NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MALLINCKRODT LLC, and MALLINCKRODT, INC., *Plaintiffs*, v. ACTAVIS LABORATORIES FL., INC., *Defendant*.	Civil No.: 2:15-cv-3800 (KSH) (CLW) **OPINION**

Katharine S. Hayden, U.S.D.J.

I. BACKGROUND

Plaintiffs Mallinckrodt LLC and Mallinckrodt Inc. (collectively, "Mallinckrodt") own various patents covering an extended release drug product containing the active ingredients acetaminophen and oxycodone, which Mallinckrodt sells under the trade name XARTEMIS® XR. This case arises out of the filing of ANDA NO. 207113 by Actavis Laboratories Fl., Inc. ("Actavis") with the U.S. Food and Drug Administration seeking approval to market a generic version of XARTEMIS® XR.

Mallinckrodt filed an amended complaint on November 2, 2015 (D.E. 37), alleging that by submitting the above-referenced ANDA, Actavis infringed 11 patents held by Mallinckrodt and/or co-plaintiff Depomed.[1] On May 25, 2016, the parties stipulated to the dismissal of all claims and counterclaims pertaining to 7 of the 11 above-mentioned patents (D.E. 66). In anticipation of a *Markman* hearing, the parties submitted a Joint Claim Construction and

[1] On June 22, 2016, the parties stipulated to the dismissal of all claims and counterclaims as to Depomed (D.E. 71).

Prehearing Statement (D.E. 64), along with opening and responsive *Markman* briefs (D.E. 72, 73, 79, 80), identifying disputed claim terms in the remaining patents-in-suit—patent numbers 8,658,631 (the "'631 Patent"), 8,741,885 (the "'885 Patent"), 8,992,975 (the "'975 Patent"), and 9,050,335 (the "'335 Patent")—and setting forth proposed constructions.

II. LEGAL STANDARD

A. Claim Construction

"[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). To interpret a claim, the Court first looks to "intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (internal citation omitted).

Thus, "[c]laim construction begins with the language of the claims themselves." *Imaginal Systematic, LLC v. Leggett & Platt, Inc.*, 805 F.3d 1102, 1108 (Fed. Cir. 2015) (citing *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). Words of a claim should be given their customary meaning – that is, "the meaning that the term would have to a person of ordinary skill in the art at the time of the invention." *Id.* (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc)). A court must read the claims "in view of the specification, of which they are a part." *Phillips*, at 1315. 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." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). However, a court should "avoid

importing limitations from the specification into the claims." *Phillips*, 415 F.3d at 1323. Under the doctrine of claim differentiation, a court should also endeavor not to read a limitation from a dependent claim into an independent claim. *Summit 6, LLC v. Samsung Electronics Co., Ltd.*, 802 F.3d 1283, 1290 (Fed. Cir. 2015). A court may also look to the patent prosecution history to help understand the claim language, but the history may not "'enlarge, diminish, or vary' the limitations in the claims." *Markman*, 52 F.3d at 980 (quoting *Goodyear Dental Vulcanite Co. v. Darvis*, 102 U.S. 222, 227 (1880)).

Additionally, a court must adopt a term's plain and ordinary meaning unless a patentee "sets out a definition and acts as his own lexicographer," or unequivocally "disavows" a certain meaning in order to obtain the patent. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed.Cir.2012) (citation omitted); *see also Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed.Cir.2003). Absent lexicography or disavowal, courts "do not depart from the plain meaning of the claims." *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed.Cir.2016) (citation omitted). In other words, a patentee should ordinarily receive the benefit of "the full scope of its plain language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed.Cir.2004).

"Although courts are permitted to consider extrinsic evidence, like expert testimony, dictionaries, and treatises, such evidence is generally of less significance than the intrinsic record." *Summit 6, LLC*, 802 F.3d at 1290 (citing *Phillips*, 415 F.3d at 1317). "Undue reliance on external evidence poses the risk that it will be used to change the meaning of claims in derogation of the [public record of intrinsic evidence], thereby undermining the public notice function of patents." (*Phillips*, 415 F.3d at 1319.) Accordingly, courts should only rely on extrinsic evidence "when the claim language remains genuinely ambiguous after consideration of

the intrinsic evidence." *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed. Cir. 2001). "Extrinsic evidence may not be used 'to contradict claim meaning that is unambiguous in light of the intrinsic evidence.'" *Summit 6, LLC*, 802 F.3d at 1290 (quoting *Phillips*, 415 F.3d at 1317).

