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NAME PROTECTION FOR HEMP (AND OTHER PLANT VARIETIES)

Author: Christine Lebrón-Dykeman

You have by now heard that the 2018 Farm Bill removed hemp as a Schedule I substance, and recently the United States Department of Agriculture (USDA)'s Plant Variety Protection Office—which reviews applications and grants certificates to protect new, distinct, uniform and stable plant varieties—began permitting the issuance of Plant Variety Protection Certificates (PVP) for seed-propagated hemp varieties. With this change, hemp breeders now have more options than ever before for protecting their genetics. Potentially, under U.S. law, a single seed-propagated hemp variety can now be protected by a PVP certificate, a Utility Patent and a Plant Patent—providing multiple layers of complementary legal protections.

The USPTO has also recently issued guidance on how the 2018 Farm Bill affects trademark applications for cannabis and CBD products. The USPTO will now grant some cannabis/CBD/hemp-related trademark applications, but with a few significant caveats. Now that at least some cannabis/CBD/hemp applications may be protected as trademarks, we want to remind hemp producers of the following "name choosing" rules applicable to all plant varieties.

Under U.S. law, the varietal/cultivar denomination used for the PVP or patent on any plant variety can never be registered as the product's trademark. The underlying concept is that the "variety denomination" used for a PVP or patent is the generic designation that must be used by any third party producing that variety even after the expiration of the PVP or patent. Because any person who sells the variety must use the denomination, and consumers need to have a common descriptive name to describe the particular variety of plant they want to purchase, the generic varietal/cultivar designation can never become associated with a single source, and thus cannot act as a brand name (trademark) for that variety. Therefore, these designations cannot be registered as trademarks. Likewise, any varietal/cultivar name will also be refused registration on the Principal Register for products that incorporate the varietal/cultivar as an ingredient.

Before filing any patent or PVP, breeders should consider what brand they want to eventually sell under and reserve that name for trademark protection. They should use a different designation (e.g., letters, numbers, or code names) as the varietal/cultivar denomination used in patent or PVP applications, or anywhere where they are describing the varietal/cultivar.

The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.

Christine Lebrón-Dykeman is the Chair of the MVS Trademark Practice Group. To learn more, visit our MVS website, or contact Christine directly via email.

MOVEMENT OF CANNABIS–RELATED PATENTS IN THE LEGAL INDUSTRY: FIRST CASES TO UNDERGO REVIEW

Author: Tina Yin Sowatzke, Pharm.D.

In the past 25 years, there has been substantial growth surrounding the interests and developments of the cannabis industry, particularly involving intellectual property protections. With legalization of cannabis gaining traction across the United States, 2019 has been particularly constructive in paving the start of a roadmap for cannabis inventors. Within 2019, the Patent Trial and Appeal Board (PTAB) has adjudicated its first cannabis-related inter partes review (IPR), and a federal district court has adjudicated the first cannabis-related patent to make its way through the federal court system.

Despite the various handlings of cannabis legalization across the states, the United States Patent and Trademark Office (USPTO) has continued to issue cannabis-related patents without regard to legal status. The first of these patents to undergo an infringement suit in a federal court is *United Cannabis Corp. (UCANN) v. Pure Hemp Collective, Inc,* providing the first 35 U.S.C. §101 patentable subject matter challenge over cannabis formulations.

The patent at issue—U.S. Patent No. 9,730,911 issued to UCANN—claims "[a] liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is [tetrahydrocannabinol (THC), cannabidiol (CBD), cannabinol (CBN), or a combination thereof]". Pure Hemp alleged the claims were directed to an unpatentable natural phenomenon of the claimed chemical compounds. In response, UCANN argued the claims were neither directed to laws of nature nor natural phenomena as they claimed, "human-modified liquid formulations that require[d] converting solid cannabinoids into a different state with markedly different physiological characteristics".

