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 GRUNENTHAL GmbH Plaintiffs, v. ALVOGEN PINE BROOK, LLC, and ACTAVIS LABORATORIES FL, INC., Defendants.	C.A. No. 15-687-GMS (Consolidated)

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 6,733,783, 8,361,499, 8,551,520, 8,647,667, 9,023,401, 8,309,060, 8,529,948, 8,808,740, 9,056,052, 9,060,940, 9,084,816, 9,095,614, 9,096,615, 9,198,863, AND 9,205,056

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. 6,733,783 ("the '783 patent"), 8,361,499 ("the '499 patent"), 8,551,520 ("the '520 patent"), 8,647,667 ("the '667 patent"), 9,023,401 ("the '401 patent), 8,309,060 ("the '060 patent"), 8,529,948 ("the '948 patent"), 8,808,740 ("the '740 patent"), 9,056,052 ("the '052 patent"), 9,060,940 ("the '940 patent"), 9,084,816 ("the '816 patent"), 9,095,614 ("the '614 patent"), 9,095,615 ("the '615 patent"), 9,198,863 ("the '863 patent"), and 9,205,056 ("the '056 patent"):

1. The term **"controlled release material,"** as used in the '783, '499, '520, '667, '401, '052, and '940 patents, is construed to mean "a material other than the active

ingredient that causes the release of the drug (e.g., hydrocodone) at such a rate that blood concentrations are maintained within the therapeutic range but below toxic concentrations over a period of time of about 12 hours or longer."[1]

2. The term "**matrix,**" as used in the '783, '499, '060, '520, '667, '052, '056, '740, '816, '614, and '615 patents, is construed to mean "pharmaceutical preparation that incorporates a dispersed/embedded active ingredient/agent".[2]

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[1] After the *Markman* hearing, the parties reached agreement on the construction of "controlled release material." (D.I. 120 at 1).

[2] The parties' dispute centers on whether the term "matrix" should be considered a pharmaceutical preparation or a discrete solid structure. (D.I. 101 at 6). The court finds that the term should be construed as a "pharmaceutical preparation that incorporates a dispersed/embedded active ingredient/agent" because that construction comports with the description of the term in the asserted patents.

First, there is no evidence that the "matrix" needs to be a discrete structure. To the contrary, during the prosecution of the '499, '520, '667, '052, and '056 patents, applicants submitted a definition of matrix which defined it as a "substance containing something: a substance in which something is embedded or enclosed." *Matrix Definition*, Microsoft Encarta 2006. The '783 patent also describes the invention as "a tablet comprising a matrix of drug and controlled release material, and optionally other pharmaceutically desirable ingredients (e.g., diluents, binders, colorants, lubricants, etc.)." The patent and the prosecution history make no mention that the matrix must be separate from other pharmaceutical ingredients. Additionally, Defendants offer no explanation of what they mean by "discrete" except to say that "discrete just means it has to be distinct. It has to occupy some sort of contiguous identifiable space." *Markman* Hr'g Tr. 41:4–5. The court finds that Defendants' construction imports unwarranted and unnecessary confusion into the claims. Accordingly, the court finds no reason to import the term "discrete" into the construction of matrix.

To further support inclusion of the word "discrete," Defendants allege that a POSA must be able to identify individual matrices because claim 17 of the '401 patent discloses "a plurality of pharmaceutically acceptable matrices." '401 patent, col. 26 ll. 30–31. According to Defendants, the matrix must occupy some discrete, identifiable space because that is the only way to determine whether a dosage form has multiple matrices; therefore, satisfying the limitation of claim 17. *Markman* Hr'g Tr. 41:5. Defendants posed a question to the court during the *Markman* Hearing: "[h]ow is one to know if a dosage form with an active ingredient and say half a dozen excipients has one matrix or two matrices or six matrices if there [does not] . . . have to be any special distinction between them." Id. 41:24–42:2. The court is not persuaded by Defendants' argument because the claims do not require a certain number of matrices. Defendants admit that "*examples* of dosage forms . . . include a core, and then another layer, or a shell," implying multiple matrices. Tr. 42:6–7. Just because examples of dosage forms require the matrices to be discrete, that does not mean that every dosage form has to have discrete matrices. Accordingly, the court finds Plaintiff's position persuasive—the term "matrices" is just the plural of the term "matrix."

Second, outside of preferred embodiments discussed in the '783 patent, there is no evidence supporting the inclusion of "solid" in the construction of "matrix." Defendants argue that the specification solely provides examples of a solid dosage forms, which would inherently require solid matrices. (D.I. 102 at 4). That does not convince the court that it must adopt Defendants' construction, however. The Federal Circuit has repeatedly cautioned against importing limitations from the specification into the claims. *See Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998); *Phillips v. AWH Corp.*, 415

3. The term **"matrices,"** as used in the '401 patent, is construed to be the plural version of "matrix"—"pharmaceutical preparations that incorporate a dispersed/embedded active ingredient/agent."[3]

4. The term **"controlled release matrix material"** in the '740 patent is construed to mean "a material other than the active ingredient that is in a matrix and causes the release of the drug (e.g., hydrocodone) at such a rate that blood (e.g., plasma) concentrations are maintained within the therapeutic range but below toxic concentrations over a period of time of about 12 hours or longer."[4]

