IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELTIS USA, INC., LABORATORIOS LEON FARMA, S.A., CHEMO IBERICA, S.A., and CHEMO RESEARCH, S.L.,

Plaintiffs,

v.

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 22-434-RGA

MEMORANDUM OPINION

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February 20, 2024

ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 11,123,299 ("the '299 patent"), 11,291,632 ("the '632 patent"), 11,351,122 ("the '122 patent"), 11,478,487 ("the '487 patent"), 11,413,249 ("the '249 patent"), and 10,179,140 ("the '140 patent"). I have considered the parties' letters. (D.I. 286, 287, 295, 296).

I. BACKGROUND

Plaintiffs filed U.S. Patent Application No. 13/171,410 ("the '410 application") in 2011. The '410 application issued as U.S. Patent No. 10,849,857 and is not asserted in this case. (*See* D.I. 82 at 26). The '140 patent is a continuation-in-part of the '410 application. (*Id.* at 28 n.4). The other asserted patents are continuations of the '410 application. (D.I. 109 at 14:21–25). In March 2023, I construed various terms in the asserted patents. (*See* D.I. 107, 111).

The trial is scheduled to begin on February 26, 2024. (*See* D.I. 282). On January 26, 2024, the parties filed a joint letter raising claim construction disputes. (D.I. 272). I ordered the parties to submit proposed constructions prior to the pretrial conference. (D.I. 278). After reviewing the proposed constructions (D.I. 279, 280), I asked the parties to brief the disputed terms (D.I. 285 at 13:21–23).

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (cleaned up). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (alteration in original) (quoting

Phillips, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (cleaned up). "While claim terms are understood in light of the specification, a claim construction must not import limitations from the specification into the claims." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1354 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1323).

"[T]he words of a claim 'are generally given their ordinary and customary meaning.' . . . [It 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, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312–13 (citations omitted). "[T]he 'ordinary meaning' of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely on the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). The court may also make factual findings based on consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (quoting *Markman*, 52 F.3d at 980). Extrinsic

evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

III. CONSTRUCTION OF DISPUTED TERMS

I set forth claims 1 and 14 of the '299 patent and claims 1 and 33 of the '140 patent to illustrate the disputed terms. These claims state:

> 1. A pharmaceutical composition comprising:
> 6β, 7β:15β, 16β-Dimethylene-3-oxo-17α-pregn-4-ene-21, 17-carbolactone ***in the form of particles*** that have: (i) a ***median particle size*** ranging from 10 micrometers (μm) to 30 μm; (ii) a ***d90 particle size*** of less than 100 μm; and (iii) a ***d10 particle size*** of more than 3 μm, wherein the 6β, 7β:15β, 16β-Dimethylene-3-oxo-17α-pregn-4-ene-21, 17-carbolactone is present in an amount ranging from 3 milligrams (mg) to 4.5 mg; and
> one or more pharmaceutically acceptable excipients,
> wherein the pharmaceutical composition does not comprise estrogen; and
> wherein the pharmaceutical composition is formulated such that no more than 50% of the 6β, 7β:15β, 16β-Dimethylene-3-oxo-17α-pregn-4-ene-21, 17-carbolactone initially present in the pharmaceutical composition is dissolved within 30 minutes if subjected to ***an in vitro dissolution test according to the USP XXIII Paddle Method***.

('299 patent at 61:38–56 (disputed terms bolded and italicized)).

> 14. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is formulated as a tablet or a capsule.

('299 patent at 62:40–42 (disputed terms bolded and italicized)).

> 1. A method of providing contraception in a patient having a BMI of 25 kg/m^2 or more and bleeding events, the method comprising:
> ***administering a pharmaceutical composition*** comprising 2.5 mg to 5.5 mg of crystalline drospirenone and one or more pharmaceutically-acceptable excipients ***to a patient*** having a BMI of 25 kg/m^2 or more for an initial treatment cycle and for subsequent consecutive treatment cycles, the pharmaceutical composition being administered daily for at least portions of the initial and subsequent consecutive treatment cycles;
> wherein the administering results in ***a limited number of days of bleeding events per treatment cycle in at least one of the subsequent consecutive treatment cycles***
> and wherein the pharmaceutical composition does not contain an estrogen.

