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VIA ECF

October 21, 2024

The Honorable Michael E. Farbiarz, U.S.D.J.
United States District Court
Martin Luther King Jr. Fed. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

Re: Jazz Pharm. Res. UK Ltd. v. Teva Pharm., Inc., et al. CV No. 23-cv-0018 (MEF)(AME)

DEFENDANTS' RESPONSIVE SUPPLEMENTAL CLAIM CONSTRUCTION BRIEF

A. CBD: Defendants[1] have met their burden of proving Plaintiff disavowed claim scope, which disavowal is further supported by the prosecution history of the '498 Patent on which Plaintiff now relies in rebuttal. The '498 Patent is not in the same family as the '185 Patent, Ex. A ('185 Patent claims priority to GB 1506550.1 and GB 1410771.8; '498 Patent to GB 1410771), and issued in 2022, 4 years after the '185 Patent. D.E. 309-1 at 5. Plaintiff's excerpt shows that Examiner in 2020, 2 years after the issuance of the '185 Patent, "requested that Applicant 'provide data demonstrating that the sole administration of [at least] 98% pure CBD" was effective. Ex. B (D.E. 319-1 at 74). *See also* Ex. C ("given that Applicant wanted a broader scope (i.e., recitation of the sole administration of CBD. . .), the examiner explicitly requested data supporting such treatment as the specification failed to teach administration of CBD alone[.]") (emphasis added). The Examiner did not find patentee's declaration persuasive because the data did not compare products with unpurified CBD compositions to show that purity conferred superiority. Ex. D. Examiner noted "that applicant's main arguments reside with the purity of the composition of 98% pure CBD . . . such effect is not unobvious as the prior art clearly teaches the use of composition containing CBD with low THC[.]" *Id.* The'498 Patent prosecution history, *years* after the '185 Patent, cements that the specification does not support treatment with CBD alone, "purity" alone could not overcome prior art, "synthetic" data could not overcome prior art, and allowance was obtained by limiting the scope of the claims to a drug substance with some Δ9THC that was NMT 0.15%. [2]

Plaintiff's reliance on Dr. ElSohly's testimony is unavailing. Plaintiff queried Dr. ElSohly about the "specification," not in the file history which shows the repeated disavowals. Ex. E, D.E. 270-1, 88:22-89:5. Plaintiff alleges that Dr. ElSohly testified that purely synthetic CBD "can" contain THC. D.E. 319 at 9. But Plaintiff cannot point to any testimony or evidence that it is possible to produce a stable, purely synthetic CBD with THC within the claimed limits. D.E. 318 at 7-8. Indeed, Plaintiff has told both the FDA and USPTO that purely synthetic CBD does not contain any THC at all. *Id.* at 6-7. Plaintiff's reliance on the '071 Patent also fails because, consistent with all other intrinsic and extrinsic evidence, it does not disclose a purely synthetic CBD composition with THC within the claimed limits. Further, as Examiner in the '498 Patent noted, data with pure synthetic CBD was unpersuasive to overcome prior art because Plaintiff did not establish that it was superior to unpurified CBD. *See supra*, Ex. D. Finally, Plaintiff incorrectly asserts that Defendants' position is that "synthetic CBD . . . would not (and cannot) require a purity limitation." D.E. 319, fn. 9. Defendants' position is that "synthetic" CBD would not require a limitation of NMT of 0.15% Δ9THC, because there was no disclosure showing that it was possible to make a stable, purely synthetic drug substance with some Δ9THC restricted to the claimed limits

B. NMT: Plaintiff mischaracterizes *AK Futures v. Boyd Street Distro*, 35 F. 4th 682 (9th Cir. 2022) for its construction of "NMT." The Court there addressed whether Δ8THC, synthetized from hemp-derived CBD, fell within 7 U.S.C. § 1639o (the "Farm Act"), and was thus eligible for trademark registration. *Id.* at 689. The Court did not determine the "plain meaning" of NMT, and indeed, it is the USDA that defines how the NMT 0.3% THC limit in hemp is determined under the Farm Act. *See* Ex. F, 7 C.F.R. § 990. USDA calculates THC content in hemp as Total THC = (0.877 x THC**A**) + THC. *Id.*, 7 C.F.R. § 990.1. USDA's formula defeats Plaintiff's argument that

[1] Defendants have never conceded that meaning of "synthetic" CBD is irrelevant to construction of "NMT" or "w/w", [D.E.319, fn. 2], and the cited exhibit does not support Plaintiff's overreach.

