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

Martina T. Hufnal (argued), Douglas E. McCann (argued), Gregory R. Booker, FISH & RICHARDSON P.C., Wilmington, DE; Brian Coggio, FISH & RICHARDSON P.C., New York, NY; Megan A. Chacon, Bernard Cryan, FISH & RICHARDSON P.C., San Diego, CA.

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March 1, 2023

/s/ Richard G. Andrews
**ANDREWS, U.S. DISTRICT JUDGE:**

Before me is the issue of claim construction of multiple terms in U.S. Patent No. 9,603,860 (the "'860 patent"), U.S. Patent No. 10,179,140 (the "'140 patent"), U.S. Patent No. 10,987,364 (the "'364 patent"), U.S. Patent No. 11,123,299 (the "'299 patent"), U.S. Patent No. 11,291,632 (the "'632 patent"), U.S. Patent No. 11,291,633 (the "'633 patent"), U.S. Patent No. 11,351,122 (the "'122 patent"), U.S. Patent No. 11,413,249 (the "'249 patent"), U.S. Patent No. 11,439,598 (the "'598 patent"), U.S. Patent No. 11,452,695 (the "'695 patent"), U.S. Patent No. 11,478,487 (the "'487 patent"), U.S. Patent No.11,491,113 (the "'113 patent"), and U.S. Patent No. 11,504,334 (the "'334 patent") (the "Asserted Patents"). The parties submitted a Joint Claim Construction Brief (D.I. 82) and Appendix (D.I. 83; D.I. 84; D.I. 85), and I heard oral argument on February 16, 2023 (D.I. 96). The parties submitted additional letters. (D.I. 102; D.I. 105; D.I. 106).

## I. BACKGROUND

Plaintiffs filed their first patent application, 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. (D.I. 82 at 26). The '860 and '140 Patents are continuations-in-part of the '410 Application. (D.I. 82 at 28 n.4). The other Asserted Patents are continuations of the '410 Application. (Markman Hearing Tr. 14:21-25).

## 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) (internal quotation marks omitted). "'[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 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which 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." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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 upon 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 upon 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 AGREED-UPON TERMS

I adopt the following agreed-upon constructions:

| **Claim Term** | **Claims**[1] | **Construction** |
|---|---|---|
| "bleeding events" | '180 Patent claims 1-40;<br>'140 Patent claims 1-39. | "vaginal bleeding and spotting that occurs during a woman's treatment cycle" |
| "a [female[2]] patient" / "the patient" | '180 Patent claims 1-40;<br>'140 Patent claims 1-39;<br>'632 Patent claims 20;<br>'633 Patent claims 20;<br>'249 Patent claims 1-10;<br>'598 Patent claims 1-27;<br>'695 Patent claims 1-28;<br>'487 Patent claims 1-30;<br>'113 Patent claims 1-30;<br>'334 Patent claims 1-30. | "one or more [female] patients" (D.I. 96) |

## IV. CONSTRUCTION OF DISPUTED TERMS

Plaintiffs are asserting the following claims: '860 Patent claims 1-40; '140 Patent claims 1-39; '364 Patent claims 1-7, 10, 12-14, 17, 20; '299 Patent claims 1-7, 10, 12-14, 17, 20; '632 Patent claims 1-7, 10, 12, 15, 18, 20, 21; '633 Patent claims 1-7, 10, 12, 15, 18, 20, 21; '122 Patent claims 1-7, 10, 12, 15, 18-26, 29; '249 Patent claims 1-5, 7, 8, 10; '598 Patent claims 1-7, 10, 12, 15, 18-27; '695 Patent claims 1-7, 10, 12, 15, 18, 20-28; '487 Patent claims 1-7, 10, 12, 15-17, 19-30; '113 Patent claims 1-7, 10, 13-30; '334 Patent claims 1-7, 10, 12, 15-17, 19-30. (D.I. 104 at 2). The following claims are representative for claim construction purposes.

[1] The parties did not identify which claims contained which terms. These are the claims I identified to contain the terms. Not all claims are asserted. (D.I. 104 at 2). If there are any asserted claims that I failed to identify, these agreed-upon constructions apply to them too.

[2] "A female patient" only appears in the '249 Patent.