('140 patent at 64:14–29 (disputed terms bolded and italicized)).

> 33. The method of claim 1, ***wherein the crystalline drospirenone is present in an amount of 4 mg***.

('140 patent at 66:17–18 (disputed terms bolded and italicized)).

1. **"an in vitro dissolution test according to the USP XXIII Paddle Method" ('299 patent, claim 14; '632 patent, claims 12 and 21; '122 patent, claim 29; '487 patent, claim 19; '249 patent, claim 7)**

    a. *Plaintiffs' proposed construction*: plain and ordinary meaning as understood by a POSA reading the intrinsic record: in vitro dissolution test performed in 900 mL of water at 37° C (±0.5° C) using apparatus 2 at a stirring rate of 50 rpm / not indefinite
    b. *Defendants' proposed construction*: an in vitro dissolution test using the Paddle (Apparatus 2) Method described in USP XXIII (D.I. 286 at 1)
    c. *Court's construction*: an in vitro dissolution test using the USP XXIII Paddle Method

Plaintiffs contend the patents disclose "specific test conditions" for using the USP XXIII Paddle Method. (D.I. 287 at 1; *see also* D.I. 295 at 1). Based on the specification, Plaintiffs argue that a POSA would understand the claim term to mean, "in vitro dissolution test performed in 900 mL of water at 37° C (±0.5° C) using apparatus 2 at a stirring rate of 50 rpm." (D.I. 287 at 1 (citing '249 patent at 19:61–65)). Plaintiffs contend that the examples in the specification are consistent with this view (*see id.* (citing '249 patent at 38:26–31, fig.2, 44:65–66, 48:65–67)), and that the specification does not disclose any other conditions for performing the method (*id.*). Plaintiffs further rely on the file history, as Dr. Blatnik performed testing under these conditions. (*Id.*).

Defendants contend that neither the claims nor the U.S. Pharmacopoeia require any particular media, media volume, or stirring rate for the Paddle Method. (D.I. 286 at 1). Defendants contend that Plaintiffs have not presented lexicography or disclaimer arguments and are attempting to read limitations from the specification into the claims. (*Id.* at 2). Although the

specification describes parameters that may be used with the Paddle Method, Defendants argue that the specification does not state that these are the only permissible parameters. (*Id.*; *see also* D.I. 296 at 2). Defendants also contend that Plaintiffs' proposed construction is inconsistent with Plaintiffs' infringement contentions. (D.I. 286 at 2).[1] Defendants further note that prior art patents reciting use of the Paddle Method claim testing parameters, unlike the claims at issue. (*Id.*).[2]

I am unpersuaded by Plaintiffs' argument that the claims require specific test conditions. The plain language of the claims does not indicate that the Paddle Method must be performed under any particular conditions. (*See* '299 patent at 61:54–56 (reciting "an in vitro dissolution test according to the USP XXIII Paddle Method")). Claim terms are "generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313). Two exceptions apply: (1) when patentees act as their own lexicographers by setting out definitions, and (2) when patentees disavow a claim term's full scope during prosecution or in the specification. *Id.* (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996)). A patentee acts as its own lexicographer only if it "clearly set forth a definition of the disputed claim term" in the specification. *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Disavowal, meanwhile, requires the specification to be "both so clear as to show

[1] Plaintiffs dispute this and contend that Defendants "had no dissolution testing in water in [their] ANDA." (D.I. 295 at 2).

[2] Plaintiffs argue that Defendants' citations to prior art patents actually support Plaintiffs' position. (D.I. 295 at 2).

reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer." *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1322 (Fed. Cir. 2012) (citation omitted).

