

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,
PURDUE PHARMACEUTICALS L.P.,
THE P.F. LABORATORIES, INC., and
GRÜNENTHAL, GmbH,

Plaintiffs,

v.

ALVOGEN PINE BROOK LLC, and
ACTAVIS LABORATORIES FL, INC.,

Defendants.

Civil Action No. 15-687-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 9,675,610 (“the ‘610 Patent”) and 9,750,703 (“the ‘703 Patent”).¹

After considering the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 9,675,610 (“the ‘610 Patent”) and 9,750,703 (“the ‘703 Patent”):

1. The term **“layer encasing the core”** in the ‘703 patent is construed to mean “one or more materials enclosing a space or surrounding the core.”²

¹ All docket citations refer to Civil Action No. 15-687-GMS. The abbreviation “Tr.” refers to the transcript from the *Markman* Hearing on February 13, 2018, D.I. 312. The phrase “First Phase Construction” refers to the first *Markman* Hearing held on November 30, 2016 (D.I. 121) and *Markman* Order entered on March 10, 2017. (D.I. 178.)

² The parties’ dispute centers on whether (1) “layer” requires a single material or “one or more” materials to encase the core; and (2) whether “encasing” requires “surrounding” or “covering” the core. (D.I. 270 at 3.) After First Phase Construction, the court granted Plaintiffs’ Motion for Reconsideration (D.I. 207) and rejected Defendants’ (D.I. 217) proposed construction of “*shell* encasing the core” from Patent No. 8,808,740 (“the ‘740 Patent”) as “a layer or surface enclosing a space or surrounding an object.” (D.I. 207 at n.1.) The specification of the ‘703 Patent discloses that the preferred inner and outer regions “are configured as an inner core (e.g., a compressed tablet) and a shell encasing the core (e.g., a compression coating).” ‘703 Patent at 11:3-6. Specifically, the specification states that: [t]he shell of the dosage form can be formed, e.g., by compression coating, molding, spraying *one or more layers* onto the core, dipping *one or more layers* onto the core or a combination thereof.

2. The term **“average molecular weight . . . as measured by correlation to viscosity”** in the ‘703 patent is construed to mean “the average of the molecular weights . . . based on rheological measurements.”³
3. The term **“one or more viscosity-increasing agents in a quantity such that an aqueous extract of a total content of the dosage form when comminuted and**

Id. at 11:50-55. The specification further explains that in some embodiments an “optional coat” may be “alternatively or additionally applied as an intermediate layer between the core and the compression coating.” ‘703 Patent at 17:31-35. Claim 34, for instance, describes “a layer” as “a second portion of hydrocodone bitartrate dispersed in a second matrix material.” *Id.* at 50:20-22. The prosecution history provides additional support that the claim allows for more than one layer describing layers that “each contain[] multiple ingredients.” WO 2008/011169, Table 1. The court, therefore, agrees with Plaintiffs that “layer” means “one or more materials,” which form the layer.

Next, Plaintiffs argue that adopting Defendants’ proposed construction where “encasing” means “surrounding” ignores that the layer is proximate to the core. (D.I. 280 at 5.) The court agrees. Defendants have applied the First Phase Construction of “encasing” to its construction without additional support. (D.I. 271 at 13.) Similarly, Plaintiffs’ construction of “encasing” fails to acknowledge that the specification does not differentiate between “encasing” depending on whether the structure “encasing” the core is a “shell” or another “layer.” ‘703 Patent at 11:51-55. The court, therefore, declines to adopt either parties’ construction of “encasing.” Instead, for the reasons above and stated in D.I. 178 and D.I. 207, the court construes the claim term to mean “one or more *materials* enclosing a space or surrounding the core.” *See Tr. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016).

³ The parties’ dispute centers on (1) “average molecular weight” and (2) “as measured by correlation to viscosity.” *Markman* Hr’g Tr. 4:7-8, 13:1-5. Defendants argue that the “average molecular weight” should have its plain and ordinary meaning of “the average of the molecular weights.” (D.I. 178); *Markman* Hr’g Tr. 9:20-21. Specifically, Defendants argue that “average” and “approximate” are not interchangeable because the specification distinguishes between approximate and average rheological measurements. *Markman* Hr’g Tr. 11:20-23. Plaintiffs argue that the inventor equated “average molecular weight” to “approximate molecular weight” by using the terms interchangeably. ‘703 Patent at 12:9-23, 8:30-37. The court disagrees with Plaintiffs. (D.I. 178, n.18.) During First Phase Construction, the court determined that there was insufficient guidance in the specification to construe the term “average molecular weight” beyond its plain meaning. (D.I. 178 at n.19.) Likewise, the ‘703 Patent specification uses “average molecular weight,” “molecular weight,” and “approximate molecular weight.” ‘703 Patent at 8:23-38, 12:12. For the reasons stated above and in D.I. 178, the court adopts Defendant’s construction of “average molecular weight.”