**'860 Patent**

1. A method of providing contraception in a patient having a BMI of 30 kg/$m^2$ or more and bleeding events, the method comprising:

administering a pharmaceutical composition comprising 2.5 mg to 5.5 mg ***crystalline of drospirenone*** and one or more pharmaceutically-acceptable excipients to a patient having a BMI of 30 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 a portion 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.

15. The method of claim 12, wherein the weight loss results in a reduction in the patient's BMI of ***about*** 1% to ***about*** 20%.

('860 Patent, col. 64:14-27; 65:9-11 (disputed terms italicized and bolded)).

**'695 Patent**

1. A pharmaceutical composition comprising:

micronized 6β,7β:15β,16β-Dimethylene-3-oxo-17α-pregn-4-ene-21,17- carbolactone, 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***:

(1) when orally administered to a patient under fasting conditions, the pharmaceutical composition ***provides a pharmacokinetic profile for the 6β,7β:15β,16β-Dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone*** comprising:

(i) a mean $T_{max}$ ranging from 2.2 hours to 6 hours; and

(ii) a mean $C_{max}$ of less than 30 ng/ml; and

(2) no more than 50% of the 6β,7β:15β,16β-Dimethylene-3-oxo-17α-pregn4-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.

('695 Patent, col. 61:27-51 (disputed terms italicized and bolded)).

Before the Markman hearing, I proposed tentative constructions for the disputed terms. (D.I. 100). In response to my tentative constructions, the parties "agreed that they will rest on their respective papers for Term B ('causes' / 'results in'), Term E ('non-micronized' / 'micronized'),

and Term F (the particle size terms)" and did not argue these terms at the hearing. (D.I. 104 at 1). My tentative constructions for those three terms are adopted. (Markman Hearing Tr. 96:22-97:1). I now turn to the remaining disputed terms.

1. **"is formulated such that" / "is formulated to provide" / "provides a pharmokinetic profile for the drospirenone" ('860 Patent claims 37-39; '140 Patent claims 36-38; '364 Patent claims 1-7, 10, 12-14, 17, 20; '299 Patent claims 1-7, 10, 12-14, 17, 20; '632 Patent claims 1-7, 10, 12, 15, 18, 20, 21; '633 Patent claims 1-7, 10, 12, 15, 18, 20, 21; '122 Patent claims 1-7, 10, 12, 15, 18-26, 29; '249 Patent claims 1-5, 7, 8, 10; '598 Patent claims 1-7, 10, 12, 15, 18-27; '695 Patent claims 1-7, 10, 12, 15, 18, 20–28; '487 Patent claims 1-7, 10, 12, 15-17, 19-30; '113 Patent claims 1-7, 10, 13-30; '334 Patent claims 1-7, 10, 12, 15-17, 19-30).**

   a. *Plaintiff's proposed construction*: plain and ordinary meaning.

   b. *Defendants' proposed construction*: "the drospirenone consists of particles with a $d_{50}$ ranging between 10 micrometers and 60 micrometers"

   c. *Court's construction*: plain and ordinary meaning.

   The parties dispute whether there is a particle size limitation in this term. (D.I. 82 at 20).

Plaintiffs argue that importing such a limitation is unsupported by the claim language as some claims using this term recite a particle size limitation while others do not. (*Id.* (citing '860 Patent, cl. 27-28, 30)). Plaintiffs also cite to the specification for support that the particle size is specified for some embodiments, but not the invention generally. (D.I. 82 at 20-21 (citing '860 Patent, col. 4:15-23, 4:46-57, 7:31-63)). Plaintiffs contend that nothing in the prosecution history rises to clear and unmistakable disclaimer. Plaintiffs argue that the statements in the prosecution history that Defendants cite to would improperly limit the scope of the term in the '860, '140, and '281 Patents because the statements were made after those patents had issued. (D.I. 82 at 21).

Defendants argue that the particle size limitation is properly incorporated into the term because the patentee clearly and unmistakably disavowed particle sizes outside of this range. (*Id.* at 21-22). Defendants rely on statements made by the patentee (D.I. 84-21, Ex. 34 at JA0870), and a declaration by Dr. Sandra Blatnik in the response to rejections by the patent examiner (D.I. 84-

22, Ex. 35 at JA0873-77), to argue that the particle size was critical to the invention and thus particle sizes outside the range of $d_{50}$ between 10 μm to 60 μm were disavowed. (D.I. 82 at 23).

