IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

CANOPY GROWTH CORPORATION, *Plaintiff*	§	
	§	**6-20-CV-01180-ADA**
-v-	§	
GW PHARMACEUTICALS PLC, GW PHARMA LTD., GW RESEARCH LTD., *Defendants*	§	

CLAIM CONSTRUCTION ORDER AND MEMORANDUM IN SUPPORT THEREOF

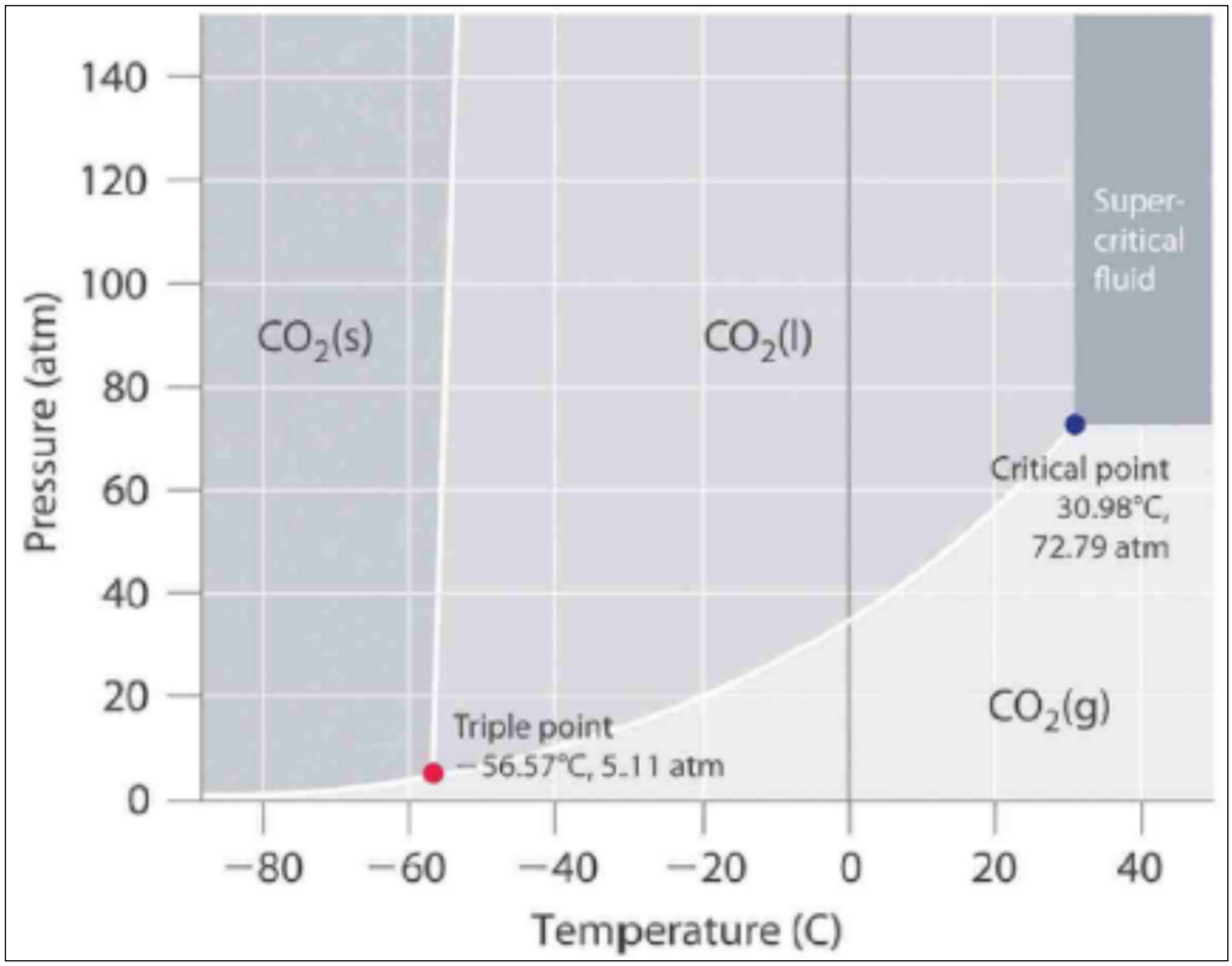
Before the Court are the parties' claim construction briefs: GW defendants' ("Defendants") Opening and (corrected) Reply briefs (ECF Nos. 27 and 32, respectively) and Plaintiff's Response and Sur-Reply briefs (ECF Nos. 30 and 35, respectively). The Court held a *Markman* hearing on October 9, 2021.

I. Background

Plaintiff filed this lawsuit on December 20, 2020 alleging infringement of at least Claims 1 and 14 of U.S. Patent No. 10,870,632. ECF No. 1 at ¶ 21. The '632 Patent is entitled "Process for producing an extract containing tetrahydrocannabinol and cannabidiol from cannabis plant material, and cannabis extracts" and is directed towards "producing an extract from cannabis plant matter, containing tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof." Abstract.

The parties dispute the meaning of "CO_2 in liquified form under subcritical pressure and temperature conditions." Carbon dioxide, CO_2, commonly exists as solid, liquid, or gas. But when both the pressure and temperature are above the "critical point," CO_2 exists as a supercritical fluid.

See, e.g., Response, Ex. 3 at 12.4.1. Supercritical fluid has the characteristics of both a liquid and a gas. Response at 2. The following figure is the phase diagram of CO_2.



Response, Ex. 3. This figure depicts the critical point at a temperature of 30.98°C and a pressure of 72.79 atm (or 73.75 bar). This figure also depicts the range of pressures and temperatures where CO_2 is a supercritical fluid.

II. Legal Standard

The general rule is that claim terms are generally given their plain-and-ordinary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*); *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014), *vacated on other grounds*, 575 U.S. 959, 959

(2015) ("There is a heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time."). The plain and ordinary meaning of a term is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Philips*, 415 F.3d at 1313.

The "only two exceptions to [the] general rule" that claim terms are construed according to their plain and ordinary meaning are when the patentee (1) acts as his/her own lexicographer or (2) disavows the full scope of the claim term either in the specification or during prosecution. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). To act as his/her own lexicographer, the patentee must "clearly set forth a definition of the disputed claim term," and "clearly express an intent to define the term." *Id.*

"Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. "Distinguishing the claimed invention over the prior art during prosecution indicates what a claim does not cover." *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378–79 (Fed. Cir. 1988). The doctrine of prosecution disclaimer precludes a patentee from recapturing a specific meaning that was previously disclaimed during prosecution. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). "[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Id.* at 1325–26. Accordingly, when "an applicant's statements are amenable to multiple reasonable interpretations, they cannot be deemed clear and unmistakable." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1326 (Fed. Cir. 2013).

"Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally

be read into the claims." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988). "[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

Under the doctrine of claim differentiation, a court presumes that each claim in a patent has a different scope. *Phillips*, 415 F.3d at 1314-15. The presumption is rebutted when, for example, the "construction of an independent claim leads to a clear conclusion inconsistent with a dependent claim." *Id.* The presumption is also rebutted when there is a "contrary construction dictated by the written description or prosecution history." *Seachange Int'l., Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005). The presumption does not apply if it serves to broaden the claims beyond their meaning in light of the specification. *Intellectual Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1326 (Fed. Cir. 2017).

Although extrinsic evidence can be useful, it is "'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). Technical dictionaries may be helpful, but they may also provide definitions that are too broad or not indicative of how the term is used in the patent. *Id.* at 1318. Expert testimony also may be helpful, but an expert's conclusory or unsupported assertions as to the meaning of a term are not. *Id.*

III. The Parties' Respective Positions and the Court's Analysis

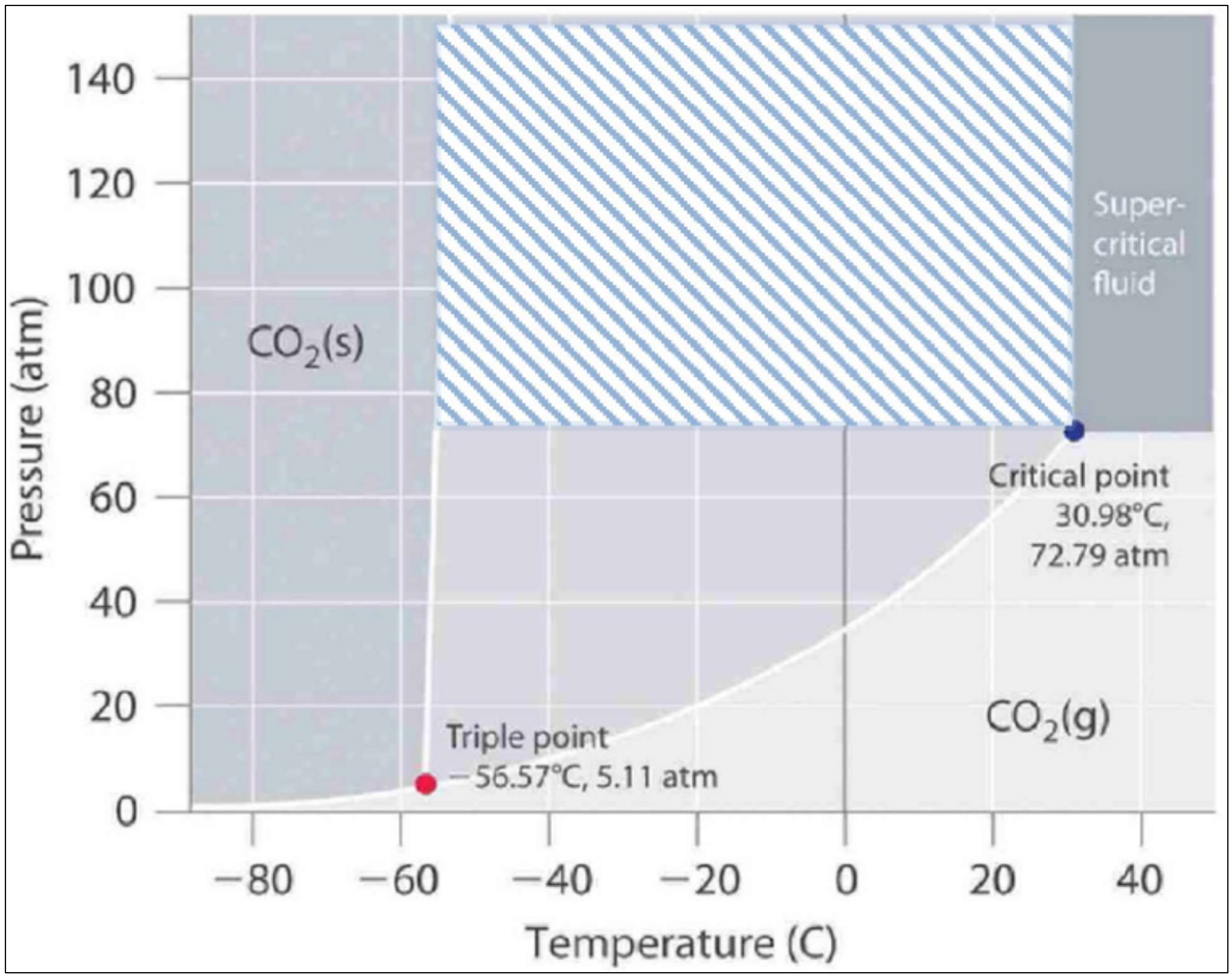
There is only one disputed term. The following table summarizes the parties' respective proposed constructions. [1]

Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"CO_2 in liquified form under subcritical pressure and temperature conditions" U.S. Patent No. 10,870,632 Patent, Claims 1, 14 Proposed by Defendants	Plain-and-ordinary meaning	CO_2 in liquified form under both subcritical pressure and temperature conditions

The key difference between the parties' position is as follows. Defendants contend that "subcritical pressure and temperature conditions" means that both the pressure and temperature need to be below the critical pressure and critical temperature, respectively. Opening at 1. Plaintiff, by contrast, contends that "subcritical" simply means "not supercritical." *See* Response at 8-10. As such, at least according to Plaintiff, because being supercritical requires both the pressure and temperature to be above the critical pressure and critical temperature, respectively, if either the pressure or temperature—but not both—is above its corresponding critical value, then the CO_2 is not supercritical, but rather is subcritical. *Id.*

Pictorially, the dispute for this term centers around whether the striped shaded area in the below figure should be included within the scope of the term. Response at 5-6. Defendants contend that the shaded area is outside the scope of this term while Plaintiff contends that it is within the scope of this term.

[1] A day or two prior to the Markman hearing, the Court provided the parties the following preliminary construction: Plain-and-ordinary meaning wherein the plain-and-ordinary meaning is "CO_2 in liquified form under both subcritical pressure and temperature conditions."