I do not think Plaintiffs have established lexicography or disavowal for the "Paddle Method" term. Any lexicography arguments fail because the patents do not include a definition for "Paddle Method." At best, Plaintiffs' argument may be framed as a disavowal of conditions other than 900 mL of water at 37° C (±0.5° C) at a stirring rate of 50 rpm. Neither the specification nor the file history, however, constitutes "unmistakable" evidence of disclaimer. In Example 2 of the specification, the dissolution rate "was determined by the USP XXIII Paddle Method using a USP Dissolution Test Apparatus 2 including 6 covered glass vessels and 6 paddles." ('299 patent at 38:27–29). The specification then states, "Tablets were placed in 900 ml water at a temperature of 37° C.± (0.5° C.) and stirred at 50 rpm." (*Id.* at 38:30–31). This language does not suggest that no other test conditions could satisfy the broad claim language of performing a dissolution test "according to the USP XXIII Paddle Method." (*Id.* at 61:54–56). Other references to the Paddle Method in the specification and file history are similarly insufficient to limit the claim scope to only one set of conditions. (*See, e.g.*, *id.* at 19:58–63).

I thus find that Plaintiffs' proposed construction would import limitations into the claims. Such a construction would contradict the claims' plain language. *See Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."). I thus reject Plaintiffs' proposed construction.

2. "particle size" / "d10 particle size" / "d90 particle size" / "median particle size" ('299 patent, claim 14; '632 patent, claims 12 and 21)

a. *Plaintiffs' proposed construction*: the diameter of an equivalent sphere expressed as a volume based distribution / not indefinite

b. *Defendants' proposed construction*: plain and ordinary meaning as previously decided by the Court. That meaning includes: particle size as determined by any means, and "d10 particle size," "d50 particle size," "d90 particle size" as determined by any means, including by volume, number or weight
c. *Court's construction*: plain and ordinary meaning: particle size as determined by any means

Plaintiffs contend that the term "particle size" refers to a volume-based distribution only. (D.I. 287 at 2–3; *see also* D.I. 295 at 2). Plaintiffs rely on their expert, Dr. Bugay, to contend this is a customary use of "particle size" in the field of pharmaceutical products. (D.I. 287 at 3). Plaintiffs argue that the specification is consistent with this customary use, as the disclosed examples "uniformly" recite using laser diffraction to determine particle size distribution. (*Id.* (citing '632 patent at 37:45–48)). Laser diffraction, Plaintiffs contend, is a volume-based technique. (*Id.*). Plaintiffs argue that Defendants are merely "attempting to create a[n] indefiniteness problem where none exists." (*Id.* at 4).

Defendants argue that I previously rejected Plaintiffs' current position. (D.I. 286 at 4; *see also* D.I. 296 at 3). Defendants contend that Plaintiffs are attempting to import limitations into the claims, as "no explicit statement in the specification mandates a volume method." (D.I. 286 at 4–5). Defendants note that the specification states, "particle size distribution, in particular d90, d10 and d50 values, may be determined by well-known methods of the prior art such as sieve analysis, laser diffraction methods, photoanalysis or optical counting methods." (*Id.* at 4 (citing '299 patent at 22:46–50); *see also* D.I. 296 at 3 ("At least 'optical counting' produces a *number*-based distribution . . . .")).[3] Defendants further argue that Plaintiffs are advancing mutually exclusive positions: (1) that individual particle size measurements should not be limited

[3] Plaintiffs respond, "Lupin does not explain why that one, general sentence would suggest to a skilled artisan that the claimed particle size distribution can be number- or volume-based . . . ." (D.I. 295 at 2–3).

to a particular method, and (2) that particle size distribution should be limited to volumetric measurement. (D.I. 296 at 3–4).