Ultimately, the Court was persuaded by UCANN's argument, finding that Pure Hemp failed to establish that a liquified formulation of cannabinoid, at the concentrations specified in the '911 patent, was anything like a natural phenomenon. Specifically, the Court concluded that the claims were not mere restatements of "the handiwork of nature," but instead, were UCANN's own handiwork by providing concentrations of cannabinoids that do not occur in liquid form in nature.

Although the patent survived a §101 subject matter eligibility challenge, the Court found reason to question the novelty and non-obviousness of the patent. Current court opinions fail to provide additional insight surrounding §102 and §103 rejections. However, the results of the first IPR proceeding involving a cannabis-related patent—U.S. Patent No. 9,066,920—may provide additional direction. The '920 patent covered a method of treating partial seizures comprising administering CBD to a patient with a dose of at least 400 mg. The PTAB found that because CBD does not impair cognitive function, it would have been obvious to increase the daily dosage to 400 mg or more through routine optimization. However, claims including additional limitations such as combination therapies with other cannabinoids and using pure, isolated CBD, were not present in the cited art and therefore non-obvious.

Although these two cases are only the first to make their way through an IPR or federal court proceeding, they provide a starting framework for how cannabis-related patents may be adjudicated. Certainly, additional cases surrounding cannabis-related patents will be closely observed as interest in this technology area rises in a growing cannabis industry.

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NEW LEGISLATION AIMED AT SUBJECT MATTER

Author: Oliver P. Couture, Ph.D.

Subject matter has been getting more attention from Congress lately. Several recent cases and future appeals may be spurring Congress into action over Section 101. Early this year the Supreme Court has asked the United States Solicitor General to submit a brief for *Berkheimer,* which is on petition for *certiorari*. Also, recent holdings in *Cleveland Clinic v. True Health* and *Henry Schein, Inc. v. Archer & White Sales, Inc.* have highlighted the tensions in current subject matter jurisdiction.

The reasoning in recent *Cleveland Clinic* has highlighted how currently far apart the judicial branch is from the United States Patent & Trademark Office (USPTO). In *Cleveland Clinic,* the United States Court of Appeals for the Federal Circuit (CAFC), siding with True Health, unsurprisingly held Cleveland Clinic's claims invalid over Section 101. The CAFC further stated that while they recognize the USPTO's expertise, they are not bound by the USPTO's guidelines but are by the court's precedence, such as *Ariosa*. Therefore, depending on the subject matter of the patent, even if the USPTO grants your patent under the new Section 101 guidelines, it may be unenforceable in court under one of the judicial exceptions.

However, the Court has also put into question their own judicial exceptions. In *Henry Schein* the Court, in a unanimous opinion, held that since there was no exception in the Act in question, they could not rewrite the statute to accommodate policy concerns. Effectively stating that judicial exception cannot exist. As subject matter is heavily steeped in judicial exceptions, it is only a matter of time, barring new legislation, until the Court must resolve this contradiction.

Indeed Sens. Thom Tillis and Chris Coons have released a draft outline of Section 101 reform. The draft reform incorporates several provisions proposed by Intellectual Property Law Association of Chicago (IPLAC), American Intellectual Property Law Association (AIPLA), Intellectual Property Owners Association (IPO), and the American Bar Association-Intellectual Property Law (ABA-IPL) and contains seven points: 1) keep the existing statutory categories; 2) eliminate the "new and useful" clause while simply requiring the invention meet the existing statutory utility requirement; 3) define a closed list of exclusive ineligible categories; 4) create a "practical application" test; 5) ensure generic technical language does not salvage a claim; 6) statutorily abrogate judicially created exceptions; and 7) make sure the claim is analyzed as a whole without regard to considerations under 102, 103, and 112.