The statements Defendants cite to may be relevant to claim construction notwithstanding the fact they were made after three patents had already issued. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004). These statements in the prosecution history, however, do not rise to the level of clear and unmistakable disclaimer. "When the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply." *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007). The statements Defendants cite to in the prosecution history are directed to claims that explicitly recite a particle size limitation. (*See, e.g.*, D.I. 84-20, Ex. 33 at JA0843, JA0861 (disagreeing with rejection but amending claims to add particle size range limitation); D.I. 84-22, Ex. 35 at JA0873-74 (discussing claims that recited a particle size limitation)). Because those statements were not made in connection with the claim language at issue here, or the scope of the invention generally, I find they do not rise to the level of prosecution disclaimer. *See Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636, 650 (Fed. Cir. 2017).

Therefore, I adopt Plaintiffs' proposed construction of "plain and ordinary meaning." I reject Defendants' proposed limitations.

**2. "crystalline drospirenone" / "crystalline of drospirenone" ('860 patent claims 1-40; '140 patent claims 1-39)**

a. *Plaintiff's proposed construction*: plain and meaning, which is "drospirenone in crystalline form"

b. *Defendants' proposed construction*: "drospirenone in which over 50% as measured by weight is in crystallized form"

c. *Court's construction*: plain and ordinary meaning.

The dispute with respect to this term is whether the term specifies a threshold for the percentage of the drospirenone by weight that must be in crystalline form.

Plaintiffs argue there is nothing in the claims, specification, or prosecution history that requires crystalline drospirenone to be over 50% by weight in crystalline form. (D.I. 82 at 28-29). Plaintiffs contend that statements in the prosecution history that Defendants cite to were to distinguish prior art that "taught the complete exclusion of crystalline forms of drospirenone" and that the "percentage of drospirenone was not discussed." (*Id.*).

Defendants present two arguments for their proposed construction. First, Defendants argue that Plaintiffs disclaimed crystalline drospirenone where the crystalline form was less than 50% by weight through prosecution history disclaimer. (*Id.* at 30). Defendants cite statements made in the '410 Application where Plaintiffs amended claim language to include the phrase "the dosage form or unit consists essentially of crystalline drospirenone" after Plaintiffs "were cautioned of the phrase 'crystalline form' since said term encompasses any degree of crystallinity." (*Id.* at 30 (quoting D.I. 84-24, Ex. 37 at JA0911)). Defendants contend that Plaintiffs' proposed construction would cover embodiments with any degree of crystallinity, which Plaintiffs disclaimed during prosecution. (D.I. 82 at 30). Second, Defendants argue that "there is *no disclosure* in the specification of a formulation containing crystallized drospirenone where the percentage falls below 50%." (*Id.* at 31).

I agree with Plaintiffs that importing a limitation for the percentage of drospirenone that is in crystalline form is improper. First, the statements in the '410 Application pertain to amended claims that recite "wherein the progestogen-only contraceptive consists essentially of at least about 2 mg of crystalline drospirenone." (*See, e.g.*, D.I. 84-25, Ex. 38 at JA0914). That claim language is not present in the '860 or '140 Patents and the statements in the prosecution history are directed

to that claim language, not the invention generally. *See Sanofi*, 875 F.3d at 650. The statements and amendments do not rise to the level of clear and unmistakable disclaimer.

Second, the specification describes an "essentially crystallized form" as being preferred or as "one embodiment," not an attribute of the invention generally. ('860 Patent, col. 37:58-61; '140 Patent, col. 38:2-5). Including this limitation in the construction would improperly import a limitation from the specification into the claim. *See Phillips*, 415 F.3d at 1323 (Fed. Cir. 2005).

Therefore, I adopt Plaintiffs' proposed construction of "plain and ordinary meaning." I reject Defendants' proposed limitations.