In summary, the Court must first look to the language of the claim itself and determine the terms' meanings as they would be understood by a person of ordinary skill in the art ("POSITA"). *Philips*, 415 F.3d at 1312-13. The Court may also look to the specification and prosecution history. *Id.* at 1315, 1317. If the terms are still ambiguous, the Court may consult extrinsic evidence such as dictionaries or expert testimony. *Id.* at 1317-18.

B. Indefiniteness

Section 112(b) of the Patent Act requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). A claim is sufficiently definite "[i]f one skilled in the art would understand the bounds of the claim when read in light of the specification." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, [courts] have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Id.*

A claim is indefinite when "an accused infringer shows by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton Energy Servs., Inc. v. M–I LLC*, 514 F.3d 1244, 1249–50 (Fed. Cir. 2008).

The "determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Exxon,* 265 F.3d at 1376. The Supreme Court has stated that "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.*, 134 S.Ct. 2124 (2014).

III. DISCUSSION

A. "AUC"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"AUC"	Plain and ordinary meaning. No construction necessary. In the alternative, the term means "area under the plasma concentration curve."	"Total exposure."

The term "AUC" is recited in claims 1 and 22 of the '885 Patent and claims 8, 9, 10, and 18 of the '975 Patent. At oral argument, the parties agreed that "AUC" means "area under the plasma concentration curve from time equals zero to infinity." *See* Markman Hearing Tr., at p. 53:5–11. Accordingly, the Court adopts the parties' agreed-upon construction of this claim term.

B. "in a fasted state"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"in a fasted state"	Plain and ordinary meaning. No construction necessary. In the alternative, the term means "in a state following at least 10 hours without food."	"Not having ingested food for at least 1 hour prior to administration of each dose of the composition."

The term "in a fasted state" is recited in claims 1 and 22 of the '885 Patent and claim 1 of the '335 Patent.

The specification for the '885 Patent states in relevant part:

> A fasted state may be defined as not having ingested food for at least 10 hours prior to administration of the composition. In some embodiments, the subject may have fasted for at least 10 hours prior to the first dose and refrains from ingesting food for at least one hour prior to administration of subsequent doses. In other embodiments, the fasted subject may not have ingested food for at least 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 7 hours, 8 hours, 9 hours, or 10 hours prior to administration of each dose of the composition.

'885 Patent, col. 37, ll. 42–57 (emphasis added).

The specification for the '335 Patent states in relevant part:

> In general, a fasted state is defined as not having ingested food for at least 10 hours prior to administration of the composition. In some embodiments, the pharmaceutical composition may be administered to a subject who has fasted for at least 10 hours prior to the first dose and who fasts for at least one hour prior to administration of subsequent doses. In other embodiments, the pharmaceutical composition may be administered to a subject who has fasted for at least 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 7 hours, 8 hours, 9 hours or 10 hours prior to administration of each dose.

'335 Patent, col. 67, l. 63–col. 68, l. 14. (emphasis added).

Actavis argues that by virtue of the above language in the '885 and '335 Patents, the patentees explicitly defined the "fasted state" as not having ingested food for anywhere between at least one to ten hours before administration of each dose. Accordingly, Actavis asks the Court to construe the claim term "fasted state" to mean "not having ingested food for at least 1 hour prior to administration of each dose of the composition." By contrast, Mallinckrodt argues that the term "fasted state" has a plain and ordinary meaning that need not be construed. In the alternative, Mallinckrodt argues that the '885 and '335 Patents expressly define the term as "not having ingested food for at least 10 hours prior to administration of the composition."

