

Canna We Talk Cannabis? Not So Patently Obvious: Patent Infringement in the Cannabis Industry

March 02, 2020



There are many obstacles and complexities that cannabis companies face in securing IP rights on their products. In this podcast, Carlton Fields intellectual property attorney Coy Stull discusses a

pending patent infringement case involving two cannabis companies, and the key takeaways for entities selling CBD products.

Transcript:

Kevin McCoy: Welcome back. We are here at Canna We Talk Cannabis at Carlton Fields and this is our third podcast on issues impacting those in the cannabis industry. I'm Kevin McCoy. I'm the co-chair of our National Cannabis Taskforce. I'm based here in Tampa. I had the opportunity recently to talk with one of our specialists here, the guru of intellectual property about some additional cannabis issues that I thought our audience might be interested in. Coy Stull is joining us today and, as I said, he focuses his practice here at Carlton Fields on intellectual property issues including patent issues. And we have a very interesting case that those in the cannabis space, particularly those who are dealing with CBD, should be aware of. So, without further ado, Coy, why don't you introduce yourself to our audience and then we'll just right into it.

Coy Stull: Thank you for that kind introduction. My name's Coy Stull. I'm predominantly a patent lawyer. I have a background in chemical engineering and for the past 12 years or so, I've been focusing my work on chemical patents and technology patents. So, I have a pretty broad base, but a lot of my experience is related to issues like the one Kevin just mentioned - patents that are directed to chemical products. And that's what this is.

Kevin McCoy: So let's first introduce the audience to the case and kind of acquaint them with what's going on in the particular case. And why don't you explain what is the core issue and what the name of the case is and then we'll kind of work through why this is such an interesting case for not only those who specialize or track what's going on in your particular practice, but everybody across the spectrum that's dealing with cannabis.

Coy Stull: Sure. This case was filed in July 2018 and it was filed by a company called United Cannabis Corporation who owns a patent that they received in, I believe 2017 is when it was issued. They filed this case for patent infringement against Pure Hemp Collective. These are two Colorado companies. And, UCan, who I will abbreviate as that's the plaintiff - United Cannabis Corporation - asserted that the Pure Hemp's products infringed the patent that had been issued.

Now, what does that mean, patent infringement? A patent includes something called a claim, and one of the claims in this patent is directed to liquid formulations that include CBD, particularly a formulation that include cannabinoids with CBD exceeding 95%, which is arguably many formulations on the market.

Kevin McCoy: So, when we're talking about CBD, we're talking about the stuff that everybody's seen on the internet, that it's everywhere in products, it's in edibles, it's in vapes, it's in tinctures, it's in

patches. Same stuff here. And this is an effort by one of these companies to basically claim the market. Is that a fair assessment?

Coy Stull: That's a fair assessment and that's precisely what Pure Hemp, the defendant, has asserted that this case is all about, that this is an attempt to monopolize the entire supply chain and market for liquid CBD products. That is directly in their pleadings.

Kevin McCoy: You mention that this is a test case. What does that mean in the world of IP and for those who are not involved in the case by should be monitoring this case if they're in the cannabis industry?

Coy Stull: So, the reason I mention that it's a test case is because this case, this claim could arguably be asserted against many entities. For instance, all the entities you see selling CBD products that have formulations with pure CBD or, you know, arguably pure CBD in them.

Kevin McCoy: So, wait. If you're a company right now that is selling a pure isolate or even a spectrum pure liquid CBD and that's your formulation, then this case could potentially impact your ability to do business without what? Well, I guess your ability to operate and then secondly your ability to operate without paying the plaintiff here a royalty.

Coy Stull: Yeah, that's correct. So, for instance, say these claims are valid and we can get to that, you would have to pay for a license or risk a patent infringement suit for damages against you, like the one being asserted against Pure Hemp right now.

Kevin McCoy: Why is the patent that's at issue unique? Why isn't there a flood of this litigation already?

Coy Stull: That's a good question. And it's probably because they are going to see if the claims in this patent are upheld by the court. People probably don't understand the patent system. Many don't. Claims come out of the patent office and they issue a patent to you. And you say, "That's the end of it, right? I have a patent." Well, it's not the end of it. Courts are the final arbiter of any patent, which means there are many reasons why a patent can be invalid. For instance, CBD products like this could have been on the market before the patent was filed or somebody described them. And that's what's being asserted here. And you can continue to do that in a court case. Just because the patent office didn't bring it up doesn't mean it's the end. The court is the end arbiter.

Kevin McCoy: What is the core legal issue that's going to be determinative of the outcome here? I mean, I'm sure there are a laundry list of defenses and everything else, but when you distill this down what's the core issue that the court's going to have to decide?

Coy Stull: Actually, the parties are already agreeing on that core issue right now. The issue is going to be the validity of this patent. The parties are negotiating infringement of the claims, which are probably true. The products at issue almost certainly infringe. I haven't seen the results or anything, but they probably do. And they're also negotiating damages. They just want the core issue to decide by the court is whether the claims in this patent are valid. And the core issue about that is essentially whether these kinds of products existed prior to when this patent was filed which was 2014. That is when United Cannabis Corporation filed their first application with the patent office.