The draft further indicates that the current judicial exception, including fundamental scientific principles, products that exist solely and exclusively in nature, pure mathematical formulas, economic or commercial principles, and mental activities, would be included under point 3 above. This may fix the contradiction the Court created for itself in *Henry Schein*. Point 6 also agrees with *Henry Schein* in that future judicial exceptions should not be created. It should be noted that the current expectation of organizing human behavior is not included in this list, so it may once again be able to patent games which has proven difficult under *Alice.*

Additionally, the including of a "practical application" test follows the current USPTO guidelines of applying a judicial exception making the claim eligible subject matter. This will rectify the current state of tension between the courts and the USPTO outlined in the decision in *Cleveland Clinic*. It furthers follows the idea outlined in the guidelines of separating and keeping separation 101 analysis from the other sections of analysis.

Overall, this draft seems to appear to incorporate the USPTO's interpretation of the court's various holdings on 101 analysis. However, until a full draft of a bill is available, it is uncertain exactly what subject matter exceptions will be incorporated into the statute.

Oliver P. Couture, Ph.D. is an Associate Attorney in the MVS Biotechnology & Chemical Practice Group. To learn more, visit our MVS website, or contact Oliver directly via email.

IN A HURRY? TRY PRIORITIZED EXAMINATION

Author: Michael C. Gilchrist

Have you ever seen someone "tip" a maître d' to move up the wait list for a table? Well, the United States Patent & Trademark Office (USPTO) their own version of this called "Prioritized Examination". For a fee ($4140 large entities, $2070 small entities), the USPTO will move your application to the front of the line. The goal of Prioritized Examination (also called Track One Examination) is to go from application filing to notice of allowance or final rejection in twelve months. The statistics show that the USPTO is beating this goal (average is about 8.5 months).

The average time from filing to first Office Action (without Prioritized Examination) has improved from about 24 months in 2013 to about 17 months last year. The USPTO estimates that applications filed now will average about 15 months before they receive a first Office Action. This improved time can be shortened to 3.4 months by taking advantage of Prioritized Examination.

Naturally, there are several requirements and limitations to Prioritized Examination. Prioritized Examination is available for utility and plant patent applications, but is not available for design applications, reissue applications, or reexamination proceedings. It is also not available when entering the National Phase from an International (PCT) Application; however, it is possible to file a continuation application off a National Phase that includes a request for Prioritized Examination. A request for Prioritized Examination may be filed with a request for continued examination (RCE) (or after filing an RCE but before the first Office Action after the RCE), but only with one RCE per application.

The request for Prioritized Examination, including the required fees, must be filed simultaneously with the application. The application must include (or be amended to include) no more than four independent claims and no more than 30 total claims.

The application only gets prioritized treatment until a final rejection or notice of allowance. In other words, if an RCE or appeal is necessary, the application will no longer get expedited treatment. If the applicant files a request for an extension of time to respond to anything, that will also terminate the prioritized examination.

The law that implemented this program allows the USPTO to limit the total number of Prioritized Applications to 10,000 per fiscal year (October-September). The current rate of filings is equal to about 10,000 per year, so there is some chance that applications filed late in the fiscal year (i.e. in September) would not be eligible to take advantage of the program. However, to date, the USPTO has not refused any petitions to participate based on being over the threshold.

Generally speaking, the upside to participating in the program is the possibility of getting your patent issued (or finally rejected) about a year quicker than a traditional application. The downside, of course, is the increased fees and the acceleration of other prosecution expenses. If you think you may be interested in expediting your patent application, please contact your MVS attorney to discuss the pros and cons in detail.

Sources: 37 CFR § 1.102(e) and USPTO's Patent Dashboard
(https://www.uspto.gov/dashboards/patents/main.dashxml)

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POSSIBLE ACTION ON REVERSING RECENT DENIAL OF SOFTWARE, BUSINESS, AND MEDICAL INVENTIONS AS "INELIGIBLE" FOR U.S. PATENTS

Author: Mark D. Hansing

We have been waiting for this. A progression of court decisions over the last decade, including from the United States Supreme Court, virtually eliminated patents on most software, business methods, medical testing and diagnosis innovations. For example, with respect to software-related innovations, if they (1) did not improve the functioning of computers (e.g. make them run faster) or (2) improve some other technology (e.g. make a robot move better), they were considered "ineligible" for patenting. Not only were patent applications denied on this basis alone, many granted patents were invalidated. Despite much of these ideas clearly involving high technology, patenting has been denied.