F.3d 1303, 1323 (Fed. Cir. 2005); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008). The court also sees a distinction between a solid dosage form and a solid matrix. The patents with the term matrix in their claim language do refer to solid dosages forms, but the court does not take that to mean that a solid matrix is also required. Defendants admit that the '060 patent refers to matrix materials that could exist in a semi-solid form, such as wax. *Markman* Hr'g Tr. 39:14–40:2. They contend, however, that the '060 patent requires a breaking strength of 500 N, so it does not make sense to have a dosage form with a very high breaking strength if the dosage form has a liquid matrix. *Id.* No scientific evidence was presented on that point, though. The fact that the patent mentions a semi-solid used in forming the matrix is enough to persuade the court it cannot adopt Defendants' construction. There is simply nothing in the asserted patents that convinces the court that the "matrix" must be a solid structure.

[3] The reasoning for this construction is identical to reasoning for the construction of "matrix" because "matrices" was construed as the plural of "matrix."

[4] Plaintiffs' and Defendants' proposed constructions are nearly identical, differing by only five words—"is in a matrix and." Plaintiffs contend that Defendants' inclusion of the phrase "in a matrix" removes the option of forming the matrix out of the claimed material itself. (D.I. 147 at 1). As evidence to support their argument, Plaintiffs point to the fact that polyethylene oxide can be both a matrix material and a controlled release material. '740 patent, col. 11 ll. 48–52, col. 14, l.65–col.15 l. 29. The court, though, does not understand how polyethylene oxide's status as a controlled release material and a matrix material in the '740 patent means that "controlled release matrix material" cannot be construed as "in a matrix."

In the '740 patent, regardless of whether polyethylene oxide is a matrix material or a controlled release material, it is still "in" the matrix. The patent provides a "non-limiting list of suitable controlled release materials," '740 patent, col. 14 ll.65–67, and then explains that "[c]ertain embodiments utilize mixtures of two or more of the foregoing controlled release materials *in* the matrix of the core." *Id.* col. 15 ll.11–12. When the patent describes polyethylene oxide as a matrix material it states that in certain embodiments, the first and second matrix material "comprise[] polyethylene oxide." '740 patent, col. 6 l. 3. Further, the patent states that "polyethylene oxide is contained *in* both components," where "both components" refers to the first and second matrix materials. Accordingly, requiring the controlled release matrix material to be "in a matrix" does not remove the option of forming the matrix out of the claimed material itself, as evidenced by the patents example of forming the matrix out of polyethylene oxide. The court finds that Defendants' proposed construction of "controlled release matrix material" is consistent with the usage of that phrase and related phrases throughout the '740 patent.

5. The term **"controlled release matrix material"** in the '060 patent is construed to mean "a material other than the active ingredient in which the active ingredient is embedded that also serves to control the release of the active ingredient from the dosage form."[5]

6. The term **"steady state,"** as used in the '667 patent, is construed to mean "the amount of the drug reaching the system is approximately the same as the amount of the drug leaving the system."[6]

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[5] Again, Plaintiffs' and Defendants' proposed constructions for "controlled release matrix material" in the '060 patent are almost identical. Defendants contend that the controlled release matrix material must "cause the release of the active ingredient from the dosage form at controlled rates." (D.I. 102 at 2). The court does not see an appreciable difference between "cause the release of the active ingredient from the dosage form at controlled rates" and "serve to control the release of the active ingredient." The court adopts Plaintiffs' proposed construction because the patent provides more support for it than "cause the release." *See* '060 patent, col. 16 ll. 19–20 ("Controlled release from the dosage form according to the invention is preferably achieved by embedding the active ingredient in a matrix. The auxiliary substances acting as matrix materials *control* active ingredient release.") (emphasis added).

The court also declines to adopt Defendants' proposed construction because of the phrase "at controlled rates." The court is unsure of the meaning of "controlled rates." The court agrees with Plaintiffs that the phrase implies a rate comparison to an immediate release dosage form when the patent and the prosecution history do not necessitate such a comparison. (D.I. 147 at 2). In the prosecution history, the applicants told the Examiner that "in dosage forms according to the subject invention the high molecular weight polyalkylene oxide serves as a controlled-release matrix thereby retarding the release profile of the drug." (D.I. 116, Ex. 31, Response to Dec. 28. 2006 Office Action at 12). Based on the inventor's statement to the Examiner, it seems that no comparison to an immediate release dosage form is necessary to explain the purpose of controlled-release matrix materials—to retard the release of the active pharmaceutical ingredient from the dosage form. For those reasons, the court adopts Plaintiffs' proposed construction.

[6] For the term "steady-state," the patentees acted as their own lexicographers. The '667 patent specification explicitly defines "steady state" as when "the amount of the drug reaching the system is approximately the same as the amount of the drug leaving the system." Col. 4 ll. 47–49. Defendants' proposed construction tracks the definition in the specification verbatim.

Plaintiff's main argument is that Defendants ignore the sentence that comes after the specification's definition of steady-states—"Thus, at 'steady-state,' the patient's body eliminates the drug at approximately the same rate that the drug becomes available to the patient's system through absorption into the blood." '667, col. 4 ll. 49–52. Plaintiffs contend that "the blood stream (i.e. blood serum) is the [relevant] "system" for "steady-state." (D.I. 101 at 15). Plaintiffs thus maintain that the proper construction of "steady state" is "[a] state in which the amount of drug reaching blood serum is approximately the same as the amount of drug leaving blood serum." *Id.* The court does not find Plaintiffs' argument persuasive. The court sees no reason to import the limitation "blood serum" into the patentees' explicit definition in the specification.