I did not decide this issue at the Markman stage. Plaintiffs originally argued that this term has its plain and ordinary meaning, while Defendants argued the term is indefinite. (*See* D.I. 82 at 41–53). Defendants argued the patent does not teach "the manner in which the particles should be measured to determine their size, diameter, or surface area (collectively 'particle size'), nor does the intrinsic evidence specify how the distributions of such particles be presented." (*Id.* at 43–44). The briefing obscurely raised the volume issue, but I did not resolve it. I proposed a tentative construction of plain and ordinary meaning because I did not think that Defendants had shown indefiniteness in the briefing. (D.I. 100 at 1). After meeting and conferring, the parties rested on their papers for the claim term (*see* D.I. 104 at 1), so I issued an order construing the term to have its plain and ordinary meaning (*see* D.I. 111 at 2–3). I did not rule on whether the plain and ordinary meaning of the claim term requires a volume-based distribution.

Plaintiffs' focus on laser diffraction is unpersuasive. Although Plaintiffs are correct to the extent that examples in the specification mention laser diffraction (*see, e.g.*, '299 patent at 37:46–48), the specification does not indicate that the claims only cover volume-based techniques like laser diffraction. The specification instead states, "The active drug (such as drospirenone) particle size distribution, in particular d90, d10 and d50 values, may be determined by well-known methods of the prior art such as sieve analysis, laser diffraction methods, photoanalysis or optical counting methods." (*Id.* at 22:46–50). Defendants contend that these methods are not all volume-based (*see* D.I. 286 at 4–5), and Plaintiffs do not argue otherwise.

Plaintiffs' reliance on their expert, Dr. Bugay, is also unpersuasive. Although Dr. Bugay opines that "particle size is customarily presented as the diameter of an equivalent sphere expressed as a volume-based distribution" (D.I. 287 at 3 (citing D.I. 287-6 ¶¶ 6, 8)), the specification states that well-known methods other than volume-based techniques may be used to determine particle size. Dr. Bugay's opinion is unhelpful to the extent that it is inconsistent with the claim language and specification. *See Vitronics*, 90 F.3d at 1584 ("[E]xtrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language."); *Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" (citation omitted)). I therefore reject Plaintiffs' proposed construction.

3. **"[drospirenone] in the form of particles" / "particles comprising [drospirenone]" ('299 patent, claim 14; '632 patent, claims 12 and 21; '487 patent, claim 19)**

    a. *Plaintiffs' proposed construction*: [drospirenone] in the form of discrete units of material ('299 patent, claim 14; '632 patent, claims 12 and 21) / discrete units of material which include drospirenone ('487 patent, claim 19)
    b. *Defendants' proposed construction*: a discrete unit of material, where discrete has its usual meaning of individually separate and distinct, . . . which consist essentially of molecules of drospirenone ('299 patent, claim 14; '632 patent, claims 12 and 21) / . . . which include molecules of drospirenone ('487 patent, claim 19)
    c. *Court's construction*: [drospirenone] in the form of discrete units of material ('299 patent, claim 14; '632 patent, claims 12 and 21) / discrete units of material which include drospirenone ('487 patent, claim 19)

Plaintiffs dispute that drospirenone particles must be "individually separate and distinct." (D.I. 287 at 4). Plaintiffs argue Defendants' proposed construction "is untethered to any intrinsic or extrinsic evidence and contrary to the plain wording of the claim." (*Id.* at 4–5).

Defendants, meanwhile, contend that Plaintiffs "refuse" to explain what they mean by "discrete." (D.I. 286 at 4). Defendants argue that "particles," an ordinary word, "implies discrete units of material that are individually separable and distinct from one another and from other units of material." (*Id.* at 3; *see also* D.I. 296 at 3).

I am unpersuaded by Defendants' argument. Although I agree with Defendants that "particle" is an ordinary English word, "particle" is generally defined as "a relatively small or the smallest discrete portion or amount of something."[4] Plaintiffs' proposed construction reflects that meaning, and I think it is sufficient. I therefore adopt Plaintiffs' proposed construction.