Both sides assert that the claim language, specification, prosecution history, and extrinsic evidence supports its proposed construction. After carefully reviewing the parties' arguments and the applicable law, for the reasons that follow, the Court adopts a form of Defendants' proposed contruction, namely, the Court adopts: plain-and-ordinary meaning wherein the plain-and-ordinary meaning is "CO2 in liquified form under both subcritical pressure and temperature conditions" as its final construction.

It is important to note that while the Court essentially adopts Defendants' proposed construction, the Court does not do so based on lexicography or a finding of a prosecution disclaimer. Rather, the Court bases its decision on the plain language of the claims and the

specification, and to a lesser degree, the prosecution history. Accordingly, the Court believes that the plain-and-ordinary meaning, with a further explanation as to what the plain-and-ordinary meaning is, is the correct construction. *O2 Micro Int'l v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("In this case, the 'ordinary' meaning of a term does not resolve the parties' dispute, and claim construction requires the court to determine what claim scope is appropriate in the context of the patents-in-suit.").

a. Claim language

Arguments in Defendants' Opening Brief

Defendants contend that the claim language supports their proposed construction. Opening at 6–7. In particular, Defendants contend that both claims 1 and 14 recite that the "CO_2 in liquified form under subcritical pressure and temperature conditions" requires that the CO_2 is under both subcritical pressure and subcritical temperature. *See id.* at 6. In support of their contention, Defendants point out that both claims 1 and 14 use the conjunction "and"—as compared to "or"—which indicates that both the pressure and temperature need to be below their respective critical values. *Id.* at 6. Defendants also points out that the claim term uses the plural form of "condition." *Id.*

Arguments in Plaintiff's Response Brief

In response, Plaintiff contends Defendants "overemphasi[zes]" the conjunction "and" and the plural nature of "conditions." Response at 8. Plaintiff contends that this overemphasis "ignores the full context of the claim language and is inconsistent with express embodiments in the specification, which discloses 'subcritical' embodiments in which temperature is below the critical point and pressure is above the critical point." *Id.* (The express embodiments that Plaintiff cites

are described in the specification at 5:10–20 and 6:10–12, and which are discussed in more detail below.)

Plaintiff also contends that some dependent claims support its contention that the term "subcritical pressure and temperature conditions" does not require that both the pressure and temperature need to be below their respective critical values. Response at 9. Plaintiff specifically contends that

> Dependent Claims 3–5 and 16–18 recite either specific pressures below the critical pressure (P_c) or specific temperatures below the critical temperature (T_c) for the extracting step. None of the claims, whether independent or dependent, requires "both" a pressure below the critical pressure and a temperature below the critical temperature, as GW attempts to read into all claims.

Id.

Arguments in Defendants' Reply Brief

Defendants contends that Plaintiff is attempting a sleight-of-hand by striking the words "pressure and temperature" from the claim term to leave the broader "subcritical conditions." Reply at 1-8. More specifically, Defendants contend that Plaintiff's response is directed only at "subcritical conditions" and not "subcritical **pressure and temperature** conditions," which effectively renders "pressure and temperature" to be superfluous. Reply at 1-2, 4 (emphasis added). Defendants also contend that the term "subcritical conditions" does not appear in the claims or the specification. Reply at 1-2. Similarly, Defendants claim that it defies logic and blackletter law that "subcritical conditions" is equivalent to "subcritical pressure and temperature conditions." Reply at 5.

Arguments in Plaintiff's Sur-Reply Brief

In its sur-reply, Plaintiff contends that Defendants' grammatical analysis is incorrect because it is based on "subcritical" modifying "pressure and temperature." Sur-Reply at 2.

Plaintiff contends that the correct reading is that "subcritical pressure and temperature" modifies "conditions." *Id.* To support that argument, Plaintiff points the specification and file history's use of "pressure and temperature conditions subcritical for CO_2." *Id.*

The Court's Analysis

The Court finds that the plain language of the claims supports Defendants' proposed construction for the reasons that follow. Claims 1 and 14 both use the conjunction "and," indicating that "both" pressure and temperature must be subcritical. *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1376 (Fed. Cir. 2008) (affirming the district court's construction of the term "said dial tone actuating switch electronically connected to said phone line and said electronic circuit" to mean "said dial tone actuating switch electronically connected to both the said phone line and said electronic circuit board, such that electricity can pass among these elements."). Had the patentee intended that the scope of either claim encompass either subcritical pressure or subcritical temperature, but not both, the patentee could have simply replaced "and" with "or."

With respect to the claims' usage of the word "conditions," the Court finds that this word does not favor either party's proposed construction. On its face and in a vacuum, the plural form of "condition" could support Defendants' effective proposed construction of "subcritical pressure and subcritical temperature conditions." Opening at 6. But it could also support Plaintiff's position that "pressure and temperature conditions" simply describes the fact that "pressure and temperature conditions determine the phase of CO_2." Response at 8.

With respect to this point, the specification and prosecution history potentially provide support to both sides. For example, Plaintiff correctly contends that the specification consistently uses the plural form when referring to conditions for only one of pressure or temperature.

Response at 8–9 (citing 7:49, 10:31–33). But while these passages recite "subcritical conditions" of pressure or temperature, it is not clear from the face of the specification whether "subcritical conditions" refers to 1) describing that either the pressure or temperature needs to be below its respective critical value or 2) a range of pressures or a range of temperatures.

With respect to the prosecution history, the applicant paraphrased this term as "subcritical conditions of temperature and pressure." Response, Ex. C at Canopy_000000236. Here, "subcritical" directly modifies "conditions," which unambiguously indicates that there is more than one subcritical condition. (By contrast, the word "conditions" in the phrase "subcritical pressure and temperature conditions" is ambiguous whether there is more than one subcritical condition.) Because this passage from the prosecution history recites "subcritical conditions temperature and pressure"—as compared to "subcritical conditions temperature or pressure"—this indicates that both pressure and temperature must be subcritical.

The Court does not agree with to Plaintiff's argument that the dependent claims support its contention that the term "subcritical pressure and temperature conditions" does not require that both the pressure and temperature need to be below the critical values. Response at 9. More specifically, Plaintiff contends that

> Dependent Claims 3–5 and 16–18 recite either specific pressures below the critical pressure (P_c) or specific temperatures below the critical temperature (T_c) for the extracting step. None of the claims, whether independent or dependent, requires "both" a pressure below the critical pressure and a temperature below the critical temperature, as GW attempts to read into all claims.