7. The term **"a C_{24}/C_{max} ratio,"** as used in the '783, '499, '520, '667, and '940 patents, is construed to mean "the ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval."[7]

8. The term **"A C_{24}/C_{max} hydrocodone ratio,"** as used in the '863 and '056 patents, "the ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval."[8]

9. The term **"a relatively flat serum plasma profile,"** as used in the '499 patent, is construed to mean "the plasma level of the drug provides a "C_{24}/C_{max} ratio of about 0.55 to about 1.0."[9]

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[7] Again, the patentees acted as their own lexicographer, defining "C_{24}/C_{max} ratio" as "the ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval." '783 patent, col. 4 ll. 4–7. Defendants' proposed construction restates the specification's definition of the term. Plaintiffs' proposed construction seeks to limit the dosing interval to 24 hours. The court sees no reason to unnecessarily narrow the patentees' definition to a 24-hour dosage interval. Plaintiffs' cite to one preferred embodiment where a 24-hour dosage interval is mentioned. *Id.* col. 3 ll. 11. Because the patentees acted as their own lexicographers, and because the patent only mentions a 24-hour dosing interval in a preferred embodiment, the court construes "C_{24}/C_{max} ratio" in accordance with its definition in the specification of the '783 patent.

[8] The court finds that there is no reason to construe this term differently than a "C_{24}/C_{max} ratio." Plaintiffs argue that the term should be construed to mean "a ratio of blood plasma concentration of hydrocodone 24 hours after administration of the dosage form to the highest plasma concentration of hydrocodone attained within the dosing interval (here 24 hours)." (D.I. 101 at 15–16). For the reasons previously stated, the court is not going to import the limitation of a 24-hour dosing interval into the claim language when the patent does not necessitate such a limitation. Additionally, the court finds it redundant and unnecessary to substitute "hydrocodone" for "drug." The patent's definition of a "C_{24}/C_{max} ratio" is "the ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval." When the '863 and '056 patents describe a "C_{24}/C_{max} ratio hydrocodone ratio," it is clear that said "drug" in the "C_{24}/C_{max} ratio" definition is hydrocodone. Accordingly, the court finds no reason to construe a "C_{24}/C_{max} hydrocodone ratio" differently from a "C_{24}/C_{max} ratio."

[9] The court adopts Plaintiffs proposed construction for "a relatively flat serum plasma profile." Plaintiffs contend that "[l]imiting the construction to a single data point, as Defendants propose, is incorrect." (D.I. 101 at 16). Plaintiffs argue that, in the context of the claim as a whole, the concept of a "flat profile" requires more than just a single data point on a graph." *Id.* To support their construction, Plaintiffs cite to references that the Examiner considered during prosecution. *Id.* at 17. One such reference was a patent by the same inventors where they described "a flat plasma profile" as "a plasma concentration of hydrocodone after attaining a maximum concentration during the dosing interval stays within about 60%

10. The term **"obtaining a serum profile,"** as used in the '940 patent, is construed to mean "establishing a blood plasma serum profile in a patient."[10]

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to about 100% of the maximum plasma concentration for the remainder of the dosing interval." *Id.*; U.S. Patent No. 7,943,174, col. 33 l.66–col.34 l. 4. The court does not understand how the inventors description of "a flat plasma profile" in the '174 patent is at all inconsistent with the definition they propose here. The inventors' description of a flat plasma profile in the '174 patent is essentially equivalent to saying that the C_{24}/C_{max} ratio is about 0.60 to 1.0—a ratio very close to the one in the '499 patent. Additionally, the patent discloses "[a] relatively flat serum plasma profile, meaning that the plasma level of the opioid provides a C_{24}/C_{max} ratio of about 0.55 to about 1.0. " '499 patent, col.1 ll. 45–53. Such a statement provides enough evidence that the adopted construction is the intended meaning of the claim term.

[10] The parties' disagreement centers on the word "obtaining." Defendants contend that "obtaining" requires a separate active method step—"taking a sample or assaying serum samples." (D.I. 112 at 6). To support that construction, Defendants cite to case law for the proposition that "[w]here a gerund phrase, such as 'obtaining a serum profile,' begins a subparagraph in a method claim, as it does here, that term is properly read as a distinct step requiring action in the method." (D.I. 112 at 6). Defendants also cite case law for the proposition that patent law somehow prohibits single-step method claims. The court does not think that the cases Defendant cites require that conclusion any time a gerund phrase is used in a claim. The meaning of the gerund phrase is context dependent.

The court in *Combined Sys., Inc. v. Def. Tech. Corp. of Am.*, 350 F.3d 1207 (Fed. Cir. 2003), found that the term "forming" required "deliberate and systematic creation of folds. In the court's analysis, it explained that the district court was instructed by not only the gerund form of the term, but also by the American Heritage Dictionary definition of the term and the term's use in the specification. *Id.* at 1210. Here, while the American Heritage Dictionary and the gerund form of the word might counsel against Plaintiff's proposed construction, the specification and the claim itself make clear that "obtaining a serum plasma profile" is actually a passive consequence of administering the drug.