4. "wherein the crystalline drospirenone is present in an amount of 4 mg" ('140 patent, claim 33)

a. *Plaintiffs' proposed construction*: wherein the drospirenone, some of which is in crystalline form, no particular percentage required, is present in an amount of 4 mg
b. *Defendants' proposed construction*: crystalline drospirenone that is present in the pharmaceutical composition in an amount of 4 mg
c. *Court's construction*: wherein the composition contains 4 mg of crystalline drospirenone

Plaintiffs contend Defendants are asking for reconsideration of an issue I already decided. (D.I. 287 at 5–6 (citing D.I. 107 at 7–8); *see also* D.I. 295 at 3). Plaintiffs argue that "4 mg" in claim 33 refers to drospirenone in general, not to crystalline drospirenone. (D.I. 287 at 5). Plaintiffs thus contend that only some of the 4 mg must be in crystalline form. (*Id.*; *see also* D.I. 295 at 3 (arguing "the claims . . . broadly encompass any amount of crystallinity")). A contrary construction, Plaintiffs argue, would "improperly read out" an embodiment from the

[4] *See particle*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/particle.

specification; that embodiment describes drospirenone with "at least over about 50%" in crystalline form. (D.I. 287 at 5 (citing '140 patent at 38:2–5)).[5]

Defendants argue that this issue has not already been litigated. (D.I. 286 at 6). They contend that all four milligrams of drospirenone must be crystalline. (*Id.*). Defendants argue that "4 mg" modifies "crystalline" in the claim, and "crystalline" modifies "drospirenone." (*Id.*). Defendants contend that Plaintiffs' proposed construction "would effectively vitiate the 'crystalline' limitation, allowing 99.99% of the drospirenone to be amorphous." (*Id.*).

I agree with Defendants that I have not construed this term before; I ruled on a different issue for a similar term. (*See* D.I. 107 at 6–8 (deciding whether the term "crystalline drospirenone" "specifies a threshold for the percentage of the drospirenone by weight that must be in crystalline form")). I did not discuss the constructions in the context of specific weight requirements.

I also agree with Defendants that the claim requires 4 mg of crystalline drospirenone. As Defendants argue, "4 mg" modifies the word "crystalline," and "crystalline" modifies "drospirenone." I think this interpretation is the only sensible reading of the claim language. Otherwise, if the composition does not include 4 mg of crystalline drospirenone, what does "4 mg" refer to? Plaintiffs would like it to refer to "drospirenone," which could then include some crystalline drospirenone and some amorphous drospirenone. Claims 1 and 33 twice use the phrase "crystalline drospirenone." The claims do not otherwise recite "drospirenone." "Drospirenone" only appears twice; it is always modified by "crystalline." Plaintiffs are thus

[5] Defendants dispute this. They contend, "As 'comprising' claims, the pharmaceutical composition may include additional drospirenone that is not in crystalline form, so long as it includes at least 4 mg of drospirenone in crystalline form." (D.I. 296 at 5).

seeking a major rewrite of the claims so that "4 mg" limits a term that does not appear in the claims. Defendants' proposed construction, on the other hand, reflects the term's plain and ordinary meaning.

Under Defendants' proposed construction, the preferred embodiment (*see* '140 patent at 38:2–4) would be within the scope of the claim. *See Vitronics*, 90 F.3d at 1583 (A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support."). I also note that the embodiment containing "at least over about 50%" of crystalline drospirenone is not inconsistent with the claim language. The claim requires 4 mg of crystalline drospirenone, even if amorphous drospirenone is also present. I reject Plaintiffs' proposed construction.

