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# Recent Trends in Cannabis Patent Litigation

## From the QE Cannabis Industry Litigation Group

This alert discusses developments in the cannabis patent litigation landscape. In particular, the U.S. Patent Trial and Appeal Board ("PTAB") has adjudicated its first cannabis-related *inter partes* review ("IPR") (*Insys Development Company, Inc. v. GW Pharma Limited and Otsuka Pharmaceutical Co.* (IPR 2017-00503)), and the first cannabis-related patent infringement suit is currently being litigated in federal district court (*United Cannabis Corp. ("UCANN") v. Pure Hemp Collective, Inc.* (D. Colo. No: 1:18-cv-01922-NYW)). We also address the current law regarding obviousness (35 U.S.C. §103(a)) and patent-eligible subject matter (35 U.S.C. §101) in the context of cannabis patents.

*Overview of Cannabis-Related Patents*

Despite differences in cannabis's legal treatment between (and across) state and federal levels, the U.S. Patent Office has allowed cannabis-related patents, and the U.S. Government even holds a patent for certain uses of cannabinoids as antioxidants and neuroprotectants that was issued in 2003. Since 1995, the filing and issuance of cannabis-related U.S. patent applications has increased significantly – indeed, more than half of all cannabis patent applications have been filed in the past 25 years.[1] The upward trend in the filing and issuance of cannabis-related patents may be due, in part, to more recent changes in cannabis laws that have helped spur industry innovation. As of the publication of this alert, medicinal use of cannabis is legal in 33 states, recreational use is legal in 10 states and the District of Columbia, and 13 states have decriminalized possession.[2] The U.S. Food and Drug Administration (FDA) has approved three products containing cannabinoids as drugs—Dronabinol (synthetic delta-9-tetrahydrocannabinol or "THC"), Nabilone (a chemical derivative of THC), and Epidiolex (cannabidiol or "CBD").[3] Regardless, disparities in cannabis's legal status has not yet served as an impediment to patentability or the ability to enforce cannabis-related patents in federal court.

*Section 103 – Obviousness Overview*

To be protectable, an invention must not have been obvious. Obviousness is a question of law, involving the scope and content of prior art, and inquiring whether a person of ordinary skill in the art ("POSA") would have been led to combine or modify prior art to arrive at the claimed invention with a reasonable expectation of success.[4]

*Section 103 – Obviousness in GW Pharma*

The issue of obviousness under 35 U.S.C. §103(a) concerning a cannabis-related patent was recently litigated in an *inter partes* review proceeding, *Insys Development Company, Inc. v. GW Pharma*

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[1] https://www.forbes.com/sites/julieweed/2017/07/24/us-patent-office-issuing-cannabis-patents-to-a-growing-market/#475172bb68d4

[2] http://www.governing.com/gov-data/safety-justice/state-marijuana-laws-map-medical-recreational.html

[3] https://nccih.nih.gov/health/marijuana

[4] *Grunenthal GmbH v. Alkem Labs. Ltd.*, 2019 U.S. App. LEXIS 9187, *13-14 (Fed. Cir. Mar. 28, 2019).

*Limited and Otsuka Pharmaceutical Co.* ("IPR2017-00503"). Insys challenged a single independent claim in GW Pharma's U.S. Patent No. 9,066,920 ("the '920 patent"), which covers a method of treatment for their drug, Epidiolex. Claim 1 of the '920 patent reads:

> 1. A method for treating partial seizure comprising administering cannabidiol (CBD), to a patient wherein the CBD is present in an amount which provides a daily dose of at least 400 mg.

Epidiolex is an FDA-approved CBD formulation for the treatment of two severe forms of epilepsy: (1) Lennox-Gastaut syndrome; and (2) Dravet syndrome. Though Bank of America analysts estimate 2019 sales of Epidiolex at $74 million, 2027 sales are estimated to reach $2.2 billion.[5]

Insys argued that the claim was obvious under 35 U.S.C. §103(a).[6] Its obviousness argument was primarily based on prior art that taught the administration of CBD to treat epilepsy, but did not teach the claimed daily dosage of at least 400 mg. In view of this argument, the PTAB instituted the IPR.[7]

In its Final Written Decision, the PTAB found claims 1 and 2 of the '920 patent unpatentable but found claims 3-13 patentable. Because CBD is non-toxic and does not impair cognitive function, the PTAB found that a POSA would have known to increase the daily dosage to 400 mg or more by routine optimization.[8] Dependent claims 3-13, however, were directed to additional limitations that the PTAB concluded were not found within the cited prior art, such as combination therapies with other cannabinoids, using CBD and other cannabinoids as plant extract, and using pure, isolated CBD. The PTAB concluded that these additional limitations were not found in the submitted prior art.