First, claim 20 of the '940 patent discloses "[a] method of providing effective pain relief to a patient in need thereof comprising: obtaining a serum profile," having a specific plasma level, "by administering orally on a once-a-day basis a controlled release formulation of the hydrocodone." From that language, it appears that the desired serum profile is "obtained" by administering the drug. The specification supports the courts understanding.

According to the patentees, the novelty of the invention—improving the efficiency and quality of pain management in patients experiencing moderate pain—follows from providing the controlled release opioid formulation. *See* '940 patent, col. 1 ll. 38–40. Once the drug is administered, because of the release profile, there is "an early onset of therapeutic effect," and then "after rising to a maximum concentration during the dosage interval," the controlled release opioid formulation "provide[s] a relatively flat serum plasma profile, meaning that the plasma level of the opioid provides a C_{24}/C_{max} ratio of about 0.55 to about 1.0." *Id.* ll. 50–58. The word "assaying," in Defendants' construction is never used in the patent and the specification, neither implicitly nor explicitly, requires regular blood sampling. While the court understands how "obtaining" could imply an active assaying step in other contexts, the word, as used in the context of this patent, seems to rather clearly imply a passive occurrence that is the result of administering the controlled release formulation. For that reason, the court adopts Plaintiff's proposed construction.

11. The term **"thermoformed dosage form,"** as used in the '060 patent, is construed to include the use of subsequent heat.[11]

12. The term **"breaking strength of at least 500 N,"** as used in the '060 patent, is construed to mean "only separates into two or more pieces when exposed to a force of at least 500 N."[12]

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[11] There is agreement between the parties that "thermoforming" requires the application of heat and pressure. The dispute lies in whether the '060 patent allows for the subsequent application of heat to a dosage form. The court believes it does.

Defendants propose a construction of "thermoforming" that excludes dosage forms made using pressure and subsequent exposure to heat. The asserted claim, claim 1 of the '060 patent, does not mention a heating step. Instead, it just discloses a "thermoformed dosage form comprising one or more active ingredients with abuse potential." Col. 21 ll. 6–7. Claim 25 describes "[a] process for the production of a dosage form according to claim 1, comprising" mixing a number of components and then "press-forming the resultant mixture . . . to yield the dosage form with preceding, simultaneous, or subsequent exposure to heat." '060 patent, col. 23 ll. 1–8. There are only two steps in claim 25: (1) mixing the components; and (2) press-forming the resultant mixture. There is no implication that the mixture is thermoformed and then, at some later point, exposed to heat. The claim explicitly links "yield[ing] the dosage form" with the "preceding, simultaneous, or subsequent exposure to heat."

The specification is also replete with examples of subsequent applications of heat. The use of heat, subsequent to the application of pressure, is mentioned four separate times in the specification. '060 patent, col. 11 ll. 19, 27, 33, 44. Defendants attempt to undermine the disclosure of subsequent heating by pointing to one line in the specification: "[i]n direct tableting with subsequent exposure to heat, the formed tablets are briefly heated at least to the softening temperature (glass transition temperature, melting temperature, sintering temperature) of component (C) and cooled again." Defendants contend that the reference to "cooled again" implies that the dosage form was exposed to heat, then cooled, then heated again, and then "cooled again." In that scenario, Defendants argue, the dosage form is "thermoformed" using preceding or simultaneous heat, and then later, only after thermoforming is complete, is the dosage form exposed to heat again. "[C]ool[ing] again" is only discussed in the context of "direct tableting." '060 patent, col. 11 ll. 28–40. Direct tableting is explicitly labeled as one example by which the mixture can be formed into tablets. *Id.* For that reason, the specification's disclosure of a formed tablet being "cooled again" does not alter the court's conclusion that a thermoformed dosage form can be created with pressure and the subsequent application of heat.

[12] Plaintiffs contend that Defendants' proposed construction ignores the fact that "plastic deformation (i.e., change in shape) is not breaking." (D.I. 111 at 19). Interestingly, there is no dispute over that point—Defendants agree that plastic deformation is not breaking. *Markman* Hr'g Tr. 154:2–8. The examples in the patent specification also confirm that tablets are not considered broken when they suffer plastic deformation. *See* '060 patent, col. 19 ll. 25–26 ("The tablets did not break when exposed to a force of 500 N. The tablets did suffer a little plastic deformation."). The only dispute is over whether or not the construction should explicitly include plastic deformation. Construing the phrase at issue to include the clarification that plastic deformation is not breaking would be superfluous and confusing. Accordingly, the court adopts Defendants' proposed construction.