Congress is considering legislation that would help. The legislation would keep intact the broad set of things that can be patented: machines, articles of manufacture (products), chemicals, processes, and improvements of them. But it would seek to explicitly narrow what could be labelled ineligible to the following list:

1. Fundamental scientific principles;
2. Products that exist solely and exclusively in nature;
3. Pure mathematical formulas;
4. Economic or commercial principles;
5. Purely mental activities.

Recognizing that this list alone might be difficult to apply, the legislation also includes the following concepts to try to make sure it is narrowly applied:

- Include a "practical application" test to ensure that the list is construed narrowly (in other words, patent claims that give a "practical application" to economical or commercial principles are not automatically deemed ineligible).
- Specifically overrule prior court decisions in favor of the list.
- Force the U.S. Patent Office and the Courts to determine eligibility by considering the patent claims "as a whole", and not clause-by-clause.
- Forbid allowing other patentability considerations like novelty and non-obviousness to be taken into account.

To be fair, many stakeholders believed that patent eligibility was too broad and applauded the current state of the law. They argued that merely using computers for their normal function (processing data), is not the type of technology that deserves a 20-year exclusive right.

However, there has been wide spread (and growing) acknowledgment that the current state of the law may have swung too much the other way. For a good number of years now, it is rare that any patent claim that centers on computer processing is allowed or withstands court challenge.

During this time, it has been difficult to advise clients to file these types of patent applications. However, in this same time period, the U.S. changed from a "first-to-invent" patent system to a "first-to-file" system. Because of that, we have also had to advise clients that they should at least consider filing patent applications on these types of inventions that have high potential value because action by Congress could bring them back into play.

We do not know the likelihood of this legislation passing, but it gives some hope to continuously evaluate with your patent attorney whether filing makes sense.

Mark D. Hansing is a Patent Attorney and Member in the Mechanical Patent Practice Group and has been with MVS since 1981. For more information, please visit the MVS website or contact Mark directly via email.

BIG CHANGES AHEAD FOR PLANT VARIETY PROTECTION (PVP)

Author: Heidi S. Nebel

The United States Department of Agriculture (USDA) has been hard at work developing regulations to implement the 2018 Farm Bill. The Bill introduces unprecedented changes to the United States PVP system with respect to asexually reproduced plants and hemp. Proposed regulations to implement changes for asexually reproduced plants will soon be published for comment. Those of us with an economic interest in the plant industry, both domestically and internationally, need to review and comment to ensure that our PVP system remains viable and strong.

The first change in the Farm Bill was the legalization of hemp production. Following suit, the USDA quickly adapted and went live with a variety specific form for hemp characteristics. They began accepting PVP applications for sexually produced hemp varieties on April 25, 2019.

Second, and perhaps more sweeping, the Bill directed the USDA to implement PVP protection for asexually reproduced plants. Numerous issues arise with expansion of the process to asexually reproduced plants, not the least of which is deposit. Seed deposits are made with every PVP application, but seed from an asexually reproduced plant will not be true to type, they are instead propagated by cuttings, etc. The proposed regulations will address the deposit issue. The issue of infringement also becomes complicated, as well as the breeders and saved "seed" exemptions. All will be published for discussion in the near future.

The United States does have prior legislation granting patent-like protection to asexually reproduced plants, The Plant Patent Act. The Act eased the patent enablement requirements and does not require a deposit of plant material. Instead a morphological description with an accompanying photograph is all that is required. The Act also provides that a plant patent includes only a single omnibus claim "a *(floribunda rose bush)* as shown and described herein". The Doctrine of equivalents may expand the scope of this omnibus claim some.