Id. Dependent claims 3–5 and 16–18 provide:

> 3. The process according to claim 1, wherein in step (1) the CO_2 in liquefied form is at a pressure of 70 bar or less.
> 4. The process according to claim 3, wherein in step (1) the CO_2 in liquefied form is at a temperature of between about 20° C. to about 30° C.

5. The process according to claim 1, wherein in step (1) the CO_2 in liquefied form is at a pressure of about 60 bar.

16. The process according to claim 14, wherein in step (2) the CO_2 in liquefied form is at a pressure of 70 bar or less.

17. The process according to claim 16, wherein in step (2) the CO_2 in liquefied form is at a temperature of between about 20° C. to about 30° C.

18. The process according to claim 14, wherein in step (2) the CO_2 in liquefied form is at a pressure of about 60 bar.

Plaintiff is correct that the dependent claims do not "require[] 'both' a pressure below the critical pressure and a temperature below the critical temperature." Response at 9. But Plaintiff is incorrect that, due to claim differentiation, the independent claims also do not "require[] 'both' a pressure below the critical pressure and a temperature below the critical temperature." *Id.* More specifically, Claims 3 and 16 require that the pressure must be 70 bar or lower while Claims 5 and 18 require that the pressure must be 60 bar or lower. Both of these values are lower than the critical pressure of 73.75 bar. Similarly, Claims 4 and 17 require that the temperature be between "about 20° C to about 30° C," both of which are lower than the critical temperature of 30.98°C. Therefore, because the required pressures and temperature in the dependent claims are lower than their respective critical values, the Court is not required to construe "subcritical pressure and temperature conditions" in the independent claims as requiring that <u>either</u> the pressure <u>or</u> temperature be below its respective critical value, in order to maintain at least one difference between the independent and dependent claims. Rather, the independent claims could be construed as requiring both the pressure and temperature to be below their respective critical values without violating the doctrine of claim differentiation. By contrast, if the required pressure or temperature in the dependent claims were required to be equal to or lower than their respective critical values, then in order to not violate the doctrine of claim differentiation, the Court would have to construe

that "subcritical pressure and temperature conditions" in the independent claims requires that only one of pressure or temperature can be below their respective critical value, but not both.

Finally, the Court finds that Plaintiff's position that this claim term does not require that both the pressure and temperature be below their respective critical values is incorrect because it effectively substitutes "or" for "and."

b. Specification

Arguments in Defendants' Opening Brief

Defendants contend that the specification supports their proposed construction. Opening at 7–9. Defendants primarily point to following passage, which describes extracting the "plant material" according to different temperature and pressure conditions":

> [P]lant material is extracted with the aid of CO_2 under (1) supercritical pressure and temperature conditions at a temperature in the range of approx. [sic], 31° C. to 80° C. and at a pressure in the range of approx. [sic] 75 bar to 500 bar, or in the (2) subcritical range at a temperature of approx. [sic] 20° C. to 30° C[] and a supercritical pressure of approx. [sic] 100 bar to 350 bar; or extracted under (3) subcritical pressure and temperature conditions; and the obtained primary extract is separated under subcritical conditions, or under conditions that are subcritical in terms of pressure and supercritical in terms of temperature.

Id. at 7 (quoting 5:10-20 (typos corrected; numerical annotations added by Defendants)). Defendants contend that this passage describes three different sets of pressure and temperature combinations:

> (1) **Supercritical pressure and supercritical temperature**: pressure is approximately 75 bar to 500 bar (critical pressure is 73.75 bar) while temperature is approximately 31° C. to 80° C (critical temperature is 30.98° C).
> (2) **Supercritical pressure and subcritical temperature**: pressure is approximately 100 bar to 350 bar (critical pressure is 73.75 bar) while temperature is approximately 20° C. to 30° C).
> (3) **Subcritical pressure and subcritical temperature**: pressure is less than critical pressure and temperature is less than critical temperature

Opening at 7. Defendants contends that its proposed construction captures the scope of the third set of temperature and pressure conditions, while Plaintiff's proposed construction of plain-and-ordinary meaning improperly captures the second (subcritical temperature and supercritical pressure) and third (subcritical temperature and subcritical pressure) set of conditions. *Id.* at 8.

Defendants also contend that the specification uses variations of "subcritical pressure and temperature" only in connection with pressures and temperatures that are both below the critical point. *Id.* In particular, Defendants point to the following passages from the specification:

- 7:22–24: "The obtained extract is separated out under pressure and temperature conditions subcricital [sic] for CO_2, preferably at approx. 55 bar and approx, [sic] 25° C."
- 7:51–56: "[I]n the second and third separating vessels, where Δ8-THC and Δ9-THC are separated out, conditions subcricital [sic] for CO_2 in terms of pressure and temperature are to prevail, in the second separating vessel preferably 60 bar and 30° C., in the third separating vessel preferably 55 bar and 25° C."

Id. Because these passages describe that both the pressure and temperature are below their corresponding critical values, Defendants contend that "subcritical" pressure and temperature "conditions" requires that both the pressure and temperature must be below their corresponding critical values, which is only reflected in Defendants' proposed construction. *Id.*

Arguments in Plaintiff's Response Brief

In its response, Plaintiff contends that Defendants' proposed construction is incorrect because the claims use the word "conditions." Response at 7. More specifically, Plaintiff contends that "GW ignores that the claims recite 'subcritical pressure and temperature conditions,' and not just 'subcritical pressure and temperature.'" *Id.* Plaintiff cites to 6:3-12 in support of its argument:

> The extraction process of the invention preferably operates in the supercritical range at a temperature of approx. 31° C. to 80° C. and a pressure of approx. 75 bar to 500 bar, in particular at a temperature of approx. 45° C. to 65° C. and a pressure of approx. 100 bar to 350 bar, preferably at a temperature of approx. 60° C. and a pressure of approx. 250 bar.

> In the subcricital [sic] range, in contrast, a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar are used.

Id. This passage describes two "ranges"—supercritical and subcritical—wherein the subcritical range has a supercritical pressure of approximately 100 bar to 350 bar and a subcritical temperature of approximately 20° C. to 30° C. Based on this passage, Plaintiff argues that "subcritical pressure and temperature conditions" occur when either the pressure or temperature—but not both—are below their respective critical values.