13. The term **"viscosity-increasing agent,"** as used in the '060 patent, is construed to mean "at least one substance that increases the thickness of the dosage form by forming a gel when exposed to a liquid, said substance being different from the synthetic or natural polymer (C) of claim 1 of the '060 patent."[13]

14. The term **"necessary minimum quantity of an aqueous liquid,"** as used in the '060 patent, is construed to mean "an aqueous liquid in a necessary minimum quantity."[14]

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[13] The only dispute between the parties with regard to this term is whether the viscosity-increasing agent of claim 9 must be distinct from hardening polymer (C) of claim 1. (D.I. 102 at 11). Multiple other courts have resolved this same dispute. *See Endo Pharm. Inc. v. Amneal Pharm., LLC*, No. 12 CIV. 8060 (TPG), 2015 WL 9459823, at *24 (S.D.N.Y. Aug. 18, 2015) (finding that the viscosity increasing agent is distinct from the hardening polymer of claim 1); *In re OxyContin Antitrust Litig.*, No. 04 MD. 1603 SHS, 2014 WL 2198590, at *9 (S.D.N.Y. May 27, 2014) (same); *Purdue Pharma L.P. v. Amneal Pharm., LLC*, No. 115CV01152RGASRF, 2017 WL 634939, at *6 (D. Del. Feb. 16, 2017) (same). The court agrees with the other courts that have considered the issue. The "viscosity-increasing agent" in claim 9 must be a different substance than the "synthetic or natural polymer (C)" of claim 1.

Plaintiffs contend that the claims and the intrinsic record do not exclude polymer (C) from serving as the viscosity-increasing agent. The court disagrees. Claim 9 discloses "[a] dosage form according to claim 1, which additionally comprises at least one of the following components a)-f): . . . (b) at least one viscosity-increasing agent." '060 patent, col. 21 ll. 37–42. The phrase "additionally comprises" leads the court to believe that the viscosity-increasing agent must be a component distinct from the components disclosed in claim 1. The specification confirms the court's reading of the plain language of claim 9.

The specification explains that dosage forms according to the invention cannot be crushed into a powder, effectively nullifying the possibility of intravenous or nasal abuse. '060 patent, col. 6 ll. 24–26. Polymer (C)—a component listed in claim 1—is included to increase the hardness of the dosage form and ensure that it cannot be easily pulverized or crushed. *Id.* col. 6 ll. 20–23. The specification goes on to explain that in order to prevent any abuse if a dosage form is somehow pulverized, the dosage form may "contain further agents which complicate or prevent abuse as auxiliary substances (B)." *Id.* ll. 28–34. The viscosity-increasing agent is listed as an auxiliary substance that can be included in the dosage form. *Id.* ll. 40–43. The fact that the auxiliary substance (B) is different from polymer (C) in claim 1, and the fact that the specification classifies auxiliary substances as "further agents," confirm the court's finding that the viscosity-increasing agent is distinct from polymer (C).

[14] Plaintiffs argue that the meaning of a "necessary minimum quantity of an aqueous solution" is derived from a test in the specification used to verify the suitability of a certain viscosity-increasing agent. That test provides:

> In order to verify whether a viscosity-increasing agent is suitable as component (b) for use in the dosage form according to the invention, the active ingredient is mixed with the viscosity-increasing agent and suspended in 10 ml of water at a temperature of 25°C. If this results in the formation of a gel which fulfills the above-stated conditions, the corresponding viscosity-increasing agent is suitable for preventing or averting abuse of the dosage forms of the invention.

'060 patent, col. 8 ll. 55–62. The meaning of "a necessary minimum quantity of an aqueous liquid" cannot be derived from the specification test because of key differences between it and the gelling test explained

15. The term **"combining said [opioid/hydrocodone] or pharmaceutically acceptable salt thereof with each of said low molecular weight polyethylene oxide and said high molecular weight polyethylene oxide to form at least one blend,"** as used in the '816, '614, and '615 patents, is construed to mean "forming at least one blend comprising said opioid or pharmaceutically acceptable salt thereof, said low molecular weight polyethylene oxide, and said high molecular weight polyethylene oxide."[15]

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in claim 9. Claim 9 requires that a gel form from the mixture of the "viscosity-increasing agent," a "necessary minimum quantity of an aqueous liquid," and "the extract obtained from the dosage form." '060 col. 21 ll. 41–56. As recognized in *OxyContin*, the claim 9 test "applies to the dosage form as a whole," whereas the specification test "is designed to assess whether a particular *viscosity-increasing agent* is suitable for use in the invention." 2014 WL 2198590, at *13.

Another key difference between the two tests is that the specification test calls for the mixture of the active-ingredient and the viscosity-increasing agent. The claim 9 test, by contrast, calls for a mixture of the viscosity-increasing agent and "the extract obtained from the dosage form." '060 patent, col. 21 l. 43. It is clear from claim 1 that the dosage form comprises components other than the active ingredient. *Id.* col. 21 ll. 6–14. Those additional components could affect gel formation. Accordingly, the example 3 test cannot inform the court's construction of "an aqueous liquid in a necessary minimum quantity."

Because the court finds that the patent does not provide a meaning for the claimed phrase, the court adopts Defendants' proposed plain meaning construction. The possible indefiniteness of the claim phrase is a matter that the parties can explore at trial.

