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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Ron Kramer, an Arizona resident; Sal Abraham, a Florida resident; ThermoLife International LLC, an Arizona limited liability company,

Plaintiffs,

v.

Creative Compounds LLC, a Nevada limited liability company,

Defendant.

Creative Compounds LLC, a Nevada limited liability company,

Plaintiff,

v.

Ron Kramer, an Arizona resident; and Sal Abraham, a Florida resident,

Defendants.

Case No. 2:11-cv-01965-PHX-JAT (Lead)
2:11-cv-02033-PHX-JAT (Cons)

PLAINTIFFS' REPLY IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT ON CREATIVE'S NEWLY ASSERTED DEFENSE OF INVALIDITY PURSUANT TO §§ 102(a) AND (b)

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In previous filings, Creative pointed to evidence of Derek Cornelius' testing of DIAC. Creative argued that Mr. Cornelius was a prior inventor of DIAC as a dietary supplement. When faced with case law demonstrating that Mr. Cornelius' limited work and subjective tests could not possibly establish the clear and convincing evidence needed to

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invalidate a patent, Creative repeatedly tried to lower its threshold to survive summary judgment. Creative abandoned its attempt to show prior inventorship. It ignored the clear and convincing standard. Instead, Creative switched its defense to prior use and prior sale—insisting that these defenses had a lower burden. When Plaintiffs countered with case law illustrating that the newly asserted defenses still required reduction to practice, Creative responded not with evidentiary issues regarding reduction to practice but with more excuses why it should not have to meet the necessary standard.

In its Response to Plaintiffs' Cross-Motion for Summary Judgment on Creative's Defense of Invalidity Pursuant to §§ 102(a) and (b) ("Creative's Response"), Creative rests its entire defense on the notion that it does not have to prove anything at all because possession can invalidate a properly issued patent regardless of reduction to practice. Creative cites no case law for this novel concept—and for good reason. Creative's notion that unpublished, undocumented, anecdotal, subjective tests can invalidate a properly issued patent would send shockwaves through several industries. If a defendant could invalidate a competitor's patent simply by claiming that a consultant once possessed the key ingredient and conducted some undocumented and admittedly subjective testing, patent protection would become virtually meaningless. This is the very reason for the maxim, "A party claiming anticipation under 35 U.S.C.A. § 102 because of prior use is put to the strictest of proofs." 3 Pat. L. Fundamentals § 10:9 (2d ed.).

Creative's argument has no basis in the law or, indeed, common sense. The Court should grant Plaintiffs' Cross-motion for summary judgment on Creative's invalidity defenses of prior use and prior sale.

I. THE DEFINITION OF "DIETARY SUPPLEMENT".

Unable to demonstrate reduction to practice in order to prove its defenses of prior use and prior sale, Creative opts for a complicated and extensive logical exercise regarding the definition of the term "dietary supplement." Why this is necessary is unclear as Creative concedes that "the words of a claim are generally given the meaning that the

term would have to a person of ordinary skill in the art in question at the time of the invention." (Creative's Resp. at 2:18-19.) The dictionary defines a "dietary supplement" as "a product taken orally that contains one or more ingredients (as vitamins or amino acids) that are intended to supplement one's diet and are not considered food." MIRIAM-WEBSTER'S DICTIONARY (online version). The medical definition is similar but includes the terms from DSHEA: "a product other than tobacco that is taken by mouth, that contains one or more vitamins, minerals, herbs or other botanicals, amino acids, substances supplementing the diet by increasing the daily dietary intake, or a concentrate, constituent, metabolite, extract, or combination of these, that is not represented as a food or as constituting a meal or the sole item of the diet, and that contains as part of its labeling the words dietary supplement." *Id.*

Creative's entire argument requires the Court to ignore the word "supplement" and the necessary implication that a patented compound must "supplement one's diet." Based on this selective understanding of the term, Creative argues "DIAC is no component of a dietary supplement. Standing alone, it meets the definition of a dietary supplement." (Creative's Resp. at 6:19-21.) But this argument puts the cart in front of the horse. How does DIAC ***supplement*** one's diet? This question can only be answered once the inventor has reduced the invention to practice and demonstrated what DIAC does. Cornelius concedes that he cannot remember the results of his testing other than that he "think[s] people lost a small amount of weight and felt pretty good on it." (T-SOF ¶ 22.) He admits that his tests were "subjective" and the results "anecdotal." (T-SOF ¶¶ 22-26.) He cannot even remember the effect of the DIAC on his blood pressure or weight loss and made no efforts to determine if his weight loss was due to DIAC or other factors. (*Id.* at ¶ 20.) In other words, Cornelius did not ever determine whether DIAC ***supplemented*** a diet at all.