Plaintiff points to 6:3–12 for the proposition that anything that is not supercritical is subcritical. Response at 10 ("The specification contrasts these subcritical conditions from supercritical conditions, in which both temperature and pressure are above the critical point."). Plaintiff also contends that 5:10–20 supports its contention that "subcritical range" may include the combination of subcritical temperature but supercritical pressure. Response at 10.

Plaintiff contends that Defendants are incorrect that 5:10–20 discloses three embodiments. Response at 10-11. Rather, Plaintiff contends that it discloses two embodiments, namely, that the second embodiment ("in the subcritical range at a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar;") is a subset of the third embodiment ("under subcritical pressure and temperature conditions;").

With respect to the two other passages Defendants cited as support for its construction, Plaintiff contends that Defendants incorrectly cite passages regarding "separation" when the relevant claim language focuses of "extraction." *Id.* at 12 (analyzing 7:22–24, 7:57). Plaintiff also contends that these passages use "preferably" which indicates that these examples are non-limiting. *Id.*

With respect to Defendants' argument that the claim term uses the plural form of "condition," Plaintiff contends that "the specification consistently uses the plural 'conditions,'

even when referring to conditions for only one of pressure or temperature." Response at 8–9 (citing 7:49, 10:31–33).

Based on the foregoing, Plaintiff contends that Defendants has failed to prove lexicography and that Defendants' proposed construction would improperly read out an express subcritical embodiment. *Id*.

Arguments in Defendants' Reply Brief

In its reply, Defendants contends that the passages from the specification that Plaintiff cites does not support its proposed construction because 5:10–20 discloses three embodiments, and not the two claimed by Plaintiff. Reply at 5–6. In particular, Defendants point out that the specification never describes the second embodiment as a subset of the third. *Id.* at 7.

Defendants contend that every exemplary embodiment that uses the phrase "subcritical pressure and temperature conditions" describes that both pressure and temperature are below their corresponding critical values. Reply at 7. By contrast, Defendants contend Plaintiff has not pointed to any embodiment that uses the full claim term that describes that the pressure or temperature is above the corresponding critical value. *Id.*

Arguments in Plaintiff's Sur-Reply Brief

In its sur-reply, Plaintiff contends that 5:10–20 and 6:3–12 describe the "subcritical range" and that Defendants only addresses the former passage. Sur-Reply at 3. Plaintiff further contends that the specification uses "or" to describe interchangeable concepts. Sur-Reply at 3 (citing 2:40–44). As such, the second embodiment in 5:10–20 is a subset of the third embodiment, as those are "interchangeable." *Id.* Plaintiff further argues that neither 5:10–20 and 6:3–12:

> contrasts the subcritical embodiment comprising pressure above P_c and temperature below T_c with "subcritical pressure and temperature conditions." '632 Patent at 5:10-20, 6:3-12. Thus, reading the two columns together, as a POSITA would, reveals that the embodiment for extraction in the "subcritical range" and

> "subcritical pressure and temperature conditions" are not mutually exclusive as GW assumes[.]

Sur-Reply at 4.

With respect to Defendants' argument that "subcritical conditions" and "subcritical pressure and temperature conditions" are different, Plaintiff cites *Johnson Worldwide Assocs. Inc. v. Zebco Corp.* for the proposition that "[v]aried use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition." Sur-Reply at 5 (quoting 175 F.3d 985, 991 (Fed. Cir. 1999)). Plaintiff also cites *Nichia Corp. v. Everlight Ams., Inc.* for the proposition that "that if different words are used in the claim and specification, then we must read that distinction as an intended difference." *Id.* (quoting 855 F.3d 1328, 1335 (Fed. Cir. 2017)). Plaintiff contends that the difference between these two terms is "illusory" because: "both the disclosed embodiment and the recited claim phrase use the operative term 'subcritical,' and while one recites 'pressure and temperature conditions' generally the other describes specific conditions of pressure (100 to 350 bar) and temperature (20 ºC to 30 ºC)." Sur-Reply at 5.

The Court's Analysis

The Court finds that the specification supports Defendants' proposed construction for the reasons that follow. First—and most importantly—the Court agrees with Defendants that 5:10–20 discloses three pressure and temperature combinations (as numbered below), as compared with the two combinations Plaintiff advocates, wherein the second embodiment is a subset of the third.

> [P]lant material is extracted with the aid of CO_2 under (1) supercritical pressure and temperature conditions at a temperature in the range of approx. [sic], 31° C. to 80° C. and at a pressure in the range of approx. [sic] 75 bar to 500 bar, or in the (2) subcritical range at a temperature of approx. [sic] 20° C. to 30° C[] and a supercritical pressure of approx. [sic] 100 bar to 350 bar; or extracted under (3) subcritical pressure and temperature conditions; and the obtained primary extract is separated under subcritical conditions, or under conditions that are subcritical in terms of pressure and supercritical in terms of temperature.

5:10–20 (typos corrected and numerical annotations added).

Based on three grammatical and word choice indicators, the Court concludes that Defendants are correct that this passage discloses three separate pressure and temperature combinations. The first indicator is that the word "or" separates each of the three pressure and temperature combinations. Using "or" in this manner is a natural way to separate different alternatives, and not two alternatives with a sub-alternative in the middle as Plaintiff contends.

Separately, the Court also disagrees with Plaintiff's argument that the specification uses "or" to describe interchangeable concepts in 5:10–20 such that the third pressure and temperature combination is "interchangeable" with the second. Sur-Reply at 3. The first problem with Plaintiff's argument is that the plain language of this passage does not indicate that "or" is being used to describe "interchangeable" alternatives. Rather, the use of "or" appears to describe non-overlapping alternatives. The second problem is that even if Plaintiff's argument is correct that this passage uses "or" to describe interchangeable alternatives, because "or" appears twice in this passage (between the first and second, and the second and third pressure and temperature combinations) and because the passage uses a semicolon to separate the second and third pressure and temperature combinations, the second pressure and temperature combination is more likely a subset of and/or interchangeable with the first pressure and temperature combination. Then, at least according to this reasoning, "supercritical pressure and temperature conditions" covers both when the pressure and temperature are each above their respective critical values (combination (1)) and when pressure is above its critical value, but the temperature is below its critical value (combination (2)). As such, "subcritical pressure and temperature" conditions would only cover the situation when the pressure and temperature are both below their respective critical values.