[15] The parties disagree over the ingredients that must be mixed into a single blend and when that mixing must take place. Plaintiffs contend that all three ingredients—opioid, low molecular weight polyethylene oxide, and high molecular weight polyethylene oxide—need not be mixed into a single blend. (D.I. 101 at 14). Defendants argue that the claim phrase's plain meaning, when read alongside the rest of claim 1 of the '615, '614, 'and '816 patents, compels one conclusion: at least one of the blends in the tablet contains the recited opioid, the low molecular weight polyethylene oxide, and the high molecular weight polyetheylene oxide. (D.I. 112 at 13). Plaintiffs point to claim 21 of the '615 patent to demonstrate that it would be rendered meaningless if the court adopts Defendants' proposed construction. *Id.* While the court certainly understands Plaintiffs' argument, it cannot rewrite the language of claim 1. Even considering claim 1's awkward phrasing, there appears to be no way around the requirement that, as a baseline, the tablet must include an opioid, a high molecular weight polyethylene oxide, a low molecular weight polyethylene oxide, and an additive. Under Plaintiffs' construction, there is a possibility that if the tablet comprises only one blend, that blend can have either a low weight polyethylene oxide or a high weight polyethylene oxide, plus the additive. Such a tablet would fall outside of the scope of claim 1. The court's analysis of the parties' arguments is laid out below.

Claim 1 of the '615 patent discloses a "cured shaped tablet" comprising "an opioid . . . , at least one low molecular weight polyethylene oxide . . . , at least one high molecular weight polyethylene oxide . . . ; and at least one additive." '615 patent, col. 166 ll. 13–23. Claim 1 also discloses the process by which the tablet is prepared, which requires:

16. The term **"a gelling agent comprising polyethylene oxide in an effective amount to impart viscosity of at least about 10 cP when the dosage form is subjected to tampering by dissolution in from about 0.5 to about 10 ml of an aqueous liquid,"** as used in the '948 patent, is construed to mean "dissolving the dosage form in from about 0.5 to about 10 ml of an aqueous liquid, causing the resulting mixture to have a viscosity of at least about 10 cP."[16]

> [C]ombining said opioid or pharmaceutically acceptable salt thereof with each of said low molecular weight polyethylene oxide *and* said high molecular weight polyethylene oxide to form at least one blend, wherein said at least one blend further comprises at least one additive.

Id. ll. 26–31 (emphasis added). As Defendants point out, the plain and ordinary meaning of the language in claim 1 of the '615 patent requires all three ingredients to be present in the blend. (D.I. 102 at 13). The court finds that combining the opioid with "each of" the different-weight polyethylene oxides—where the claim uses the conjunctive "and"—means that the opioid must be combined with *both* the high and low molecular weight polyethylene oxides. Plaintiffs do not seriously dispute that the plain language of claim 1 of the patents appears to require all three ingredients in a single blend. Instead, they instruct the court to consider claim 21. (D.I. 101 at 14).

Claim 21 of the '615 patent then requires a "cured shaped tablet" according to claim 1, where "said low molecular weight polyethylene oxide comprises a first blend and said high molecular weight polyethylene oxide comprises a second blend, wherein at least one said blend further comprises said at least one additive." Col. 168 ll. 16–20. Plaintiffs contend that, if the court adopts Defendants' proposed construction, claim 21 is broader than claim 1, in violation of a cannon of claim construction. (D.I. 111 at 13). The court does not agree with Plaintiffs' contention. Claim 1 states the requirements when the cured shaped tablet comprises *one* blend. Claim 1 explicitly allows for the possibility of more than one blend, however. '615 patent, col. 166 l. 29. Claim 21 discloses a cured shaped tablet of claim 1 that comprises more than one blend, making claim 21 narrower than claim 1. *Id.* col 168 ll. 16–19. Claim 21 makes clear that when the tablet has more than one blend, those additional blends can be different from each other—one blend can have a mixture of opioid and a low molecular weight polyethylene oxide, and the other blend can have a mixture of opioid and high molecular weight polyethylene oxide. Claim 21 does nothing to negate the requirement that at least one blend comprises the opioid, a high molecular weight polyethylene oxide, and a low molecular weight polyethylene oxide.

Plaintiffs also contend that claim 23 of the '615 patent supports their construction because it discloses "[a] cured tablet as defined in claim 21, wherein at least one blend is compressed by direct compression." *Id.* col. 168 ll. 26–27. Similar to claim 21, claim 23 only states a requirement for one of the blends. The court does not read claim 23 as contradicting the language of claim 1. Claim 1 discloses "applying each said blend to form a shaped tablet." *Id.* col. 166 l. 32. Claim 23 is an example of applying one of the blends, via direct compression, to form a shaped tablet.

[16] The court adopts Defendants' plain meaning construction, postponing the resolution of the indefiniteness issue to trial. Plaintiffs seek to limit the claim phrase to a specific embodiment in the specification—the syringe method of example 3. The syringe method of example 3—where it is hard to fill an insulin syringe with a solution of 10 cP—cannot serve to limit the scope of the types of viscosity tests encompassed by the '948 patent because there is absolutely nothing in the patent that warrants such a

17. The term **"viscosity of at least about 60 cP,"** as used in the '948 patent, is construed to mean "dissolving the dosage form in from about 0.5 to about 10 ml of an aqueous liquid, causing the resulting mixture to have a viscosity of at least about 60 cP."[17]

18. The terms **"based on rheological measurements, . . . molecular weight" and "molecular weight . . . based on rheological measurements,"** as used in the '816, '614, and '615 patents, are construed to mean "a measurement of the mass of a molecule based on rheological measurements."[18]

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limitation. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004) ("[I]t is improper to read a limitation from the specification into the claims.").