Ignoring this obvious conclusion, Creative doubles down on its argument, insisting: "nothing in Claim 11 requires any such characteristics of DIAC, or even any health benefits at all. All that Claim 11 requires is that Cornelius had possession of the physical em-

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bodiment of DIAC, which Plaintiffs admit they did. Once Cornelius had possession of DIAC, by the terms of the Patent, it qualified as a dietary supplement, and necessarily met all the limitations of Claim 11." (Creative's Resp. at 6:26-7:5.) But the word "supplement" necessarily implies a health benefit. One certainly would not "supplement" one's diet with something that was useless or superfluous. Creative's entire argument rests on this faulty premise.

Even Creative's reference to Claim 11 rings hallow. Creative states, "'Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.'" (Creative's Resp. at 2:20-23 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)). Creative later contradicts itself, concluding that "although the specification speaks almost entirely of using DIAC to promote lean muscle tissue or increasing the proportion of lean muscle mass to adipose tissue, the Court cannot import those limitations into Claim 11." (Creative's Resp. at 4:6-10.) The plain meaning of the use of the term "dietary supplement" in Claim 11 requires some dietary benefit (the supplementation).

Left with no support from the plain meaning of the term, Creative advances a ridiculous argument regarding the statutory definition. Ignoring DSHEA's incorporation of the plain meaning of "supplement," Creative claims that the last clause of the DSHEA definition requiring a product to be labeled as a dietary supplement invalidates the entire definition: "Construction of the term 'dietary supplement' in Claim 11 to include all the details of the statutory definition in DSHEA has the practical effect of rendering Claim 11 essentially meaningless because, to avoid the patent, all someone would have to do is put DIAC in a bottle, but not put the words 'dietary supplement' on the bottle. Claim construction should not lead to such absurd results." (Creative's Resp. at 6:6-11.) Apparently, though, Creative sees nothing absurd in its argument that the mere possession of a substance without any testing for efficacy provides clear and convincing evidence of the in-

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validation of a properly issued patent.

II. CREATIVE HAS NO EVIDENCE OF REDUCTION TO PRACTICE.

Creative's entire Response rests on the premise that Cornelius never had to do anything more than possess DIAC in order to invalidate the patent. As demonstrated above, this argument has no basis in the law or common sense. Once Creative's premise is invalidated, the reason for the argument becomes clear—Creative has no evidence of reduction to practice and no basis to invalidate the patent. Relying on its fatally flawed argument that Cornelius did not have to test for weight loss, Creative does not even try to defend Cornelius' subjective tests. Instead of maintaining that the experiments were intended to test efficacy, Creative argues that Cornelius' "anecdotal" tests were performed for safety reasons required by DSHEA. (Creative's Resp. at 8:21-9:16.) Ignoring the frightening implications that Cornelius used subjective testing for safety requirements, it is unclear how this argument advances Creative's defense. Creative claims that Cornelius needed to perform safety tests in order to market the invention. But as amply demonstrated above, Cornelius never established anything in his testing. His anecdotal results demonstrated neither safety tests nor efficacy. He did nothing and his limited experiments cannot possibly constitute prior use under the law.

Left with no evidence meeting the legal standard for invalidation, Creative points a finger back at Plaintiffs, alleging that the patent does not meet the invalidation standard.[1] (*See* Creative's Resp. at 7:26-8:20.) But Plaintiffs have a properly issued patent. Creative's standard of proof to invalidate that patent differs substantially from the standard required to acquire the patent itself. Creative has the burden to prove by clear and convincing evidence that its own actions establish the basis for invalidation. It has utterly failed to do so.

III. CREATIVE DOES NOT EVEN ADDRESS THE STANDARD REQUIRED TO PROVE PRIOR SALE UNDER § 102(b).

[1] In discovery, Creative failed to disclose any basis for this new theory of invalidation, likely because it has no support for its argument. **(*See* Plaintiff's Statement of Facts in Support of Motion for Summary Judgment, Dkt. #52, ¶29.)** This undisclosed baseless defense should be not be considered now.

