmetics) turn their attention to cannabis, patent issues are likely to shape the business landscape. Whether for purposes of competition or valuation (or both), protecting cannabis-related innovation starts with creating an intellectual property strategy centered on strong, diversified protection for core technologies and commercial applications.

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[1] Pelletier and Sterling, What Cannabis Patent Applicants Can Learn From Biopharma, *Law 360* (Jan. 19, 2019) ([link](#)), available at <https://www.sternekeessler.com/news-insights/publications/what-cannabis-patent-applicants-can-learn-biopharma>.

[2] Flora Southey, *Has Big Pharma's 'inevitable entrance' into the cannabis space arrived?*, in-Pharma, *Technologist.com* (Sept. 3, 2018) ([link](#)).

[3] Tom Angell, *World Health Organization Recommends Reclassifying Marijuana Under International Treaties*, *Forbes* (Feb. 1, 2019) ([link](#)).

[4] Kristine Oworm, *Canopy Bets on U.S. Hemp Market With \$330 Million Acquisition*, *Bloomberg* (Oct. 15, 2018) ([link](#)); Vanmala Subramaniam, *Cannabis companies race to clinch an edge in pot industry's next phase of growth: Intellectual property*, *Financial Post* (Nov. 9, 2018) ([link](#)).

[5] John Selwanes, *Buy vs. Build: The Business of Cannabis* (Mar. 26, 2019) ([link](#)).

[6] Callitas Health Press Release (announcing notice of allowance received for a biphasic oral cannabinoid patent) (April 25, 2019) ([link](#)); Cannabis Science Inc. Press Release (announcing independent valuation for cannabidiol for negotiation of licensing and marketing deals in Canada and the USA to develop and sell cannabidiol products) (Apr. 15, 2019) ([link](#)).

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Unlike its cannabis-derived cousin tetrahydrocannabinol (“THC”), CBD raises fewer red flags for regulators and, as a result, has made inroads towards legalization in countries seeking to promote hemp agriculture and industrialization. CBD can be derived from hemp, thus opening the door for legal CBD. The list of countries where CBD can be legally cultivated now includes the United States, which removed hemp from the Controlled Substances Act (“CSA”) in 2018. In the United States, “hemp” is now defined by statute as cannabis containing less than 0.3% THC.

The proliferation of CBD-containing consumer products recently prompted the U.S. Food & Drug Administration (“FDA”) to hold its first public hearing on cannabis in May. The hearing took place before a panel of 12 FDA officials, lasted almost 10 hours, and included roughly 100 speakers ranging from business owners, lab operators, manufacturers, and drug-makers to state officials, agricultural stakeholders, patients, and anti-marijuana groups. At least one important theme emerged: there is a need for more regulation of CBD-containing products in the consumer marketplace given (i) the prevalence of serious consumer fraud and (ii) the pharmacologic profile of CBD as biologically-active with the potential for drug interactions and hepatotoxicity.

In many ways the FDA hearing raised more questions than it answered; nevertheless, it has framed the policy debate and highlighted the need for regulatory-approval pathways to be defined. What we know today is that the FDA approved the first cannabis-derived drug in 2018 (Epidiolex), paving the way for cannabis therapeutics that meet the agency’s standards for safety and efficacy. And while the contours of what *other* types of CBD-related products are now legal continue to evolve, the arms race for cannabis intellectual property is well underway and is likely to intensify as the regulatory landscape matures and regulatory-approval pathways are defined.<sup>[1]</sup>

[1] Pelletier, Sterling, and Talley, *IP's Developing Role In Cannabis Business Strategy*, Law 360 (June 11, 2019) ([link](https://www.law360.com/articles/1167936)), available at <https://www.law360.com/articles/1167936>.

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In 2018, UCANN asserted its U.S. Patent No. 9,730,911 against Pure Hemp. The '911 patent claims liquid cannabinoid formulations wherein "at least 95% of the total cannabinoids" are one or more specified cannabinoids (e.g., CBD, THC, CBD/THC). In seeking to invalidate the patent, Pure Hemp argued that the claimed cannabinoids occur naturally in the cannabis plant and are therefore patent-ineligible. UCANN countered that its claims are directed to human-engineered liquidized formulations that contain threshold-amounts of cannabinoids that do not occur in nature. Judge Martinez agreed with UCANN, explaining that even if it were "logically possible" that cannabinoids in nature might appear in a form that could be deemed a "liquid," the claims nonetheless specify threshold concentrations of cannabinoids and related chemicals that do not occur naturally in liquid form. Thus, UCANN's claims are not "the handiwork of nature."

As the first of its kind, this decision is an important development for those who own, or are pursuing, patent claims in the cannabis space. Notably, the claims at issue in the UCANN litigation are not process or method-of-use claims. Meaning, they do not require a particular process for extracting or making cannabinoids. Nor do they claim a particular method of using cannabinoids to treat a particular disease, condition, or symptom. Rather, they claim cannabinoid formulations. While process and method-of-use claims may be independently patent-eligible for entirely different reasons, Judge Martinez's decision illustrates that, properly claimed, cannabis formulations that are the result of human modification can stand on their own. For example, as in the UCANN patent, cannabis compositions that require converting natural cannabinoids into a different state could, in combination with other non-natural characteristics, be patent-eligible.

In terms of the broader implications, the District of Colorado's decision offers a helpful roadmap for how to navigate subject-matter eligibility in the emerging cannabis technology



space. And since UCANN's patent survived this initial validity challenge, the suit remains a valuable test case for patent enforcement actions in a jurisdiction where cannabis patent suits are likely to be brought in the future; namely, Colorado. We expect the UCANN decision to drive further interest in this technology space and will continue to report on important developments.

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