With respect to Mallinckrodt's proposed alternative construction, Actavis counters that a definition of "fasted state" that is marked by at least 10 hours of fasting would exclude embodiments described in the specification where a "fasted subject" had not "ingested food for

anywhere between at least one to ten hours before administration." *See* Actavis Opening Br., at p. 8. Actavis further argues that Mallinckrodt's construction contradicts other disclosures in the '885 and '335 Patent specifications. For example, the patents describe a study where the composition was administered "*under fasted conditions (10 hours for the first dose on Days 1 and 5;* ***at least 1 hour for all other doses***." '885 Patent, col. 126, ll. 1–20; '335 Patent, col. 97, ll. 97–34 (emphasis added).

Mallinckrodt counters that although the specifications disclose embodiments where a "fasted subject" has not ingested food for anywhere between at least one to ten hours before administration of each dose, "nothing about the specification shows that the inventors intended to include language regarding a 'fasting subject' in the original definition of 'fasted state.'" Mallinckrodt Resp. Br., at p. 9. In other words, Mallinckrodt argues, "a subject can fast for a period of five hours, but not be 'in a fasted state.'" *Id.* at 10. By contrast, Actavis argues that a POSITA would understand the terms "the subject may have fasted," the "fasted subject," "fasted condition," and "fasted state" all refer to the same concept. *See* Actavis Resp. Br., at p. 5.

Where a patentee acts as its own lexicographer and assigns a specific definition to a term, "the patentee's lexicography must govern the claim construction analysis." *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1356 (Fed. Cir. 2014). Consistent with the language in the relevant specifications, the Court construes the phrase "fasted state" to mean "not having ingested food for at least 10 hours prior to administration of the composition." Although the specifications disclose embodiments where the composition is administered to a "fasted subject" or "a subject who has fasted" for less than 10 hours, nothing in the specifications suggests that a "fasted subject" or "a subject who has fasted" is necessarily in a "fasted state." Additionally, although the patents describe a study where the composition was administered under "fasted

conditions" of less than 10 hours, nothing in the specifications suggests that a subject who ingests a dose under "fasted conditions" is necessarily in a "fasted state." Thus, contrary to Actavis's proposed construction, the Court finds that a subject can fast for a period of less than 10 hours but not be in a "fasted state" as that term is used in the disputed claims terms, and for that reason, construing "fasted state" to mean "not having ingested food for at least 10 hours prior to administration of the composition" does not exclude any disclosed embodiments, as Actavis suggests.

C. "in a fed state"

Claim Term	**Mallinckrodt's Construction**	**Actavis's Construction**
"in a fed state"	Plain and ordinary meaning. No construction necessary.	"Having consumed food within about 30 minutes prior to administration of the composition. The food may be a high fat meal, a low fat meal, a high calorie meal, or a low calorie meal."

The term "in a fed state" is recited in claims 1 and 22 of the '885 Patent and claim 16 of the '335 Patent.

The specifications for the '885 Patent and '335 Patent both state in relevant part:

> In general, a fed state is defined as having consumed food within about 30 min prior to administration of the composition. The food may be a high fat meal, a low fat meal, a high calorie meal, or a low calorie meal.

'885 Patent, col. 37, ll. 44–48; '335 Patent, col. 67, l. 65–col. 68, l. 1.

Actavis argues that the Court should adopt the above excerpt in its entirety as a definition for the term "in a fed state." *See* Actavis Opening Br., at p. 9. By contrast, Mallinckrodt argues that the Court should afford the term its plain and ordinary meaning, which, according to Mallinckrodt, the '885 and '335 Patents define as "having consumed food within about 30 min prior to administration of the composition." *See* Mallinckrodt Opening Br., at pp. 18–19. Thus,

while the parties generally agree that a "fed state" is characterized by the consumption of food within about 30 minutes prior to drug administration, the parties disagree on whether construction of the phrase requires an explicit definition of the word "food."