The prosecution history of the '948 patent does not persuade the court to adopt Plaintiffs' construction. Plaintiffs argue that during the prosecution of the'948 patent, they pointed the Examiner to example 3 in the specification to "support the significance of the viscosity of at least 10 cP." (D.I. 115, Ex. 20 at 7). The applicants' statements only demonstrated that example 3 was one way to support the significance of the viscosity of at least 10 cP. It appears that the Examiner agreed during the interview that the Kao reference is totally "silent as to the dosage forms . . . achieving a viscosity of at least 10 cp when tampered." *Id.* The court agrees with Defendants that such a statement cannot amount to the necessary clear disavowal that would be required to limit the viscosity test of the '948 patent to xample 3. *See Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1276 (Fed. Cir. 2012) (explaining the importance of not limiting the claim scope based on statements made during prosecution unless there is a clear disavowal or different definition). The court finds that the statements the applicants made during prosecution do nothing to limit the construction of the claim phrase at issue.

[17] For the same reasons as the previous limitation, the court adopts Defendants' plain meaning construction and reserves the issue of indefiniteness for trial.

[18] The court in this instance declines to adopt either party's construction. Regardless of whether the wording of the claim is "based on rheological measurements, . . . molecular weight" or "molecular weight . . . based on rheological measurements" the construction remains the same. The specification of the McKenna patents (the '816, '614 and '615 patents) defines the claim phrase at issue. In the part of the specification that lays out the definitions of terms used therein, the specification states:

> For the purpose of this invention the approximate molecular weight is based on rheological measurements. Polyethylene oxide is considered to have an approximate molecular weight of 1,000,000 when a 2% (by wt) aqueous solution of said polyethylene oxide using a Brookfield viscometer Model RVF, spindle No. 1, at 10 rpm, at 25° C. shows a viscosity range of 400 to 800 mPa s (c).

'614 patent, col. 7 l. 61–col. 8 l. 1. The specification also goes on to define the meaning of other weights of polyethylene oxide. The specification's definition of "rheological measurements" is not found in a preferred embodiment or example, but instead, in the section where definitions of other terms are laid out. Because the court finds that the patentees essentially acted as their own lexicographers with regard to the meaning of "molecular weight . . . based on rheological measurements," the court declines to construe the term any more precisely than the patent warrants. In their briefing, Defendants took issue with the fact that Plaintiffs offered no construction for the phrase "rheological measurement." (D.I. 102 at 19). The court

19. The term **"average molecular weight,"** as used in the '863 and the '740 patents, is construed to mean "the average of the molecular weights."[19]

20. The term **"weight-average molecular weight,"** as used in the '863 and '948 patents, is construed to mean "the weighted average of the molecular weights."[20]

21. The phrase **"wherein the polymer (C) has a molecular weight of at least 0.5 million according to rheological measurements,"** as used in the '060 patent, is

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finds that the meaning of that phrase is defined by way of the specific test outlined in the specification. Accordingly, the court sees no need to be any more specific in its construction of the disputed phrases.

Lastly, Plaintiffs' proposed that the phrases be construed to mean "a measurement of the mass of a molecule [based on] correlation of molecular weight to viscosity according to rheological measurements." The specification states that the "polyethylene oxide is considered to have an approximate molecular when the "Brookfield viscometer Model RVF, spindle No. 1, at 10 rpm, at 25° C. shows a [specific] viscosity range." The court declines to infer a correlation between molecular weight and viscosity from that disclosure. '614 patent, col. 7 l. 61–col. 8 l. 1.

[19] Plaintiffs contend that when the patent says "average molecular weight" it actually means "weight-average molecular weight. (D.I. 102 at 16). Plaintiffs thus advance the same construction for both terms: "Calculating molecular weight of a polymer sample when taking into account the molecular size of each polymer chain rather than just the number of molecules." (D.I. 101 at 10). Plaintiffs outline a number of reasons why Defendant's construction is incorrect, but they never cite evidence as to why their proposed construction is correct. In their opening brief, Plaintiffs state that "number average is a simpler calculation, but the weight-average molecular weight formula accounts for longer polymer chains having more mass." *Id.* at 9. They provide no evidence to support that fact. Plaintiffs also claim that the patentees' intent to convey "weight-average molecular weight" when using the term "average molecular weight" is evidenced by their use of viscosity measurements to approximate molecular weight. (D.I. 101 at 9). According to plaintiffs, viscosity measurements and weight-average molecular weight measurements account for the different length of polymer chains. *Id.* While all of that may be true, the court received no intrinsic or extrinsic evidence—in briefing or at the *Markman* hearing—to support Plaintiffs' proposed construction. The court cannot determine the meaning of weight-average and average molecular weight based on attorney argument alone.

Further, the patents do not just use the terms "average molecular weight" and "weight-average molecular weight." The '863 and the '948 patents mention both weight-average and number-average molecular weights. '948 patent, col. 24 ll. 55–57 (number-average), col. 23 ll. 35–37 (weight-average); '863 patent, col. 9 ll. 12–15 (number-average), col. 16 ll.34–37 (weight-average). The '740 mentions neither weight-average nor number-average molecular weight, and, instead, explains approximate molecular weight as a number determined by a viscosity range. '740 patent, col. 15 l.30–col.16 l. 3. Plaintiffs admit that "there are different ways to characterize molecular weight for polymers, the two most well-known being weight-average and number-average." (D.I. 101 at 9) (internal quotation marks omitted). Defendants' Expert, Dr. Ryu, also stated in his declaration that "there are different kinds of 'average molecular weights' that can be used to characterize a polydisperse polymer such as PEO." (D.I. 105 at 7). Accordingly, the court adopts Defendants' proposed constructions, which follows from the plain and ordinary meaning of both terms, and reserves ruling on indefiniteness until trial.