The second indicator in this passage is that it describes "supercritical pressure and temperature conditions" when the pressure (75 bar to 500 bar) and the temperature (31° C to 80° C) both exceed their respective critical values (73.75 bar and 30.98° C). But, when describing the second combination—where the pressure is supercritical (100 bar to 350 bar) and the temperature is subcritical (20° C. to 30° C)—the specification notably does not use the word "conditions," but only describes the temperature as being in the "subcritical range." Simply put, because the specification uses "subcritical range" to refer to either the pressure or temperature being subcritical, the Court concludes that the specification uses the phrase "subcritical pressure and temperature conditions" to refer both the pressure and temperature being subcritical.

The third indicator in this passage is that, although described in the "separation" context, the last portion of this passage differentiates between "subcritical pressure and temperature conditions" and split conditions, *i.e.*, "subcritical in terms of pressure and supercritical in terms of temperature." This indicates that "subcritical pressure and temperature conditions" are met only when both the pressure and temperature are below their respective critical values.

The Court also does not agree with Plaintiff that 6:3–12 supports its proposed construction. This passage provides that:

> The extraction process of the invention preferably operates in the supercritical range at a temperature of approx. [sic] 31° C. to 80° C. and a pressure of approx. [sic] 75 bar to 500 bar, in particular at a temperature of approx. 45° C. to 65° C. and a pressure of approx. [sic] 100 bar to 350 bar, preferably at a temperature of approx. 60° C. and a pressure of approx. [sic] 250 bar.
>
> In the subcritical range, in contrast, a temperature of approx. [sic] 20° C. to 30° C. and a supercritical pressure of approx. [sic] 100 bar to 350 bar are used.

6:3–12 (typo corrected). The first paragraph in this passage corresponds to pressure and temperature combination (1) in 5:10–20, namely, both of these passages describe that both the pressure and temperature are supercritical. *Compare* 5:10–13 *with* 6:3–9. In fact, both passages

recite the same pressure and temperature ranges (75 bar to 500 bar and approximately 31° C. to 80° C). The second paragraph in this passage corresponds to pressure and temperature combination (2) in 5:10–20, namely, both of these passages describe that the pressure is supercritical while the temperature is subcritical. *Compare* 5:13–15 *with* 6:10–12. Both of these passages also recite the same pressure and temperature ranges (100 bar to 350 bar and approximately 20° C. to 30° C). Therefore, because 5:10–20 and 6:3–12 are directed to the same pressure and temperature combinations, for the same reasons 5:10–20 did not support Plaintiff's proposed constructions, 6:3–12 likewise does not support Plaintiff's proposed construction.

With respect to 7:22–24 and 7:51–56, the Court finds that these passages tend to support Defendants' proposed construction more than Plaintiff's argument. Both passages plainly describe that the extract is separated under "conditions subcritical" and that the "preferabl[e]" pressures and temperatures are all below their respective critical values. As such, although it is not dispositive, the Court finds that both of these passages more closely align with Defendant's position than Plaintiff's.

Plaintiff contends that Defendants incorrectly cites passages regarding "separation" when the relevant claim language focuses of "extraction." Response at 12. Although Plaintiff is correct that these passages describe subcritical conditions for "separation" while the asserted claims are directed towards "extraction," Plaintiff has not pointed to anything in the specification or otherwise that explain why the meaning of "subcritical conditions" for "separation" has a different meaning than "subcritical conditions" for "extraction." Rather, because "subcritical pressure and temperature conditions" simply describe a pressure and temperature combination, the action—extraction or separation—that occurs at that pressure and temperature combination is irrelevant.

Plaintiff also contends that because these passages use the word "preferably," they describe non-limiting examples. Response at 12. The Court agrees. But even if these passages do not support Defendants' proposed construction, because these recited pressured and temperature values are not coextensive with the entire range of subcritical pressure and subcritical temperature values, these passages do not provide support for Plaintiff's proposed construction.

c. Prosecution history

Arguments in Defendants' Opening Brief

Defendants contend that the prosecution history also supports its proposed construction for at least two reasons. First, Defendants contend that the applicants distinguished use of CO_2 under subcritical temperature and supercritical pressure during prosecution of the application for the parent patent which eventually issued as U.S. Patent No. 8,895,078. Opening at 9. More specifically, Defendants contend that pending claims of the '078 Patent's application, which ultimately issued as claims 1-3, recite pressure and temperature combinations (1) to (3) from the passage above. *See, e.g.*, *id.* at 9 (citing *id.*, Ex. 4 at 10 (Pending Claim 15), *id.*, Ex. 5 (8,895,078 Patent, Claim 1)).

15. (Currently amended) A process for producing an extract containing tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof from dried comminuted Cannabis plant material, comprising

- extracting said plant material by means of CO_2

(a) under supercritical pressure and temperature conditions at a temperature in a range of approx. $31^{O}C$ to $80^{O}C$ and at a pressure in a range of approx. 75 bar or 500 bar, or

(b) in liquefied form in the subcritical ~~subcricital~~ range at a temperature of approx. $20^{O}C$ to $30^{O}C$ and a supercritical pressure of approx. 100 bar to 350 bar; or

(c) in liquefied form under subcritical ~~subcricital~~ pressure and temperature conditions; and

- separating the obtained primary extract out under subcritical ~~subcricital~~ conditions or under conditions subcritical ~~subcricital~~ in terms of pressure and supercritical in terms of temperature.

Because alternatives (a) to (c) in Claim 1 of the parent '078 Patent, correspond to the three sets of pressure and temperature conditions described in 5:10–20, Defendants argue that "Applicants thus identified 'subcritical pressure and temperature conditions' as a separate and distinct alternative from CO2 at subcritical temperature and supercritical pressure." *Id* at 10. Defendants contend that this indicates that (1) Applicants chose only to claim alternative (c) in the '632 Patent and (2) "Applicants could have drafted the claims of the '632 patent to clearly encompass the scope that Canopy now seeks to capture through claim construction." *Id.*

Second, Defendants contend that the "Applicants narrowed their claims" in response to obviousness rejections. *Id.* at 11. In particular, claim 1 of the original as-filed claims of the application for '632 Patent recited, in relevant part:

> [E]xtracting said plant material by means of CO_2
> (a) under supercritical pressure and temperature conditions at a temperature in a range of approx. 31 °C to 80°C and at a pressure in a range of approx. 75 bar or 500 bar; or

(b) in liquefied form in the subcritical range at a temperature of approx. 20°C to 30°C and a supercritical pressure of approx. 100 bar to 350 bar; or
(c) in liquefied form under subcritical pressure and temperature conditions

Id. at 11 (citing *Id.*, Ex. 6 ('632 patent prosecution history excerpts) at 6). After a § 103 rejection, the Applicants deleted alternative (a) from all pending independent claims. *Id.* at 11 (citing *Id.*, Ex. 6 ('632 patent prosecution history excerpts) at 27).