According to Actavis, "food with different fat and calorie content will affect the delivery and absorption of a particular drug, and to evaluate fully the effect from food, a [POSITA] would administer different types of food to subjects, each of whom is considered to be in a 'fed state.'" Actavis Resp. Br., at p. 8 (citing Lipman Decl., at ¶ 40). Thus, Actavis argues, "it is important to specify, as the patentees did, the types of food suitable for such studies involving a particular drug." *Id.* (citing Lipman Resp. Decl., at ¶ 16). Mallinckrodt counters that to define the word "food" as Actavis proposes would provide minimal guidance, since the proposed definition is only a partial description of the types of food that a subject may consume (i.e. "[T]he food ***may*** be . . ."). *See* Mallinckrodt Resp. Br., at p. 13. Mallinckrodt adds that "food" is a simple, non-technical word, the meaning of which is readily apparent, even to laypersons. *Id.*

The Court adopts the first sentence of Actavis's proposal and construes the term "in a fed state" to mean "having consumed food within about 30 minutes prior to administration of the compound." There is no disagreement among the parties as to this portion of the term's meaning. However, the Court declines to further define the word "food" when construing this term. As noted above, Actavis asks the Court to include in its construction of "in a fed state" language indicating that "[t]he food may be a high fat meal, a low fat meal, a high calorie meal, or a low calorie meal." But, as Actavis's own expert concedes, this is only a "partial description of the types of food that a subject may consume." *See* Lipman Dep. At 44:18–46:1. The Court finds that incorporating a "partial description" of types of foods into the definition of "in a fed state[,]" as Actavis proposes, would only give rise to ambiguity, not clarity.

D. "wherein the composition is in the form of a tablet and a single dose comprises two tablets"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"wherein the composition is in the form of a tablet and a single dose comprises two tablets"	Plain and ordinary meaning. No construction necessary. Definite.	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

This phrase appears in claims 8 and 23 of the '335 Patent.

This term appears in dependent claims which, pursuant to 35 U.S.C. § 112(d), must "contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Accordingly, Actavis argues that:

> [w]ithout first indicating in the claims from which claims 8 and 23 depend, what a "single dose" is or what it means in the independent claims, there is no antecedent basis for "single dose," and it is improper to refer to, and further limit, this term in the dependent claims.

Thus, Actavis concludes, the term is indefinite.

Pursuant to Section 2173.05(e) ("Lack of Antecedent Basis") of the Manual of Patent Examining Procedure ("MPEP"), published by the United States Patent and Trademark Office:

> A claim is indefinite when it contains words or phrases whose meaning is unclear. *In re Packard,* 751 F.3d 1307, 1314 (Fed. Cir. 2014). The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited earlier in the claim, the recitation of "said lever" in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended. A claim which refers to "said aluminum lever," but recites only "a lever" earlier in the claim, is indefinite because it is uncertain as to the lever to which reference is made . . . .

As an initial matter, the Court finds Actavis's "antecedent basis" argument to be misplaced. Consistent with § 2173.05(e) of the MPEP, an antecedent basis issue might potentially arise if claims 8 and 23 referred to "*said* single dose" or "*the* single dose" in the absence of an earlier recitation of the phrase. However, the dependent claims here simply refer to "*a* single dose" and do not implicate an earlier use of the phrase "single dose" in the relevant independent claims.

Moreover, "the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite." *See* MPEP § 2173.05(e). Thus, the issue is not whether the phrase "single dose" appears or is defined in the independent claims, but whether the meaning of the disputed claim term as a whole would be reasonably ascertainable by a POSITA.

Although Actavis asserts that the concept of a "dose" is improperly introduced in a dependent claim for the first time, Actavis does not actually argue that the meaning of the phrase "single dose" is not reasonably clear. *See* Markman Hearing Tr., at 36:18–21 (Actavis's counsel: "our argument . . . is not that we don't understand that a single dose comprises two tablet. It is that there's not a sufficient antecedent basis in the end of claim 1, for the term single dose").

As explained above, the Court finds that Actavis's "antecedent basis" argument is without merit and, in any event, that the phrase "wherein the composition is in the form of a tablet and a single dose comprises two tablets" has a plain and ordinary meaning that does not require construction.