5. "administering a pharmaceutical composition . . . to a patient" ('140 patent, claim 33)

a. *Plaintiffs' proposed construction*: delivering drospirenone to the bloodstream of a patient
b. *Defendants' proposed construction*: the act of introducing a pharmaceutical composition to the body of a patient
c. *Court's construction*: administering a pharmaceutical composition to a patient is the patient taking the pharmaceutical composition, however delivered

Plaintiffs contend that the term "administering" has different meanings "depend[ing] on what the inventors were seeking to achieve with the invention." (D.I. 287 at 6). Plaintiffs contend that the '140 patent does not limit "administering" to the moment a patient swallows a pill. (*Id.*; *see also* D.I. 295 at 3). Instead, Plaintiffs argue that the patent uses "administering" to describe particular results—"a good bleeding profile" and "contraceptive efficacy." (D.I. 287 at 6 (citing '140 patent at 3:20–23, 4:21–28); *see also* D.I. 295 at 4). Plaintiffs thus contend that "administering" refers to "the first time the patient has enough drug levels in the body to achieve contraceptive efficacy." (D.I. 287 at 6).

Defendants contend that "administering" refers to "the act of introducing the pharmaceutical to the body of a patient." (D.I. 286 at 5). They argue that the specification and even Plaintiffs' own expert testimony are consistent with this view. (*Id.*). Defendants contend that Dr. Shoupe, Plaintiffs' expert, "was unable to identify ***any portion*** of the patent specification supporting the position that 'administration' includes changes to a tablet after it is swallowed." (*Id.*).[6]

I agree with Defendants that "administering" refers to a patient taking the drospirenone composition, not to the moment drospirenone achieves the desired effects in a patient's body. Plaintiffs' argument about the differences between administration and ingestion is unpersuasive to the extent that the relevant patent claims do not use words like "take," "intake," or "ingest." (*See* '140 patent at 64:14–29, 66:17–18). Although Plaintiffs are correct that the '140 patent's specification describes effects such as contraceptive efficacy, I do not think Plaintiffs' citations to the specification establish that "administering" continues for a prolonged period after a patient takes drospirenone. The specification suggests that the benefits of drospirenone occur after administration, not that administration itself involves these effects. For instance, the specification states:

> In one embodiment, the pharmaceutical composition may comprise an active contraceptive drug, wherein the pharmaceutical composition allows for a 28 day daily dosing regimen, and wherein after initial administration of the active contraceptive drug has established its contraceptive effect in a patient, the patient may skip up to 4 doses . . . within any 28 day daily dosing regimen period.

[6] Plaintiffs respond that Defendants distort Dr. Shoupe's testimony. Plaintiffs contend Dr. Shoupe testified that "administering" refers to delivery of the drug to the bloodstream. (D.I. 295 at 4). Defendants, meanwhile, argue that "[n]o crystalline drospirenone exists in solution or in the blood." (D.I. 296 at 4).

('140 patent at 3:32–39). The evidence is thus insufficient to construe "administering" as anything more than a patient taking a drug. I reject Plaintiffs' proposed construction.

6. **"a limited number of days of bleeding events per treatment cycle in at least one of the subsequent consecutive treatment cycles" ('140 patent, claim 33)**

    a. *Plaintiffs' proposed construction*: plain and ordinary meaning: wherein the administration results in a limited [small/low] number of bleeding events per treatment cycle in at least one of the subsequent consecutive treatment cycles
    b. *Defendants' proposed construction*: fewer days of bleeding events in at least one of the subsequent consecutive treatment cycles as compared to the initial treatment cycle
    c. *Court's construction*: plain and ordinary meaning: wherein the administration results in a limited [small/low] number of bleeding events per treatment cycle in at least one of the subsequent consecutive treatment cycles

The parties dispute the meaning of "limited" in claim 33 of the '140 patent.[7]

Plaintiffs contend that the claim does not require a comparison of one cycle to another. (D.I. 287 at 7). Alternatively, if the claim does require a comparison, Plaintiffs argue the claim contemplates a comparison to any preceding cycle, not to the initial cycle only. (*Id.* at 7–8). Plaintiffs contend, "what is 'limited' is the number of days of bleeding, as a percentage of 28 days of treatment." (*Id.* at 8). In the context of the claims, Plaintiffs thus argue that "limited" "simply means small." (*Id.*). They contend that clinical trial results described in the specification show that subsequent cycles are not compared to the initial cycle (*see id.* (citing '140 patent at 55:50–55, 56:52–63, tbls.9–10)), because "the first cycle naturally has irregular bleeding as the patient's body adjusts to the hormone therapy" (*id.*). Plaintiffs further argue that