With the expansion of the PVP, breeders will have coverage not only to the variety, but also to "essentially derived varieties". While this term remains undefined, this is at least verbiage that expands protection beyond a single variety.

Finally, the United States continues to lead world and the UPOV (Union for the Protection of New Varieties) in a proposition for use of genetic markers to establish distinctness. Currently, the PVP office will allow submission of marker data, but it is not examined.

Proposed regulations should come out later this summer and the USDA hopes to have the regulations in place to start accepting applications in early 2020. As a member of the USDA National PVP Advisory Board, I am privileged to have been a part of some of this discussion, and I will keep you informed when the regulations are available for comment.

For more information on this topic, contact Intellectual Property Attorney, Managing Member, and Chair of the Biotechnology & Chemical Practice Group, Heidi S. Nebel, by calling our office at (515) 288-3667.

Don't Tell A Soul.

At McKee, Voorhees & Sease, attorneys understand that well-kept trade secrets are critical to business success. Keeping business strategies and confidential information protected is our number one priority in order to help businesses grow.

We take pride in helping our clients **protect and utilize their trade secrets**, including licensing, contracts, nondisclosure agreements, and employee policies and procedures. Our attorneys have over 40 years of experience litigating and protecting trade secret rights.

If your client has a potential trade secret matter, call today at (515) 288-3667 and ask to speak with Scott Johnson or Christine Lebrón-Dykeman.

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We've Been and We'll Be

April 30, 2019 & May 2, 2019

R. Scott Johnson presented at the Association of Equipment Manufacturers (AEM) Product Safety & Compliance Seminar and Product Liability Seminar in Des Moines, Iowa. Scott's presentations covered writing instruction manuals accurately and cyber security.

May 16-17, 2019

Nicholas J. Krob attended EntreFEST in Cedar Rapids, Iowa. EntreFEST is a two-day conference, celebrating the spirit of entrepreneurship and innovation where professionals at every level can come together, share ideas, and own their success.

May 17-22, 2019

Bruce W. McKee, Christine Lebron-Dykeman, and Brandon W. Clark attended the International Trademark Association (INTA) Annual Meeting in Boston, MA. The conference brought together thousands of trademark professionals and industry leaders from around the world to network, learn, and discuss key initiatives in the field.

May 31, 2019

R. Scott Johnson presented at the Iowa Association of Corporate Counsel (Iowa ACC) Forum in Des Moines, Iowa. Iowa ACC represents the professional interests of over 180 in-house attorneys at over sixty companies throughout the state. Scott's presentation covered the latest in patent, trademark and trade secret news.

June 12, 2019

R. Scott Johnson is presenting at the Iowa Bar Association Annual Meeting in Des Moines, Iowa. Scott's presentation will cover intellectual property law updates and news.

June 20-22, 2019

Kirk M. Hartung is attending the LEGUS Annual Meeting in Hong Kong, China. The meetings serve as educational and networking opportunities for members. The weekend long event is always held in the location of a member to allow them to showcase their jurisdiction.

June 27, 2019

MVS is attending and sponsoring the James Arthur Albert Foundation Annual Fundraiser, Books & Bricks for Belize in Des Moines, Iowa. The James A. Albert Foundation promotes educational and economic opportunities by providing scholarships, grants and schools for the children, teachers and communities of the Toledo District of Belize.

July 8-11, 2019

MVS is sponsoring the BIO World Congress on Industrial Biotechnology and AgTech, and the IowaBio All Conference Attendees & Member Reception on July 10th in Des Moines, Iowa. Cassie J. Edgar is also speaking at the BIO World Congress conference.

July 29-31, 2019

Heidi S. Nebel, Jonathan L. Kennedy, and other MVS Biotechnology & Chemical practice group attorneys are attending the Association of University Technology Managers (AUTM) Central region meeting in Columbus, Ohio.

If you're interested to learn about what our MVS attorneys attend and learn, please contact them through www.ipmvs.com or by calling 515-288-3667.