E. "wherein the bioavailability of the acetaminophen and the oxycodone or the pharmaceutically acceptable salt thereof is not affected by the absence of food in a subject's gastrointestinal tract"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"wherein the bioavailability of the acetaminophen and the oxycodone or the	Plain and ordinary meaning. No construction necessary.	"Wherein the rate and extent of the absorption and availability at the site of action of the acetaminophen

pharmaceutically acceptable salt thereof is not affected by the absence of food in a subject's gastrointestinal tract"	In the alternative, "wherein the rate and extent of the absorption and availability at the site of action of the acetaminophen and the oxycodone or the pharmaceutically acceptable salt thereof is not substantially affected by the absence of food in a subject's gastrointestinal tract"	and the oxycodone or the pharmaceutically acceptable salt thereof is the same regardless of whether the subject is in a fed or a fasted state"

This phrase is recited in claims 13 and 29 of the '885 Patent.

At the heart of the parties' disagreement over this claim term is the phrase "not affected by the absence of food in a subject's gastrointestinal tract[,]" which Actavis ask the Court to construe to mean "the same regardless of whether the subject is in a fed or fasted state." Specifically, Actavis argues that the patentees use of the phrase "not affected" in claims 13 and 29 of '885 Patent indicates to a POSITA that "there is *no difference* in the pharmacokinetic parameters recited in these claims—i.e. they are the same." *See* Actavis Opening Br., at p. 11 (emphasis added). By contrast, Mallinckrodt argues that the clause "is not affected by the absence of food in a subject's gastrointestinal tract" means that "*there is no substantial difference* between the bioavailability of acetaminophen and oxycodone when administered to a subject in either a fed state or a fasted state," which Mallinckrodt asserts is easily understood by a POSITA. *See* Mallinckrodt Opening Br., at p. 24 (emphasis added). Mallinckrodt further argues that Actavis's proposed construction, which would require an *identical* absorption rate in the fed and fasted states, is an impermissible attempt to narrow the claims. *See id*.

In support of its proposed alternative construction, Mallinckrodt highlights a section of the specification entitled, "The Pharmacokinetic Profiles are *not Affected* by the Fed or Fasted State of the Subject," which Mallinckrodt argues provides objective guidance as to the meaning of the phrase "not affected." *See* Mallinckrodt Resp. Br., at p. 18 (emphasis added). Specifically, that section of the specification states in relevant part:

> Because non-opioid GR dosage forms of the prior art, as well as prior art extended release opioid formulation, demonstrate food effects, Applicants expected to likewise see a food effect with the pharmaceutical compositions of the present invention. Here, however, Applicants have surprisingly discovered that the pharmacokinetic profiles of the oxycodone and acetaminophen, and the hydrocodone and acetaminophen, are *not substantially affected* by the fed or fasted state of a human subject ingesting the composition. This means that there is *no substantial difference* in the quantity of drug absorbed or the rate of drug absorption when the oxycodone/acetaminophen compositions are administered in the fed versus the fasted state.

'885 Patent, at col. 90, ll. 45–55 (emphasis added).

The '885 Patent's specification further states:

> [T]he pharmacokinetic parameters of the compositions of the invention are *similar* when the composition is administered in the fed and fasted states. Benefits of a dosage form, which *substantially eliminates the effect of food*, include an increase in convenience, thereby increasing patient compliance, as the patient does not need to ensure that they are taking a dose either with or without food.

'885 Patent, at col. 90, ll. 62 – col. 91 l. 2 (emphasis added).

Finally, the same section of the specification describes an embodiment of the invention in which the administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, and further defines the conditions that are required in order to establish bioequivalence (i.e. "(1) a 90% Confidence Interval (CI) for AUC which is between 80% and 125%, and (2) a 90% CI for $C_{max,}$ which is 80% and 125%"). *See* '885 Patent, at col. 91 ll. 4–16.

When interpreted in context of the above-referenced sections of the specification, the Court construes the phrase "not affected" to mean "not substantially affected" and finds that, in context of the specification, this disputed claim term is reasonably understood to mean that there is "no substantial difference" in the composition's bioavailability in the fed and fasted states, thereby claiming a composition that "substantially eliminates the effect of food." *Vitronics*

Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (the specification "is the single best guide to the meaning of a disputed term"). Thus, the Court adopts Mallinckrodt's alternative proposed construction and construes this disputed claim term in full to mean "wherein the rate and extent of the absorption and availability at the site of action of the acetaminophen and the oxycodone or the pharmaceutically acceptable salt thereof is not substantially affected by the absence of food in a subject's gastrointestinal tract."