[2] Regarding Plaintiff's claim-differentiation arguments, Defendants refers to D.E. 271 §§ III.D and V and D.E. 318 § B.

AK Futures shows "hemp" can be free of Δ9THC because the Farm Act's calculation of Total THC also includes THC's precursor THCA. If anything, *AK Futures* shows that the *context* of NMT is important. Here, Defendants' construction is correct in the context of the CBD Patents and should be adopted.

Plaintiff mispresents Dr. ElSohly's testimony as testifying that CBD preparations did not need to contain "some amount of THC to fall within the scope of the claims." D.E. 319 at 12. Rather, Dr. ElSohly testified "it is expected that there is some level there that is less than 0.3 percent." Ex. E, D.E. 270-1, 34:14-16. Indeed, Plaintiff serially *admits* that Δ9THC is relevant to efficacy but tries to diminish it by arguing it treated patients with purely synthetic CBD and Δ9THC's role is a later discovery. First, Plaintiff admits it treated patient(s) with purely synthetic CBD, but patients in the patents received *only* plant-derived CBD. D.E 309-1 at 41. If anything, this shows that Plaintiff believed treatment with purely synthetic CBD was unpatentable. Second, during prosecution of the CBD Patents, Plaintiff represented that Δ9THC had anticonvulsant effects, D.E. 266-99 at 6, ¶19, *i.e.*, that its presence was helpful, not harmful or undesirable. D.E. 318 at 6. Third, Plaintiff's Group 3 claim construction is dependent on Δ9THC being *necessary* in the CBD drug substance to treat seizures. THC's role is not a later invention, but integral in all patents asserted.

C. W/W: During prosecution, Plaintiff calculated the purity of Realm Oil based on the drug product, versus the drug substance. D.E. 318 at 4, fn. 4. Now, Plaintiff seeks to rely on the calculation of Total THC content under the Farm Act. *See* § B. Plaintiff calculated the w/w purity of its drug substance by testing for a few cannabinoids and reagents only, D.E. 266-76, Table 1, and should be held to it, instead of constantly moving the goal posts to suit its convenience.

D. FLAVORING: Plaintiff incorrectly asserts that "there is no dispute that Defendants' proposed (and limiting) claim construction [for 'flavoring'] comes from the extrinsic record." Dkt. 319 at 10. Defendants' proposed construction reflects the plain meaning compelled by the **intrinsic** record, which unequivocally demonstrates that the plain meaning of "flavoring" does not and cannot encompass tastants, such as sweeteners. *See* Dkt. 266 at 26-29; Dkt. 318 at 9-10. In contrast, Plaintiff continues to fail to provide meaningful evidence to support their proposed construction. Plaintiff's sole attempt to muster evidence is a single citation to the Examiner's rejection of claims over the '894 Publication. Dkt. 319 at 10. However, Plaintiff's argument **ignores** the applicant's response to the rejection, which stated: "no combination of references teaches or suggests a formulation 'consisting of' or 'consisting essentially of' . . . **both** a sweetener and a flavoring," Dkt. 270-1 (emphasis added), confirming that the tastant (sweetener) and a flavoring are separate elements which must **both** be present and cannot be conflated. Plaintiff also **ignores** that the Examiner's rejection arises from an erroneous interpretation of the '894 Publication. Dkt. 319 at 10. The '894 Publication does not disclose sucralose as "both a flavoring agent and a sweetener." *Id*. Rather, it states: "**taste-masking or flavoring agents as used herein** are agents that may hide or minimize an undesirable flavor such as bitter or sour flavor" and identifies sweeteners as falling within that combined definition, not as "flavoring agents." Dkt. 271-22 at [0055] (emphases added). Notably, neither party proposed the combined definition set forth in the '894 Publication as the plain meaning of "flavoring." All record evidence confirms that the plain meaning of "flavoring" must maintain the distinction between components that impart only taste (e.g., sweetener) and those that impart flavor. Thus, Plaintiff's unsupported attempt to expand "flavoring" to include components that impart only sweet, salty, or sour tastes, as opposed to imparting flavor, should be rejected, and Defendants' plain meaning should be adopted.

Respectfully submitted,

/s/ Jorkeell Echeverria

Jorkeell Echeverria

JE/ama
cc: All counsel for record via ECF