[20] The explanation for the construction of "average molecular weight," *supra* note 19, also applies to "weight-average molecular weight."

construed to mean "wherein the mass of the molecules of polymer (C) is at least 0.5 million according to rheological measurements."[21]

22. The phrase **"a shell encasing the core,"** as used in the '740 patent, is construed to mean "the outer layer of the dosage form surrounding the core."[22]

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[21] Plaintiffs' proposed construction changed only the word "molecular weight" in the claim phrase, making it "weight-average molecular weight." Defendants claim that the phrase is indefinite, but to the extent it can be construed, it should be construed as "[w]herein the mass of the molecules of polymer (C) is at least 0.5 million according to measurements based on the change in form and the flow of matter." The court declines to adopt either party's proposed construction. The court reserves ruling on the indefiniteness issue until trial.

The '060 patent never mentions "weight-average molecular weight." Plaintiffs point to the prosecution history of the parent application, now U.S. Patent No. 8,114,383, as evidence that when the applicant's used the word "molecular weight" they meant "weight-average molecular weight." It is true that the applicants described component (C) in Example 3 as having an "average molecular weight M_w of 100,000 g/mol." (D.I. 116, Ex. 31, Aug. 25, 2008 Bartholomaus Decl. at 5). There does not appear to be a disagreement between Plaintiffs and Defendants that M_w is a symbol commonly used in scientific literature to denote weight-average molecular weight. See (D.I. 101 at 12); (D.I. 105 at 7). Still, the court is not persuaded that "average molecular weight" should be limited to weight-average molecular weight in the '060 patent. The court does not find it proper to limit the scope of "average molecular weight" when the only evidence in support of such a limitation comes from the prosecution history of a related patent. There is nothing in the specification or claims of the '060 patent that counsels in favor of limiting the scope of "average molecular weight."

The court also declines to limit the term "rheological measurement" to "measurements based on the change in form and the flow of matter." Again, the '060 patent does not support that construction. The '060 patent indicates what it means by "rheological measurements." The specification of the '060 patent discloses:

> [P]olyethylene oxides, with a molecular weight of at least 0.5 million, preferably of up to 15 million, determined by rheological measurements, are very particularly preferred. These polymers have a viscosity at 25° C. if 4500 to 17600 cP, measured on a 5 wt. % aqueous solution using a model RVF Brookfield viscometer.

'060 patent, col. 5 l.66–col.6 l. 4. Accordingly, the court construes "rheological measurements" to have its plain and ordinary meaning to a person skilled in the art, in the context of the entire patent. *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016) (explaining that the plain and ordinary meaning "of a claim term is its meaning to the ordinary artisan after reading the entire patent").

[22] The dispute as to this issue can be distilled to one question: can the "shell" be an internal layer of the dosage form? Though Plaintiffs proposed a construction for "core," Defendants did not propose a counter-construction. There does not appear to be a genuine dispute over the meaning of "core." *Markman* Hr'g Tr. 106:6–9. As for the term "shell," Plaintiffs contend that it is "a layer or surface enclosing a space or surrounding an object." By contrast, Defendants argue that when the inventor used the word "shell" he meant to refer to only the very outer layer of the dosage form comprising the opioid and polyethylene oxide. For the reasons that follow, the court adopts Defendants' construction.

The specification uses two different definitions to describe the layer that "encase[es] the core" and comprises "a second portion of the opioid analgesic," '740 patent, col. 47 ll. 38–40, depending on the layer's location. When that layer is the outermost layer, the specification refers to it as "the shell." *See id.* col. 28

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ll. 17–41. When that layer is the interior layer, the specification refers to it as the "dry coat." *See id.* col. 32 l. 43–col. 33 l. 48. It is clear from the patent that the inventors wanted to refer to the layers differently despite the fact that they have close to the same composition. The necessary implication is that when the dosage form includes a cosmetic coat, the layer previously described as "the shell" becomes the "dry coat" because it is no longer the outermost layer.

Plaintiffs argue that construing the "shell" to be the "outer layer of the dosage form," somehow makes it so that the cosmetic layer becomes the "shell" in examples 7–12 and 14–20. *Markman* Hr'g Tr. 115:14–19. The court disagrees. Defendants admitted during the *Markman* Hearing that examples 7–20 and 14–20 do not disclose a shell. *Id.* 116:3–14. There is no dispute that the cosmetic coat disclosed in examples 7–12 and 14–20 cannot be the "shell" discussed in the asserted claims. It simply does not meet the claim requirements for a "shell." '740 patent, col. 47 ll. 38–40. Further, there seems to be no issue with the fact the examples 7–12 and 14–20 do not disclose a shell because claims 91–95 do not require a shell. Id. col. 52 l. 38–col. 54 l. 19. Therefore, examples 7–12 and 14–20 do not fall outside of the scope of all of the claims. The court thus adopts Defendants' proposed construction for "a shell encasing the core."