THE
NATIONAL LAW REVIEW

PTAB Brings Promise to Pot Patent Protection

STARK & STARK
ATTORNEYS AT LAW
Article By
Gene Markin
Stark & Stark
New Jersey Law Blog

- Biotech, Food, Drug
- Intellectual Property

- New Jersey

Wednesday, April 3, 2019

The Patent Trial and Appeal Board (PTAB) issued an opinion earlier this year lending support to those interested in seeking patents related to cannabis. GW Pharmaceuticals, a U.K. company focused on therapeutic cannabinoids, walked away with a partial win concerning a patent that involved the use of cannabinoids to treat epilepsy.

This decision was part of an *inter partes review (IPR)*, a PTAB trial proceeding where third parties can challenge the validity of claims of a patent that the U.S. Patent and Trademark Office has granted. Here, Insys Development Co., Inc. challenged U.S. Patent No. 9,066,920 ("the '920 Patent") for use of one or a combination of phyto-cannabinoids in the treatment of epilepsy, which was originally assigned to GW Pharma and Otsuka Pharmaceuticals Co., Ltd.

GW Pharma previously made history when it became the first entity to receive FDA approval of Epidiolex, a drug for epilepsy containing CBD, an active ingredient derived from the cannabis plant. CBD is a nonpsychoactive cannabinoid that does not produce a "high," which is caused by the THC cannabinoid.

CBD is being heavily studied and is showing great promise as a nutritional and wellness supplement; products infused with CBD are currently being used to treat the pain and symptoms resulting from a wide range of medical conditions, such as epilepsy, multiple sclerosis, and arthritis.

Generally, in order to obtain a patent for an invention, the applicant must make a

sufficient showing that the invention is (1) of the type of subject matter eligible for protection, (2) novel in that at least some aspect of it must be new, and (3) non-obvious. In challenging GW Pharma's patent, Insys attempted to demonstrate that the public knew about the claimed technology before GW Pharma filed for its patent, negating the novelty and/or non-obviousness of the invention and allowing for patent invalidation.

Insys sought to cancel all thirteen claims of the '920 Patent as obvious based on three different combinations of references, including scientific articles describing two studies from the 1980's that examined the potential for CBD to treat epilepsy as well as one of GW Pharma's own published Patent Cooperation Treaty applications. Independent claim 1 of the '920 Patent (which the other 12 claims derive from) reads:

> *A method of treating partial seizure detailing administering CBD to a patient wherein the CBD is present in an amount which provides a daily dose of at least 400 mg."*

Dependent claim 2 of the '920 Patent reads:

> *The method of claim 1, wherein CBD is present in an amount which provides a daily dose from 400 to 800 mg.*

The first issue the PTAB considered was whether the term "partial seizure" needed to be construed. GW Pharma, however, did not dispute that the asserted references applied to the treatment of partial seizures, and therefore the PTAB did not find it necessary to construe the term in order to determine the patentability of the challenged claims.

The parties also argued over whether certain experts were qualified to opine on the patented technology. For the obviousness challenge, Insys argued that all claims were obvious because a person of ordinary skill in the art ("POSA") would know that a claimed daily dosage of at least that amount in the '920 patent was predictably safe and expected. It supported this assertion through the scientific studies mentioned above.

This was not surprising, given that dosage ranges are often challenged and argued during prosecution of biotechnology and pharmaceutical patent applications. GW Pharma countered that at the time of the patent's creation, CBD's potential medical benefits made at best a "promising candidate for further study," meaning a POSA would not expect CBD to treat partial seizures at all, let alone at a dose of 400 mg or higher.

After weighing these two arguments, the PTAB concluded that claim 1 (the broadest claim of the patent) and dependent claim 2 were obvious over two of the three asserted combinations of references and invalidated them. Both combinations relied on the same primary reference of clinical studies regarding CBD's effect on epileptic patients, notwithstanding describing a lower dose than 400 mg, because a POSA would still believe that the amount of CBD could be safely increased to at least 400 mg, since at that time, people knew humans generally tolerated CBD without serious side effects for doses up to 600 mg.

In contrast, The PTAB ruled for GW Pharma on claims 3-13 because Insys failed to identify where most of the limitations on those claims were disclosed in the prior art and did not offer expert testimony on the issue. Therefore, Insys could not demonstrate obviousness of the invention.

With 11 out of 13 claims affirmed, the ‘920 Patent remains largely intact with claims that are fairly broad. This decision has great significance for patent rights, which are enforced through federal law, and since cannabis remains a Schedule I illegal substance under the Controlled Substance Act, inventors and businesses can now be sure that cannabis patent rights could actually be asserted and protected.

Putting aside issues of a potential appeal of the Final Written Decision, GW’s cannabis patent was treated identical to any other patent facing an IPR challenge, which bodes well for cannabis patent owners and prospective owners.

Some commentators believe this approach will be followed by federal courts in a patent infringement case pending in the District of Colorado, *United Cannabis Corporation v. Pure Hemp Collective, Inc.,* which has not yet addressed the Schedule I status of cannabis.

Courts and the industry should also expect to see more patent infringement lawsuits and/or IPR challenges to proposed cannabis patents, in addition to more patent application filings as courts begin recognizing legitimate canna-patent infringement cases.

Above all, cannabis entrepreneurs are reminded of the importance of seeking patent protection; that protection will become more and more valuable as the market continues to normalize and expand and inventors seek to register their new devices to keep up with the growing industry.

Source URL: https://www.natlawreview.com/article/ptab-brings-promise-to-pot-patent-protection