1. (Currently Amended): A process for producing an extract containing Tetrahydrocannabinol (THC), cannabidiol (CBD) and optionally the carboxylic acids thereof from dried comminuted industrial hemp plant material, comprising

- extracting said plant material by means of CO_2

~~(a) under supercritical pressure and temperature conditions at a temperature in a range of approx. 31°C to 80°C and at a pressure in a range of approx. 75 bar or 500 bar, or~~

(b) in liquefied form in the subcritical range at a temperature of approx. 20°C to 30°C and a supercritical pressure of approx. 100 bar to 350 bar; or

(c) in liquefied form under subcritical pressure and temperature conditions at a pressure of 70 bar or less and a temperature of approx. 20°C to 30°C; and

Applicants also deleted alternative (b) from two of the pending three independent claims (claims 16 and 22). *Id.* at 11 (citing *Id.*, Ex. 6 ('632 patent prosecution history excerpts) at 28–29).

16. (Currently Amended) A process for producing an extract containing tetrahydrocannabinol (THC), cannabidiol (CBD) and optionally the carboxylic acids thereof from dried comminuted industrial hemp plant material, comprising

- extracting said plant material by means of CO_2

~~(a) under supercritical pressure and temperature conditions at a temperature in a range of approx. 31°C to 80°C and at a pressure in a range of approx. 75 bar or 500 bar, or~~

~~(b) in liquefied form in the subcritical range at a temperature of approx. 20°C to 30°C and a supercritical pressure of approx. 100 bar to 350 bar; or~~

~~(c)~~ in liquefied form under subcritical pressure and temperature conditions at a pressure of 70 bar or less and a temperature of approx. 20°C to 30°C; and

22. (Currently Amended) A process for producing an extract containing tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof from dried comminuted industrial hemp plant material, comprising

(1) subjecting said plant material to a stream of CO_2

~~(1a) under supercritical pressure and temperature conditions at a temperature in a range of approx. 31^{0} C. to 80^{0} C. and at a pressure in a range of approx. 75 bar [[or]]to 500 bar, or~~

~~(1b) in liquefied form in the subcritical range at a temperature of approx. 20^{0} C. to 30^{0} C. and a supercritical pressure of approx. 100 bar to 350 bar; or~~

~~(1c)~~ in liquefied found under subcritical pressure and temperature conditions at a pressure of 70 bar or less and a temperature of approx. 20°C to 30°C;

After a second § 103 rejection, the applicants deleted alternative (b) from the only pending independent claim that recited it, claim 1. *Id.* at 12 (citing *Id.*, Ex. 6 ('632 patent prosecution history excerpts) at 44).

1. (Currently Amended): A process for producing an extract containing Tetrahydrocannabinol (THC), cannabidiol (CBD) and optionally the carboxylic acids thereof from dried comminuted industrial hemp plant material, comprising

- extracting said plant material by means of CO_2

~~(b) in liquefied form in the subcritical range at a temperature of approx. 20°C to 30°C and a supercritical pressure of approx. 100 bar to 350 bar; or~~

~~(c)~~ in liquefied form under subcritical pressure and temperature conditions at a pressure of 70 bar or less and a temperature of approx. 20°C to 30°C; and

As part of both amendments, Applicants noted that the claims had been amended to indicate that extraction under supercritical conditions was not required. *Id.* at 11 (citing *Id.*, Ex. 6 ('632 patent prosecution history excerpts) at 22, 53–54).

Based on the Applicant's prosecution statements, Defendants conclude that

> Thus, to avoid the prior art, over the course of the '632 patent's prosecution Applicants narrowed their claims to specifically exclude the two additional alternatives claimed in the parent '078 patent but not the '632 patent—namely, extraction with CO_2 under supercritical conditions, and with CO_2 under subcritical temperature and supercritical pressure. In doing so, Applicants surrendered the scope covered by these alternatives.

Opening at 12.

Arguments in Plaintiff's Response Brief

Plaintiff contends that Defendants have not met the "exacting" standard necessary to support a finding of prosecution history disclaimer. Response at 14-15. In particular, Plaintiff contends that Defendants relies on claims that were canceled, and therefore do not relate to the presently asserted claims before the Court. Response at 14. Plaintiff contends that portions of the prosecution history that Defendants relies on pre-date the applicant's April 20, 2020 amendment, where the applicant canceled all claims and submitted new claims that do not contain the limitations or amendments that Defendants attempt to distinguish from the recited limitation in

dispute. *Id.* Plaintiff further contends that Defendants' reliance on the parent patent ('078 Patent) is misplaced because the claims in the parent patent are similar to the claims that were canceled in the '632 Patent, and not those that ultimately issued. *Id.*

Plaintiff contends that "in all three of the office action responses applicant submitted after canceling the claims that GW relies on and submitting new claims, applicant distinguished the claimed CO_2 under subcritical pressure and temperature conditions from supercritical conditions in the prior art, after which the examiner allowed the claims." Response at 17.

Arguments in Defendants' Reply Brief

Defendants contend that the prosecution history that Plaintiff cites does not support its proposed construction because it simply contrasts supercritical and subcritical conditions, and not what "subcritical pressure and temperature conditions" are. Reply at 6.

Defendants quote *Omega Eng'g* for the proposition that claim construction should be read and interpreted in accordance with, *inter alia*, canceled claims. *Id.* at 9 (quoting 334 F.3d at 1323). Accordingly, Defendants contend that it is proper to rely on the parent patent in this case. Reply at 8.

Arguments in Plaintiff's Sur-Reply Brief

In its sur-reply, Plaintiff contends that the prosecution history indicates that "subcritical conditions" / "subcritical pressure and temperature conditions" are simply pressure and temperature conditions that are not supercritical. Sur-Reply at 6. Plaintiff further argues that the applicants never distinguished "subcritical conditions" and "subcritical pressure and temperature conditions" in the prosecution history. *Id.* at 7.

