# Cannabis Patent Implications

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With cannabis now legal in Canada for both medical and recreational use, as well as legal for medical and/or recreational use at the state level in the majority of U.S. states, it is no secret companies are ramping up their research and development and rushing to pursue patent protection of their intellectual property rights. The U.S. Patent and Trademark Office has issued 127 patents containing the words "cannabis" or "cannabinoid" in their claims in 2018, up from 43 in 2014, while the Canadian Intellectual Property Office ("CIPO") has issued 22 such patents in 2018, up from 9 in 2014.

In both Canada and the United States, it is possible to obtain patents for inventions related to cannabinoid formulations, methods and devices for cannabis plant cultivation and extraction, genetically modified cannabis plants or plant cells, therapeutic uses of cannabinoids, and devices and methods for consuming cannabinoids, among others. In seeking patent protection, companies in the cannabis field should be mindful of the following considerations in building a balanced Canadian and U.S. patent portfolio, to protect assets and shield against competition in both jurisdictions.

## Patentable Subject Matter

Certain subject matter is excluded from patentability. One example particularly relevant to cannabis inventions is plants. Plants are not patentable in Canada because our laws provide that "higher life forms" (which includes plants as well as animals) are not patentable subject matter. In contrast, a cell of a higher life form, methods of making higher life forms, as well as use of a higher life form, may constitute patentable subject matter. Therefore, even if a breeder or grower has created a new cannabis cultivar, unless the cells of the new cultivar can be identified by technical features (*e.g.*, genetic modifications), it may not be possible to protect the cultivar via patents (although protection may be available under Plant Breeders' Rights; see Smart & Biggar article).

The current patent regime may encourage companies to apply existing agricultural biotechnology methods and tools to develop genetically modified cannabis strains (for example, strains with altered cannabinoid profiles and strains with altered resistance to mould or pests) that can be protected by patents.

In addition to the subject matter issues related to patenting plants, there is also a prohibition against the patentability of methods of medical treatment (*e.g.*, a method of treating pain comprising a step of administering compound X to a subject). However, it is nevertheless possible to obtain protection for inventions relating to methods of medical treatment by presenting method claims as use claims (*e.g.*, use of compound X for treating pain).

## Accelerating Examination

Given how rapidly the cannabis industry is evolving, obtaining patents in the cannabis field more expeditiously may present several advantages. For example, in addition to being able to assert the granted patents against competitors in the market, having patents with definitive claims (compared to patent applications with unknown claim scope) may improve the patentee's negotiating position during a commercial transaction.

Currently, it may be at least a year after the request for examination is made before CIPO issues a first Examiner's Report in a Canadian patent application and, in some cases, a subsequent Examiner's Report or Notice of Allowance may not issue for an additional 6 to 9 months after the applicant's response. This means it may take at least 2 years from the time of requesting examination to obtain a Canadian patent.

That said, the Canadian patent system does offer an excellent option for accelerating examination via a request for Special Order. A Special Order may usually be obtained without difficulty upon payment of a government fee of CAD $500. In comparison, a similar program in the United States for accelerating examination, namely the Track 1 examination program, has a filing fee of USD $4,000.

Under CIPO's current service standard, for an application granted a Special Order, a response will be provided to the applicant within 2 months from when the correspondence is received at CIPO. Therefore, by using a Special Order, it may be possible to significantly shorten the length of time from requesting examination to patent grant.

## Unique Challenges for Assessing Freedom-to-Operate

For companies interested in entering the cannabis field or developing a new line of cannabis products, conducting freedom-to-operate ("FTO") searches may represent some unique challenges that are not commonly encountered in other industries.

First, although the number of granted patents in the United States and Canada related to cannabis or cannabinoid is much smaller than the numbers seen in more mature industries like pharmaceuticals and telecommunication, some of the cannabis patents have very broad claim scope. For example, U.S. Patent No. 9,730,911, which is the patent at issue in an ongoing patent infringement law suit in the United States, claims a liquid cannabinoid formulation wherein at least 95% of the total cannabinoids is tetrahydrocannabinolic acid ("THCA"). One of the key issues in this case, experts say, is whether the claims of U.S. Patent No. 9,730,911 can survive a validity challenge. "As far as the claims are concerned, I've never seen a weaker cannabis patent in my life", one U.S. patent attorney said.

Issuance of patents like U.S. Patent No. 9,730,911 may be explained by the lack of prior art documentation for cannabis due to its legal status. However, the existence of these patents nonetheless creates a potential barrier for companies that are considering entering the cannabis market. Invalidation of an issued patent can be a very costly procedure with unpredictable outcome. Companies may have to choose between pursuing a license agreement with patent holders and undertaking the risks of infringement based on legal infringement/validity opinions.

Furthermore, as mentioned at the beginning of this article, it is expected that a large amount of cannabis-related patent applications have been filed in recent years. Many of these applications remain in the 18-month confidentiality period (patent applications are generally not published until 18 months from the earliest priority date) and cannot be detected by any search.

All FTO searches, regardless of the field, are restricted by inevitably missing potentially relevant patent filings that are not published. However, the effect of this limitation is expected to be more profound for the cannabis field, given the obvious increase in patent filings in this field in recent years. Even if an FTO search does not reveal any potential patent barrier for product entry in a given market, companies should be alert to the rapidly evolving patent landscape and consider updating the FTO search periodically, especially when new market intelligence is obtained about potential competitors.