F. "multiple doses"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"multiple doses"	Plain and ordinary meaning. No construction necessary.	"More than one dose."

The term "multiple doses" appears in claim 17 of the '631 Patent and claims 13, 16, and 17 of the '975 Patent. At oral argument, the parties came to an agreement that "multiple doses" means "more than one dose." *See* Markman Hearing Tr., at p. 53:14–18. Accordingly, the Court adopts the parties' agreed-upon construction of this claim term.

G. "oral administration of" and "orally administered to"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"oral administration of a single dose of the composition to a subject" "oral administration of multiple doses of the composition to a subject" "oral administration of the composition" "wherein upon oral administration of two solid oral	Plain and ordinary meaning. No construction necessary.	This phrase appears in connection with specifically claimed pharmacokinetic properties. Thus, the proper construction of this language requires that "oral administration of" the claimed composition to a subject always results in the claimed pharmacokinetic properties, regardless of whether the subject is in the fed or fasted state.

dosage forms of the composition in multiple doses" "wherein upon oral administration of two solid oral dosage forms of the composition" "orally administered to a subject in need thereof"		

The "oral administration of" term appears in claims 2 and 4 of the '631 Patent and claims 1, 8, 13, 16, 17, 23, and 30 of the '975 Patent. The "orally administered to" term appears in claims 1 and 22 of the '885 Patent and claim 31 of the '335 Patent.

Each of the disputed "oral administration" terms appear in the context of administering the claimed composition to a subject, who then exhibits specific pharmacokinetic properties. Actavis argues that the absence of any reference to a specific food state (i.e. fasted or fed) in a given "oral administration" term creates ambiguity as to whether the pharmacokinetic properties exhibited by the claimed compositions must be met by a subject who is in the fed state, the fasted state, either, or both. *See* Actavis Resp. Br., at p. 14. Accordingly, Actavis argues that where the phrase "oral administration" is used and the food state of the subject is not specified, "this means that the specifically claims parameters must be met when the subject is in *both* the fed and fasted states." *Id.* Thus, Actavis requests the court to construe these terms to mean that oral administration of the claimed compositions to a subject "always results in the claimed pharmacokinetic properties, regardless of whether the subject is in the fed or fasted state." By contrast, Mallinckrodt argues that the disputed "oral administration" terms have a plain and ordinary meaning and that no construction is necessary.

Actavis offers two general arguments in support of its proposed construction. First, Actavis argues that "[e]ven though the claim language itself does not specify a fed or fasted state, the specifications demonstrate that the patentees knew how to specify an individual food state when they intended to." Actavis Moving Br., at p. 15. Thus, Actavis argues, "[b]y not so specifying in the claims, the claims require both the fed and fasted food states." *Id.*

The Court finds this first argument unavailing. By stating that the patentees knew how to specify an individual food state when they intended to, Actavis is implicitly suggesting that patentees' lack of indication of a food state in the disputed "oral administration" terms was also intentional. Accordingly, to construe these terms to mean that, once administered, the claimed compositions "always result[] in the claimed pharmacokinetic properties, regardless of whether the subject is in the fed or fasted state[,]" as Actavis requests, would be to import limitations into the claims from the specifications absent a clear intention to do so. *See Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) ("When consulting the specification to clarify the meaning of the claim terms, courts must take care not to import limitations into the claims from the specification"); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using the words or expressions of manifest exclusion or restriction").

Second, Actavis argues that during the patent prosecution, inventor Dr. Ralph Healey emphasized that the claimed composition can be administered "without regard to food." Actavis Moving Br., at p. 15. Thus, by claiming that the composition can be administered without regard to food, Actavis argues that the patentees were indicating that "oral administration" of the composition is not specific to one, but encompasses both, food states. With respect to this

argument, the Court finds that Dr. Healey's indication that the claimed composition can be administered "without regard to food" is consistent with—not contradictory to—the absence of any reference to food state in the disputed "oral administration" terms.

Accordingly, the Court finds that no construction is necessary for these terms.