[7] I note that Plaintiffs' proposed construction is for a slightly different term, as Defendants do not start with "wherein."

certain dependent claims—which do require a comparison between the initial cycle and subsequent cycles—support their position.[8] (*Id.*; *see also* D.I. 295 at 5).[9]

Defendants note that the phrase "limited number of days of bleeding events" only appears in the claims. (D.I. 286 at 7). The specification, though, includes the phrase "a number of days of bleeding events." (*Id.* (citing '140 patent at 32:9–11)). Based on the specification's use of that phrase, Defendants contend that "limited number of bleeding days" "must be a term of degree referring to a number of days in a treatment cycle." (*Id.*). Defendants argue, however, that the specification refers to bleeding days in various ways without explaining which of those ways are "limited."[10] (*Id.*). Defendants contend that the term cannot be definite if it does not provide a standard for measuring whether a particular number of bleeding days is low/small. (*Id.* at 8). Still, Defendants argue that the claim requires a comparison of bleeding events between the initial treatment cycle and a subsequent cycle. (*Id.* at 7–8).

I agree with Plaintiffs that claim 33 does not require a comparison of one treatment cycle to another. The clinical trial data disclosed in Tables 9 and 10 of the specification do not support Defendants' argument, as the tables suggest that a comparison to the initial treatment cycle is not required. Claim differentiation principles support Plaintiffs' position as well. Whereas claims 2

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[8] Claim 33 of the '140 patent depends from claim 1.

[9] Defendants contend that claim differentiation principles actually support their position, as "claims 7–11 specify the amount of *reduction* (expressed as a percentage) from the initial cycle to the subsequent cycle." (D.I. 296 at 5).

[10] Defendants contend that the specification mentions bleeding days as an overall percentage of the treatment cycle, as a comparison between overweight women and those who are not overweight, and as ranges for reduction in certain treatment cycles. (D.I. 286 at 7 (citing '140 patent at 33:49–60, 34:26–33, 35:6–10)). In their answering letter, Plaintiffs argue that the specification and dependent claims show the number of bleeding days that satisfy the "limited" requirement. (D.I. 295 at 5).

through 6 include the phrase "limited number of days of bleeding events," claims 7 through 11 include the phrase "number of days of limited bleeding events."[11] (*See generally* '140 patent at 64:30–65:2). Because claim 1 recites "limited number of days of bleeding events," and that is the same language that appears in claims 2 through 6, but not in claims 7 through 11, I think claims 2 through 6 are more pertinent in construing claim 1.

Claim 2 states:

> The method of claim 1, wherein the limited number of days of bleeding events in at least one of the subsequent consecutive treatment cycles of administration does not exceed about 13% per treatment cycle.

(*Id.* at 64:30–33). The language in claims 3 through 6 only differs in the percentage recited. (*See id.* at 64:34–49). These dependent claims, which appear to track the results reported in Table 9 of the patent, indicate that the "limited" limitation in claim 1 refers to a small or low number of bleeding events within a particular treatment cycle. Dependent claims 7 through 11, on the other hand, add a new limitation, requiring a comparison between the initial treatment cycle and a subsequent cycle. (*See id.* at 64:50–65:2). Defendants have not shown that the comparison limitation in claims 7 through 11 should apply to independent claim 1 (and, by extension, to dependent claim 33).

I thus reject Defendants' proposed construction, and I adopt Plaintiffs' proposed construction. I will not allow an indefiniteness challenge to this claim term, as the issue was not raised at the Markman stage and does not appear to be the subject of any expert report.

IV. CONCLUSION

For the reasons stated, I adopt the above constructions.

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[11] I have my doubts that "number of days of limited bleeding events" makes much sense.