This holding provides an example of how obviousness may play a role in other cannabis patent litigations. Cannabis patents are enforceable and treated like other patents. The obviousness issues that cannabis patents may face are complicated by the apparent fact that cannabis research has been limited, among other reasons, due to decades of prohibition.

*Section 101 – Patent-Eligible Subject Matter Overview*

Under 35 U.S.C. §101, Congress allowed four categories of patent-eligible subject matter: (1) processes; (2) machines; (3) manufactures; and (4) compositions of matter. The U.S. Supreme Court has identified three categories of exceptions to these patent-eligible subject matters—also known as patent-ineligible subject matters: (1) laws or products of nature; (2) physical phenomena; and (3) abstract ideas.[9] Moreover, natural products—such as naturally-found chemicals, life forms, and substances—fall within the patent-ineligible subject matter of "products of nature."[10] Thus, cannabis-related patents may face Section 101 challenges.

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[5] https://www.benzinga.com/markets/cannabis/19/02/13248930/gw-pharmaceuticals-sees-68-q1-revenue-growth-following-epidiolex-lau?mod=mw_quote_news

[6] IPR2017-00503 Institution Decision at 4.

[7] *Id.* at 20.

[8] IPR2017-00503 Final Written Decision at 19.

[9] *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

[10] *See* 35 U.S.C. §101.

*Section 101 in UCANN v. Pure Hemp*

The applicability of Section 101 to a cannabis-related patent is being litigated in *United Cannabis Corp. (UCANN) v. Pure Hemp Collective, Inc.* The Complaint alleged infringement of U.S. Patent No. 9,730,911 ("the '911 patent") which claims specific liquid cannabinoid formulations (*e.g.*, specific percentage concentrations of tetrahydrocannabinolic acid ("THCa"), CBD, THC, cannabinolic acid ("CBDa"), and/or cannabinol ("CBN")). Dependent claims include further limitations for various terpenes, flavanoids, and formulation types.

UCANN claimed that Pure Hemp infringed at least claim 10 of the '911 patent because UCANN tested Pure Hemp's liquid CBD product and found that it contained at least 95% CBD in its cannabinoid profile (claim 10 was directed to 95% CBD liquid formulations).[11] In its Answer, Pure Hemp stated that CBD has been a known molecule since it was isolated in 1963, liquid CBD formulations have been available since at least 2011, and that the idea of formulating these concentrations of cannabinoids into liquids was not novel.[12] Further, Pure Hemp argued that the '911 patent claimed unpatentable subject matter because CBD is a naturally-occurring compound.[13]

On November 29, 2018, Pure Hemp filed a motion for partial summary judgment based on its §101 arguments—that these cannabinoids are naturally-occurring and unpatentable. After the U.S. Patent Office issued its Revised Patent Subject Matter Eligibility Guidance ("Guidance") stating that a patent claim is not "directed to" patent-ineligible subject matter if the subject matter is integrated into a practical application,[14] UCANN argued that the cannabinoid profiles in its patent have practical medicinal applications. Pure Hemp responded that the Guidance's "practical application" analysis is not authoritative. Pure Hemp argued that the Supreme Court and Federal Circuit's "conventional, routine, well understood" analysis is authoritative and that an invention may be unpatentable if it is conventional, routine, and well understood. And, Pure Hemp argued that the '911 patent claims are nevertheless unpatentable under the Guidance because "they merely limit a natural phenomenon to a particular technological environment."[15] Therefore, according to Pure Hemp, the '911 patent does not do enough to transform a natural product into something inventive.

It will be important to monitor this case closely to see how the district court rules on the partial summary judgment motion based on Section 101. At the least, this case may provide some first insights into judicial thinking about Section 101 challenges as they relate to cannabis-related patents.

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11 *UCANN v. Pure Hemp* Complaint at 6.
12 Pure Hemp's Answer at 7-8.
13 *Id.* at 9.
14 https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf
15 Pure Hemp's Response to UCANN's Briefing on Supplemental Authority at 5.

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If you have any questions about the issues addressed in this memorandum, or if you would like a copy of any of the materials mentioned in it, please do not hesitate to reach out to:

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