Kevin McCoy: What are some of the reasons why you wouldn't be able to get a patent or maybe you shouldn't be able to get a patent on a substance that some would argue is naturally occurring like cannabidiol or formulations of cannabidiol which come from a plant that's been around forever?

Coy Stull: Sure. So, there are actually bars to those things. And that was already litigated in this case. In fact, litigated very quickly. Three things that you cannot patent, or are not even eligible for patent is more accurate, are laws of nature, natural phenomena, and abstract ideas. The issue here is natural phenomena, as you bring up. For instance, a plant that exists in nature. You can't patent that. You can patent specific kinds of plants, asexually reproduced plants. That's not an issue here. That's a totally separate type of patent. The issue here is whether these kinds of claims are directed to natural phenomena. Pure Hemp brought that up four months into the case. They said they are directed to natural phenomena. The judge decided that issue quickly and they lost.

Kevin McCoy: And why did they lose on that natural phenomena issue?

Coy Stull: So, the court said, and I will use the court's words because this particular judge really understands this case. He put a lot of thought into this opinion, and I think he understands that people are watching this case. He said, "The claims here are not like anything found in nature. The precise concentrations - 95% CBD - do not occur in liquid form in nature." And that's true. Right? There is no plant on earth that has 95% liquid CBD. And that's what the judge said. He said it's that simple; that's not natural.

Kevin McCoy: So, to kind of turn the corner on that, is what he's saying that you can get a patent on the fact that you have extracted out the CBD, cannabidiol, into a liquid form? You can't patent the plant itself, but once you get to a place where you move away from just the plant, which you can't patent, and you put it into a different form, the judge said now you're outside of the natural phenomenon?

Coy Stull: That is absolutely correct and it's a great summary of what took the Supreme Court almost 100 years to get to about what separates nature from sort of a patent-eligible extract or sort of a slight separation from nature, which, again, that has been litigated for a long time in patent law.

Kevin McCoy: So, we move, well, I guess the defendant comes out of that and has to move on to this next phase. So, what's going to be the timeline for a decision on this? And then I want to talk about what should everybody else in the market be doing, if anything, while this is happening and their potential business is sitting on the sideline watching the events?

Coy Stull: That's a great question. And I think Pure Hemp has brought that up that basically this monopoly attempt could shut down the entire industry if they really wanted it to. The risks are large. What I can tell you is, there has apparently been letters sent out by UCan to certain entities. I don't know that for a fact. That's what Pure Hemp has said. Now, if you've received one of those letters, you probably should talk to an attorney about what the ramifications are for you. I don't think they've sent them to every entity that's marketing these types of products, or allegedly infringing products. But the question is, how much risk is out there? Pure Hemp would say there are no damages here because this is an invalid patent. And they have been very clear about multiple sources of what we call prior art.

Kevin McCoy: What does that mean, because that sounds like what you would call - prior art sounds like a term of art.

Coy Stull: It is a term of art.

Kevin McCoy: It has a special meaning?

Coy Stull: It has a special meaning in the patent world. It essentially means things that were written down or brought out into the public prior to your filing of the patent application. Priority is essentially everything when it comes down to novelty because you can't get an invention that's not novel. And Pure Hemp has laid out in fairly detailed form in some of their pleadings all of the prior art items and disclosures that indicate that liquid formulations of 95% CBD were in the art well before 2014. It wasn't an issue of a year before or two years before. They're citing things from 1960s.

Kevin McCoy: Sure. I mean, people are just distilling down the elements of the plant into the liquid format, right? That's essentially what they're claiming.

Coy Stull: That's correct.

Kevin McCoy: Alright. So, how does the interaction with Epidiolex, which for those who are listening and aren't familiar, is an FDA approved drug that has high concentrations of CBD in it that is used to treat epilepsy in children. How does that interplay with this particular case and are there any arguments that are being made about Epidiolex's position in this space, or the company that, I should say, owns or created Epidiolex?

Coy Stull: Yes, there actually is one particular very what I'd say is very detailed patent-type argument that is being made by Pure Hemp where epidiolex, that company, that GW Pharmaceuticals has a patent and Pure Hemp has accused UCan of what is effectively plagiarism in taking swathes of that patent and incorporating it into their own and basically saying, "You should have told the patent office that you did that." Right? Because that prior patent, the GW Pharma patent existed prior to their own. And what they're saying is, "You should have told the patent office that you copied portions of that." And that's a technical patent argument. It's made frequently. People do copy, but in the sense there's two arguments being made that this material existed prior to their own patent and you're not allowed to plagiarize.

Kevin McCoy: So, as I'm thinking that through, though, that could help out the current defendant, but what about everybody else? Doesn't that make the position of epidiolex's creator, does that make them stronger or does it not affect them at all?

Coy Stull: Not knowing enough about what their particular formulation is, they existed prior to that. They obviously, if their formulation that they had prior to this arguably infringes this current formulation, they may have an argument that essentially their own product is prior art.

