

DEVELOPMENTS IN PROTECTING CANNABIS IP

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Intellectual Property Practice Alert
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Following a noteworthy year for the cannabis industry, medical marijuana is now making strides in the Patent Office.

In a recent *inter partes* review (“IPR”) before the Patent Trial & Appeals Board (the “Board”), the Board upheld the validity of eleven out of thirteen patent claims of a method patent related to the use of one or more cannabinoids[1] (one example is cannabidiol, CBD) in the treatment of epilepsy to minimize or eliminate seizures.

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By way of background, Insys Development Company, Inc. (“Petitioner”) filed a petition requesting *inter partes* review of claims 1-13 of U.S. Patent No. 9,066,920 (the “’920 Patent”), owned by GW Pharma Ltd. at Otsuka Pharmaceutical Co., Ltd. (“Patent Owner”). The ’920 Patent claims are directed to the use of CBD in the treatment of epilepsy, in particular generalized or partial seizures. One objective of the ’920 Patent is “to determine dose ranges which are likely to prove effective” in treating seizures associated with epilepsy. See ’920 Patent, Col. 3, lines 33-34.

Petitioner showed by a preponderance of evidence that independent claim 1 and dependent claim 2 of the ’920 Patent were obvious over cited prior art.[2] For context, claim 1 recites:

A method of 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.

Specifically, Petitioner argued, and the Board agreed, that prior art teaches treatment of epilepsy with CBD and that one of ordinary skill in the art would have concluded that the claimed dosage in claim 1 of the ’920 Patent, of at least 400 mg of CBD, is “predictable, safe and expected.” See *Insys Dev. Co., Inc. v. GW Pharma Ltd.*, 2019 WL 101791 (PTAB Jan. 3, 2019), at *6. Thus, the Board held that claims 1 and 2 of the ’920 patent are invalid as obvious over prior art. *Id.* at *7.

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Although the Board deemed claims 1 and 2 invalid, it upheld claims 3-13 of the '920 Patent, finding that these cannabis treatment related method claims are non-obvious, inventive and therefore valid. The distinction, according to the Board, is that claims 3-13 of the '920 Patent cover more defined treatment and dosage methods for use of cannabis to minimize seizures in patients with epilepsy. For example, dependent claim 3 recites a method wherein the CBD is used in combination with another cannabinoid, tetrahydrocannabivarin (THCV).

This is a significant decision for the cannabis industry. It is an example of how patent protection can be obtained for cannabis-related use, which may have an impact on the growing acceptance of medical marijuana in the country.

For more information on the protectable intellectual property developed by your cannabis company and continued developments in the industry, contact Jessica L. Copeland or Melissa N. Subjeck.

[1] Cannabinoid acids are produced by the cannabis plant. The cannabinoids developed and used for medical marijuana are generally not produced directly from the plant, but developed through synthesizing acids. See <https://www.leafly.com/news/cannabis-101/list-major-cannabinoids-cannabis-effects>

[2] Claim 1 is the only independent claim in the '920 Patent. The upheld claims 3-13 are dependent claims.

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