Second, the court construes “as measured by correlation to viscosity” to mean “based on rheological measurements.” (D.I. 178 at n. 18.) The phrase “correlation to viscosity” is only found in claims 2, 32, and 38 of the Patent. The specification discloses that “polyethylene oxide is considered to have an approximate molecular weight of” varying amounts when it has a viscosity falling within a particular range when using a particular test. ‘703 Patent at 15:58-16:31. Part of the specification lays out the definitions of the terms used therein and states:

The term “high molecular weight polyethylene oxide (PEO)” is defined for purposes of the present invention as having an approximate molecular weight of at least 1,000,000, *based on rheological measurements*.

The term “low molecular weight polyethylene oxide (PEO)” is defined for purposes of the present invention as having an approximate molecular weight of less than 1,000,000, *based on rheological measurements*.

‘703 Patent at 8:30-38. The specification, however, does not define “rheological measurements” or “as measured by correlation to viscosity.” The court held in the First Phase Construction that a substantively identical disclosure to this claim term did not disclose a correlation between molecular weight and viscosity. (D.I. 178 at 11-12, n.18.) The only difference between the two patents is that the ‘703 Patent substitutes the phrase “the PEO” for “polyethylene oxide.” ‘703 Patent at 15:59-62. “PEO” is polyethylene oxide. ‘703 Patent at 8. For the same reasons as discussed in D.I. 178, the court declines to infer a correlation between molecular weight and viscosity from the disclosure. ‘703 Patent at 15:58-16:31.

combined with 10 ml of water at 25° C forms a gel that can be drawn up into and injected back out of a hypodermic needle having a diameter of 0.9 mm, into a further quantity of water, wherein threads of the gel injected from said needle remain visible to the naked eye in said further quantity of water at 37°C” in the ‘610 patent is construed to mean “one of more viscosity-increasing agents in a quantity such than an aqueous extract of a total content of the dosage form when comminuted and combined with 10 ml of water at 25° C forms a gel that can be drawn up into and injected back out of a hypodermic needle having a diameter of 0.9 mm, into a further quantity of water, wherein threads of the gel injected from said needle can be seen with the naked eye when introduced into said further quantity of water at 37° C and do not immediately disappear.”⁴

⁴ The parties’ dispute centers on the phrase “wherein threads of the gel . . .” *Markman* Hr’g Tr. 17:1-8. Specifically, the parties dispute whether the threads must (1) remain visible to the naked eye; and (2) immediately disappear. *Markman* Hr’g Tr. 17:9-10, 22:24-25-23:1-6. Plaintiffs argue that the phrase “visible to the naked eye” should have its plain and ordinary meaning. *Markman* Hr’g Tr. 17:11-14. The court agrees. “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.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (internal citations omitted). Defendants argue that the specification lacks a written description, is indefinite, and that the word “remain” means to remain visible when stirred. *Markman* Hr’g Tr. 26:15-21. The court does not typically entertain indefiniteness at this stage in the proceedings, and will not do so in this instance. Regardless, Defendants argue that the limitations apply to “remains visible to the naked eye” because “visually distinguishable” in a different patent with different language carries the same meaning. The court disagrees. *Kara Tech., Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1347 (Fed. Cir. 2011) (different claim terms in related patents are presumed to carry different meanings). During prosecution, Applicants explained that “visible to the naked eye” is different from “visually distinguishable.” Preliminary Amendment in Application No. 15/245,424 August 24, 2016, p. 3. In the context of the ‘610 Patent, “visible” means “can be seen.” Amendment to Application No. 15/245,424 dated December 16, 2016, at 9, n.1. Defendants also argue that the structural and functional requirements of the threads should be included in the construction. The court disagrees. *Thorner v. Sony Comput. Entn’t. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Claim 1 specifically states that “threads of the gel injected from said needle *remain visible to the naked eye* in said further quantity of water” without any additional restriction on the structure or function of the thread. ‘610 Patent, Claim 1; *Lairam Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998). In fact, the ‘610 Patent does not mention applying any mechanical action to the visible threads in any claim. The phrase “remain visible to the naked eye,” therefore, shall have its plain and ordinary meaning.

Second, Plaintiffs assert that the disavowal used to overcome prior art necessitates the inclusion of the phrase “do not immediately disappear” in the construction of the term. *Markman* Hr’g Tr. 23:7-9. The court agrees. During prosecution of a related patent, the inventors explained the claimed invention *excludes* dosage forms resulting in threads that immediately disappear. (D.I. 270 at 10-11); *ALA Engineering Ltd. v. Magotteaux Intern. S/A*, 657 F.3d 1264 (Fed. Cir. 2011) (the purpose in consulting the prosecution history in claim construction is to exclude any

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interpretation that had been disclaimed during prosecution). The parties appear to agree that a dosage form for which the threads “immediately disappear” would not meet the limitations of the claim at issue. *Markman* Hr’g Tr. 24:3-7; (D.I. 271 at 12.) Because the inventors disclaimed threads that “immediately disappear” during prosecution, the court adopts Plaintiffs’ proposed construction.