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The parties argue past each other. Creative claims the alleged sale counts because (based on its flawed argument) nobody ever had to invent the invention and because the employees of Syntrax are members of the public. But these arguments ignore the tautologous truth that the invention must exist for it to be sold. And as demonstrated above, the invention must ***do*** something in order for it to be an invention. Creative never addresses the Supreme Court's edict that "the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. . . . ***Second, the invention must be ready for patenting***. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67-68 (1998).

Creative never argues that it can meet this standard. And for good reason—meeting this standard is utterly impossible based on the evidence. Accordingly, Plaintiffs are entitled to summary judgment on Creative's prior sale defense.

IV. CREATIVE'S DEFENSES RELY ON UNDOCUMENTED AND CORROBORATED EVIDENCE.

Highlighting Creative's evidentiary deficiency is the fact that Creative intends to meet its burden of clear and convincing evidence with nothing but oral testimony. Creative dismisses the issue: "Plaintiffs' argument concerning corroboration is another red herring." (Creative's Resp. at 14:4.) As an initial note, the reasons stated above are more than sufficient to warrant summary judgment. Creative's lack of corroboration simply provides an evidentiary reason for summary judgment even if the Court were to ignore the uncontested legal reasons stated above.

But Creative's Response is replete with examples of the need for corroboration for the asserted defenses. Creative calls its evidence "undisputed and uncontradicted corroborating evidence." (Creative's Resp. at 14:16.) Creative alleges that "Plaintiffs have admitted that Cornelius had possession of DIAC no later than early 2001. . . ." (*Id.* at 9:19-20.)

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Creative repeatedly paints the evidence as undisputed. Which begs the question, how are Plaintiffs supposed to dispute the testimony of Cornelius if he never kept records? Why should the Court simply accept Cornelius' testimony? The law is clear that the Court does not have to simply accept Cornelius' word for it: "The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony." *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1366 (Fed. Cir. 1999); *see also Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 737-38 (Fed. Cir. 2002) ("When the asserted basis of invalidity is prior public use, the party with the burden of proof must show that 'the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention.' . . . Generally, oral testimony of prior public use must be corroborated in order to invalidate a patent."). This reasoning is sound considering it is ***Creative*** that bears the ***clear and convincing*** burden to establish its defenses.

Creative tries to save its case by relying on Brenda Nixon's oral testimony. But "in light of the absence of any written corroboration and the length of time between the anticipating events and the trial, the oral evidence alone [i]s insufficient to invalidate the patent. . . . The Supreme Court's view of human nature as well as human recollection, whether deemed cynical or realistic, retains its cogency. This view is reinforced, in modern times, by the ubiquitous paper trail of virtually all commercial activity. It is rare indeed that some physical record (e.g., a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other contemporaneous record) does not exist." *Juicy Whip*, 292 F.3d at 742 (quoting *Woodland Trust v. Flowertree Nursery*, 148 F.3d 1368, 1373 (Fed. Cir. 1998)). Creative's argument that Brenda Nixon did not get along with Cornelius does nothing to change the fact that Creative relies on the nearly decade old recollection of an employee in order to establish clear and convincing proof.

In a final effort to excuse its lack of evidence, Creative lists a number of reasons

why it did not keep records of Cornelius' work. (*See* Creative's Resp. at 17:1-18.) Syntrax's choice to not keep records does not lower the evidentiary bar required to invalidate a properly issued patent. That is the trade off for the decisions Syntrax made. Creative's evidence is insufficient and summary judgment is appropriate.

V. CONCLUSION.

Creative seems to have accepted that Cornelius' testimony that at some time over a decade ago he conducted "subjective" tests with "anecdotal" results is not sufficient to invalidate a patent. Creative's solution is to argue that Cornelius did not need to do anything at all. In order to reach this result, Creative ignores the word "supplement" in the term "dietary supplement." According to Creative, a dietary supplement does not have to do anything at all. Creative offers no authority in support of this concept and ignores the copious law calling its entire defense into question.

The simple truth is that Creative lacks any evidence, let alone clear and convincing proof, establishing its defenses of prior use or sale. ThermoLife is entitled to judgment as a matter of law that Creative infringed the '533 Patent and has no defense for doing so.

RESPECTFULLY SUBMITTED this 15th day of July, 2013.

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CERTIFICATE OF SERVICE

I certify that on July 15, 2013, I electronically transmitted the foregoing to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following.

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