**3. "about" ('860 patent claims 2-11, 13-16, 20-21, 25-31, 37-39; '140 patent claims 2-11, 13-16, 20-21, 25-31, 36-38; '364 patent claim 20; '299 patent claim 20; '632 patent claim 18; '633 patent claim 18; '122 patent claims 1-7, 10, 12, 15, 18–26, 29; '598 patent claims 1-7, 10, 12, 15, 18–27; '695 patent claim 18)**

a. *Plaintiff's proposed construction*: plain meaning ("approximately")

b. *Defendants' proposed construction*: indefinite

c. *Court's construction*: indefinite

Defendants argue that the patentees acted as their own lexicographer and defined "about" in such a way that the term is indefinite. The Defendants cite to the specification:

> As used herein, the term "about" before a "specific value" defines a range from "the specific value minus at least 10% of the specific value" to "the specific value plus at least 10% of the specific value." For example, "about 50" defines a range from 45 or less to 55 or more. In addition, it may define a range where "the specific value minus at least 20% of the specific value" to "the specific value plus at least 20% of the specific value." Further, it may define a range where "the specific value minus at least 30% of the specific value" to "the specific value plus at least 30% of the specific value" and so on.

('860 Patent, col. 20:32-42). Defendants argue that the plain and ordinary meaning for "about" should not apply because the patentees "provided (and meant to provide) an explicit definition of 'about' in the specification." (D.I. 82 at 56). Defendants contend the claim is indefinite because

"the specification provides no guidance concerning which types of specific measurements should be subjected to a 10% deviation, or a 20% deviation, or 30%, or even more." (*Id.*).

Plaintiffs argue that this part of the specification does not constitute lexicography and, therefore, the plain and ordinary meaning should apply. (D.I. 102 at 1). Plaintiffs contend that this part of the specification is just exemplary language and guidance consistent with the idea that "the boundaries of 'about' depend on context." (*Id.* at 1-2). Plaintiffs cite to the use of "may" and examples in the paragraph to support their argument that "[a] person of ordinary skill would not read the excerpt as mandating one definition but would understand 'about' has different meanings depending on the value described." (*Id.* at 2). Plaintiffs also argue that even if this is lexicography, the specification is consistent with the construction of "approximate." (D.I. 102 at 3).

"Where a patentee has not acted as his own lexicographer in redefining the word 'about,' courts have construed 'about' to mean 'approximately.'" *Silvergate Pharms. Inc. v. Bionpharma Inc.*, 2018 WL 1610513, at *4 (D. Del. Apr. 3, 2018). I find, however, that Plaintiffs have acted as their own lexicographer to redefine "about." First, the term "about" "is set off by quotation marks—often a strong indication that what follows is a definition." *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007). Second, "[t]he 'as used herein' leading into the definition, . . ., indicates that the patentee became [its] own lexicographer." *Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, 2012 WL 4103880, at *4 (D.N.J. Sept. 14, 2012). I find these indicators are sufficient "to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005).

I disagree with Plaintiffs that the language here is consistent with the ordinary meaning of "about" (i.e., approximately). The specification recites "the term 'about' before a 'specific value' defines a range from 'the specific value minus at least 10% of the specific value' to 'the specific value plus at least 10% of the specific value.'" ('860 Patent, col. 20:32-35). This defined range is boundless. The next sentence of the specification confirms this as it defines "about 50" to be "a range from 45 or less to 55 or more." (*Id.* at 35-36). Instead of defining "about" to be something akin to "approximately" (e.g., a value a little below or little above a specific value), the specification defines "about" before a "specific value" to cover an unbounded range.

Turning to the content of the specification, I find "about" is indefinite. "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). As discussed, "about" before a specific value would cover an unbounded range – all values would be covered. Therefore, a person of ordinary skill in the art would not be reasonably certain what the scope of the claims are because "about" a specific value would cover any value despite the claims reciting a specific value.

The rest of the definition is consistent with claiming unbounded ranges. The remainder of the paragraph in the specification says "about" can define a range of plus or minus a 10% deviation, or a 20% deviation, or a 30% deviation, "and so on." (*See* '860 Patent, col. 20:42). Deviations exceeding 30% are clearly contemplated by the "and so on" language. Therefore, there is no definitive upper bound on the size of the deviation that is encompassed by "about" a specific value. A person of ordinary skill would not be informed as to the scope of "about" a specific value because a deviation of any size, no matter how large, could fall within the scope of the claim.

The patentees took a perfectly good and easily understood word and defined it into indefiniteness.

## V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.