Kevin McCoy: Understood. Going back to what folks in the industry can do, if anything, I mean, is there anything that people out there making product can do right now? Are there any ways that they can be involved here or they can deal with the outcome? Because this is kind of being adjudicated while they're sitting out doing business and it's like having your rights determined while you're sitting on the sideline.

Coy Stull: Yeah, so this is a district court case. So, there's not much role they can play in this particular case. I'm sure maybe they if wanted to donate to Pure Hemp's cause they probably wouldn't refuse that money. I will say that this case, however it's decided, one way or the other, for or against UCan's patent, it will ultimately end up in a federal circuit which is the appeals court where all patent disputes end up. And at that point in time I suspect many of the organizations associated with the cannabis industry will start filing amicus curia, you know, because all of the ramifications of this particular case. Because, as stated by Pure Hemp, this affects everybody and this case is going to affect them one way or the other. Right? It's a test case if the patent is upheld. That is going to be bad news probably for the industry, although not necessarily the end. There could be, you know, you could try to litigate validity in another way. But, still, that's unlikely, and the result of this case will likely affect all of the parties one way or the other.

Kevin McCoy: If this was ultimately upheld and they wanted to send out more letters and do all of that stuff, I mean, they're going to track down, they're going to have to go after an entire industry and one by one. Right? Because just because you get a letter, everybody's going to have their own

defense, everybody's going to have their own claim and try to get around their particular circumstance.

Coy Stull: Yeah, that's absolutely true. So basically every accused product is different, unless you can somehow prove they are the same, but they will have to go after each individual entity and their product and prove infringement. That's required under the law. Essentially that that product contains 95% cannabinoid CBD or greater.

Kevin McCoy: And it's only the liquid stuff.

Coy Stull: Only liquid.

Kevin McCoy: Well, any final words or parting thoughts that you can give our audience on this case or the take-aways as we wrap up today's session?

Coy Stull: Yeah, my final thought is that the judge initially appears to be very skeptical of the novelty of this particular product. He has called out the patent itself for having numerous statements that show a lack of novelty. I'm not saying that's completely unusual, but he was doing it in a format where he didn't necessarily have to do that. The judge has a very strong grasp of this case in my opinion. I have read the pleadings. And he understands all these issues, even the ones that involve, you know, fairly complex chemical technology. So, I suspect that this will be a well-informed decision, one way or the other. And, you know, given his previous statements, there is a strong likelihood that this patent may be invalidated. But, I give one strong caveat in litigating patent cases before: the burden to invalidate a patent is very difficult. It requires clear and convincing evidence. That's not the typical situation where it's preponderance. It's hard. Right? It's supposed to be hard because the patent office had their say.

Kevin McCoy: Right. You're coming in behind a government agency to basically check their work and try to undermine their expertise essentially.

Coy Stull: Exactly. That is the argument that every patent holder makes in the entire universe, that the patent office is the expert here. But, sometimes that can backfire because truly, who gets to be the expert in the end? It's the judge. And the judge is going to decide this case. And it's not unheard of that patents are invalidated by judges. As a matter of fact, it happens all the time.

Kevin McCoy: You mentioned the judge here, and forgive my ignorance on this, but I presume that all of this is judge decision. There's no jury involved in anything that's going to happen here.

Coy Stull: If and when infringement is eliminated from this case and damages are taken out of this case, the judge will decide the validity of this case. It is his province to decide the validity. That is a

matter of law. Sometimes in cases involving damages, there will be fact findings by a jury, but ultimately the validity of this will be decided by the judge and then the federal circuit, without giving deference to the judge will uphold it one way or another because it's a matter of law.

Kevin McCoy: So that means it's going to get a complete fresh set of eyes no matter which way he goes if somebody takes it to appeal?

Coy Stull: That is absolutely correct. And patent cases are almost always appealed to the federal circuit because given that there are issues of validity and decided by law, there's a good chance of reversals. And they do happen quite frequently because the federal circuit is divided frequently and people have different views.

Kevin McCoy: Understood. Well, I hope this was helpful to the audience. It was certainly enlightening to me to hear what's going on because we get very consumed with the growth of the industry and the projections of the industry and multiple billions of dollars of growth year over year and where this is headed. But then you read about a case like this and it kind of stops you in your tracks a little bit. You know, test case or however you couch it, this is a play that's being made here to grab the industry. So, I can't say that I disagree with the characterization of the defendant here.

But, this is another installment of *Canna We Talk Cannabis?*. I hope it's been helpful to the audience. I hope it's thought provoking. I appreciate, Coy, you coming in and chatting with us today about these issues because this impacts everybody and it's something that everybody should be thinking about. Please be sure to subscribe to our blog and our podcast. You can find them at Carltonfields.com (at *Canna We Talk Cannabis?*) where we have regular updates on issues affecting the entire industry whether you're on the high THC marijuana side or you're dealing with CBD or areas in between. So, Coy, thank a lot. And with that I think we'll sign off.

Presented By



Kevin P. McCoy



J. Coy Stull

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