With respect to the Defendants' argument that the parent patent disclosed three "alternatives," but the current patent only claimed one of them, Plaintiff contends that the

statement in question is over "10 years old" and is not a clear disclaimer. Sur-Reply at 7. More specifically, Plaintiff argues that the applicant "implicitly" disclaimed the limitations recited in the claims by canceling them and submitting new claims. *Id.* at 8. According to Plaintiff, the old claims differed by contrasting supercritical pressure and temperature versus supercritical pressure and subcritical temperatures while the new claims simply contrasted supercritical pressure and temperature versus "subcritical pressure and temperature conditions." *Id.*

The Court's Analysis

The Court does not find that the prosecution history provides any additional insight as to the meaning of this term beyond the plain language of the claims and the specification. Overall, the statements in the prosecution history mirror those in the specification, namely, that the claims in the parent patent and the as-filed/amended claims in the asserted patent recite three pressure and temperature conditions: 1) supercritical pressure and supercritical temperature, 2) supercritical pressure and subcritical temperature, and 3) subcritical pressure and temperature. But as was the case for the specification, the prosecution history does not explicitly recite that both the pressure and temperature need to be below their respective subcritical values. Additionally, like the specification, there is no unambiguous statement—at least beyond the usage of the word "and"—that describes that "subcritical pressure and temperature conditions" requires that both the pressure and temperature need to be below their respective subcritical values.

The standard for a disclaimer is that it needs to be clear and unambiguous. *Liebel-Flarsheim*, 358 F.3d at 900. After considering the parties' arguments, the Court concludes that the evidence is not clear and unambiguous that the applicant made a disclaimer during prosecution. More specifically, nothing in the prosecution history further limits the plain language of "subcritical pressure and temperature conditions." Rather, the basis for the alleged prosecution

disclaimer is that the applicant amended the claim to exclude pressure and temperature combinations (1) and (2), but notably, the applicant did not amend pressure and temperature condition (3) in any way that changes the scope of this term. As such, although the applicant changed the scope of the as-filed claims, because the applicant did not change the claim scope of this term during prosecution, the Court finds the evidence for a prosecution disclaimer is not clear and ambiguous.

That said, although there is no prosecution disclaimer, applicant's statements in the prosecution history are consistent with and tend to support Defendants' proposed construction, for the same reasons as the claim language and the specification support Defendants' proposed construction.

d. Extrinsic evidence

Arguments in Plaintiff's Response Brief

Plaintiff contends that based on the extrinsic evidence, a POSITA would understand that subcritical pressure and temperature conditions includes when one is supercritical. Response at 17–20. In particular, Plaintiff quotes from a paper that describes that "[s]ubcritical CO_2 can be achieved by either lowering the pressure below P_c or the temperature below T_c." Response at 18 (quoting Response, Ex. A at Canopy_0000013332). Plaintiff also quotes from another paper in support of its proposition that "POSITAs describe subcritical conditions in contrast with *supercritical* conditions, consistent with its plain and ordinary meaning." *Id.* (emphasis in original) (quoting Response, Ex. D. at Canopy_000001272 ("The term subcritical refers to a liquid at temperatures between the atmospheric boiling point and the critical temperature, whereas in the supercritical state, experimental conditions are higher than the critical temperature and pressure.")). Plaintiff finally cites to several papers that describe that extraction may be performed,

using CO_2 and not using CO_2, with either the pressure or temperature below its respective critical value, but not both. Response at 18–20.

Arguments in Defendants' Reply Brief

In its reply, Defendants reminds the Court that *Phillips* says that extrinsic evidence is less reliable and is given little weight. Reply at 10. Defendants also contend that of the references that Plaintiff cites, only two pre-date the priority date of the patent. *Id.*

Arguments in Defendants' Sur-Reply Brief

In its sur-reply, Plaintiff appears to repeat the same arguments from its Response. Sur-Reply at 9–10. With respect to most of the extrinsic evidence post-dating the priority date of the patent, Plaintiff argues that its proffered extrinsic evidence is still instructive. Reply at 10.

The Court's Analysis

After carefully reviewing Plaintiff's proffered extrinsic evidence, the Court finds that the extrinsic evidence is not directly relevant and certainly does not outweigh the intrinsic evidence. *Phillips*, 415 F.3d at 1317. The reason that Plaintiff's proffered extrinsic evidence is not directly relevant is because none of the extrinsic evidence is directed to the term "subcritical pressure and temperature conditions," but rather, the extrinsic evidence uses a wide range of somewhat similar terms. Response, Ex. A at Canopy_000001332 ("subcritical CO_2"); Ex. D at Canopy_000001273 ("subcritical"), 1275 ("Super/subcritical fluid extraction tested conditions"); Ex. E at Canopy_000001106 ("subcritical conditions"); Ex. F at Canopy_000001301 ("Subcritical (CO_2) extraction"), 1302 ("sub-critical pressure"); Ex. G at Canopy_000001182 ("subcritical CO_2"), 1214–16 ("subcritical conditions"); Ex. H atCanopy_000001260 ("subcritical CO_2"); Ex. I at Canopy_000001285 ("subcritical fluid extraction"); Ex. J at Canopy_000001263 ("Subcritical (CO_2) extraction); Ex. K at Canopy_000001323("subcritical fluid extraction"); Ex. L at

Canopy_000001314 ("subcritical 1,1,1,2-tetrailuoroethane"). Because "subcritical pressure and temperatures conditions" is a narrower than "subcritical conditions," the relevance of extrinsic evidence directed towards the latter (and variants of the latter) is minimal. Therefore, Plaintiff's proffered extrinsic evidence does not –and cannot—outweigh the intrinsic evidence.

IV. Conclusion

In conclusion, for the reasons described herein, the Court finds that the claim language, specification, and prosecution history support adopting Defendants' proposed contruction. Furthermore, because the extrinsic evidence is not directed to claim term at issue, it does not outweigh the intrinsic evidence. Therefore, for the reasons described herein the Court adopts the following as its final construction:

Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Final Construction
"CO_2 in liquified form under subcritical pressure and temperature conditions" U.S. Patent NO. 10,870,632 Patent, Claims 1, 14 Proposed by Defendant	Plain-and-ordinary meaning	CO_2 in liquified form under both subcritical pressure and temperature conditions	Plain-and-ordinary meaning wherein the plain-and-ordinary meaning is "CO2 in liquified form under both subcritical pressure and temperature conditions."

Finally, to the extent the Court did not specifically summarize and/or analyze any other arguments, the Court did not do so because the Court did not find those arguments to be persuasive in general or as persuasive as the arguments that it did summarize and/or analyze.

SIGNED this 27th day of November, 2021.

ALAN D ALBRIGHT
UNITED STATES DISTRICT JUDGE