H. "% by weight"; "% of the total amount"; "% of the amount of"

Claim Term	Mallinckrodt's Construction	Actavis's Construction
"% by weight" "% of the total amount of [oxycodone or salt thereof/acetaminophen" "% of the [oxycodone or salt thereof/acetaminophen"	Plain and ordinary meaning. No construction necessary.	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

The term "% by weight" appears in claims 3 and 13 of the '631 Patent, the term "% of the total amount" appears in claim 1 of the '631 Patent, and the term "% of the amount of" appears in claim 6 of the '631 Patent.

When appearing in the '631 Patent, each of these terms is generally used in reference to the amount of oxycodone or acetaminophen released from the composition, at various points in time, in an *in vitro* dissolution test. Mallinckrodt argues that "[it] is clear from the language of the claims that these terms provide straightforward quantitative values for the amount of acetaminophen and oxycodone released from the tablets as the percentage of the total weight of the pharmaceutical composition." *See* Mallinckrodt's Opening Br., at p. 38. By contrast, Actavis argues that "the term 'total amount' could refer to the amount of drug as measured by weight *or concentration*." Actavis Resp. Br., at p. 20 (emphasis added). Thus, according to Actavis, because "it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims," *see* Actavis Resp. Br., at p. 20 (citing

Clearstream Waste Water Sys., Inc. v. Hydro-Action, Inc., 206 F.3d 1440, 1446 (Fed. Cir. 2000)), these disputed terms do not inform a POSITA with reasonable certainty of what is claimed and are therefore indefinite.

Although the doctrine of claim differentiation creates a presumption that different words in different claims have different meanings, the doctrine does not create a *per se* rule. *See Tate Access Floors, Inc. v. Maxcess Techs., Inc.*, 222 F.3d 958, 967–69 (Fed. Cir. 2000). Rather, where inventors use terms interchangeably in the specification and the intrinsic evidence demonstrates that the terms should have the same meaning, courts have held that the clear intention of the inventors overrides the claim differentiation doctrine. *Id.* Thus, the question for the Court is not whether the disputed terms as used *could* have different meanings—in this case, "total amount" or "%" as measured by weight *or* concentration—but whether the meanings of the disputed terms as used are not discernable. "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, [courts] have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Moreover, "the burden of proving indefiniteness remains on the party challenging validity and . . . they must establish it by clear and convincing evidence." *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 809 F.3d 1223, 1227 (Fed. Cir. 2015).

Mallinckrodt argues that the claims of the '631 Patent in which these disputed terms appear provide "significant context and certainty" as to their meanings. Mallinckrodt Moving Br., at p. 36. For example, claims 1 sets forth the "total amount" of acetaminophen and oxycodone in the composition *by weight* in milligrams, "about 325 mg to about 650 mg" and "about 7.5 mg to about 10 mg" respectively, and then further sets forth the percentage of the

"total amount" of those compositions released during an *in vitro* dissolution test. Claim 6, which depends on claim 1, similarly refers to the percentage of the compositions (which are set forth in claim 1 *by weight* in milligrams) being released in an *in vitro* dissolution test. And claims 3 and 13 expressly refer to release of the compositions in an *in vitro* dissolution test in terms of total amount "by weight."

The Court finds that the intrinsic evidence and context in which the terms are used support Mallinckrodt's position that "% by weight", "% of the amount of", and "% of" refer to the amount of acetaminophen and oxycodone released from the tablets as the percentage of the total weight of the pharmaceutical composition. Each of the disputed claims terms either expressly indicates that the percentage of composition being released in an *in vitro* dissolution test is "by weight," or appears in or depends upon a claim that expressly sets forth the "total amount" of the compositions *by weight* in milligrams. Although the Court acknowledges Actavis's position that the "total amount" or "%" of composition released *could* theoretically be measured in terms of concentration as opposed to weight, as the party challenging validity, Actavis bears the burden of proving indefiniteness by clear and convincing evidence. In light of the context in which the disputed terms are used, the Court finds that Actavis cannot meet its burden and the terms are not indefinite.

IV. CONCLUSION

For the foregoing reasons, the Court adopts the various constructions of the disputed claim terms as set forth above. An appropriate order will be entered.

Dated: May 9, 2017

s/ Katharine S. Hayden
Katharine S. Hayden, U.S.D.J.