IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRIS PHARMA, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 16-cv-603-GMS
ACTAVIS ELIZABETH LLC,	)	
Defendant.	)	

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 9,545,399

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 No. 9,545,399 ("the '399 patent"):

1. The phrase **"wherein said barrier coating is present in an amount of about 20% w/w to about 50% w/w %,"** as used in the '399 patent, is construed to mean "wherein said barrier coating is present in an amount of about 20% w/w to about 50% w/w, as a percentage of the weight of the pre-coated component."[1]

[1] The parties' dispute centers on whether the barrier coating of the racemic methylphenidate-cation exchange resin complex ("resin complex") is measured as a percentage of the pre-coated resin complex or post-coated resin complex. The court finds that the term should be construed as "wherein said barrier coating is present in an amount of about 20% w/w to about 50% w/w, as a percentage of the weight of the pre-coated component."

First, Plaintiff argues that a plain reading of the claim language supports its construction. The claim reads: "a sustained release racemic methylphenidate component comprising a water-insoluble, water-permeable, pH-independent barrier coated, racemic methylphenidate-cation exchange resin complex in an optional polymeric matrix, wherein said barrier coating present in an amount of about 20% w/w to about 50% w/w % . . . is over the racemic methylphenidate-cation exchange resin complex-option matrix." '399 patent, col. 31, ll. 7–16. Plaintiff suggests that the word "over" indicates that the "w/w %" equation consists of the entire barrier coated complex in the numerator and the described resin complex in the denominator. (D.I. 50 at 4.) Defendant disagrees, and argues that "over" only indicates the location of the barrier coating with respect to the resin complex and does not have any relationship to the calculation of the barrier coating's weight percentage. (D.I. 57 at 2.)

The court agrees with Defendant. The specification explains that "[t]he barrier coating is applied *over* the uncoated or precoated MPH-ion exchange complex-optional matrix." '399 patent, col. 12, ll. 16–17 (emphasis added). Thus, it seems clear that "over" does not a reference how the barrier coating is measured, but rather it indicates its location on the resin complex.

Defendant makes a similar argument with respect to the phrase "present in." Defendant argues that a person of ordinary skill in the art would know that the phrase "present in" refers back to the "sustained release racemic methylphenidate component comprising a water-insoluble, water-permeable, pH independent barrier coated, racemic methylphenidate-cation exchange resin complex." (D.I. 51 at 5.) Defendant asserts that the claim language "present in" indicates that the barrier coating is "20% w/w to 50% w/w %" of the entire coated resin complex. '399 patent, col. 31, ll. 11–12. The court disagrees. "Present in" like "over" is simply an indication of the location of the barrier coating relative to the resin complex and does not suggest that it is "present in" any specific amount.

Next, Defendant argues that the claim language of dependent claim 12 suggests that the measurement of the barrier coating is a percentage of the entire coated resin complex. (D.I. 57 at 3–4.) Claim 12 states that "the barrier coating layer is about 25% to about 35%, by weight, of the *coated* racemic methylphenidate-cation exchange resin complex-optional matrix." '399 patent, col. 32, ll. 27-30 (emphasis added). Plaintiff acknowledged that its proposed construction would create inconsistent constructions of the independent and dependent claims, but argues that the Federal Circuit's decision in *Multilayer Stretch Cling v. Berry Plastics Corp.*, 831 F.3d 1350 (Fed. Cir. 2016) permits this result. *Markman* Hr'g Tr. 27:16–17. In contrast, Defendant argues that *Wright Medical Technology, Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997) requires the court to interpret both claims consistently. *Markman* Hr'g Tr. 18:3–19:4; (D.I. 57 at 3–4.)

While *Multilayer* does permit courts to interpret independent claims differently than dependent claims, it also suggests that a court must only do so in certain circumstances not present in the instant case. *Multilayer*, 831 F.3d 1350 (Fed. Cir. 2016). "[D]ependent claims can aid in interpreting the scope of claims from which they depend, [but] they are only an aid to interpretation and are not conclusive." *Multilayer*, 831 F.3d at 1361. In *Multilayer*, the independent claim at issue contained a Markush group "consisting of" four elements required to be present in each respective layer of the invention. *Id.* at 1357. The plaintiff in *Multilayer* argued that even though the dependent claim listed an additional element that was absent from the independent claim's Markush group, that additional element should be included in the group. *Id.* at 1360. The court found that the patent owner could not overcome the presumption that the Markush group was closed to elements not listed in the independent claim because of the phrase "consisting of," which indicated that the group was closed to elements listed elsewhere in the patent. *Id.* at 1360. As a result, the court found that despite the dependent claim's mention of an additional element, "the dependent claim tail cannot wag the independent claim dog." *Id.* at 1360. Here, claim 1 of the '399 patent does not contain a Markush group or the phrase "consisting of." Thus, *Multilayer* is distinguishable from the present facts.

Nevertheless, Defendant attempts to persuade the court that it "must not interpret an independent claim in a way that is inconsistent with a claim from which it depends." *Wright,* 122 F.3d at 1445. In *Wright*, however, the court followed well-established patent law doctrine that the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic*, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); *see also Wright*, 122 F.3d at 1443. Instead of relying solely on the asserted dependent claim to inform the meaning of the asserted independent claim from which it dependence, the court first used the specification to interpret the independent claim. *Id.* After construing the independent claim in accordance with the specification, the court used that construction to construe both the asserted independent claim and dependent claim in alignment with one another and, consequently, in alignment with the specification. *Id.*; *Markman* Hr'g Tr. 18:8–10, 27:8–10. Here, the court will follow *Wright* and look to the specification, and not the dependent claim, to interpret claim 1's language.

The specification describes an embodiment where "the barrier coating layer is about 20% to about 50% . . . by weight of the precoated methylphenidate-ion exchange resin." '399 patent, col. 12, ll. 4–13. Plaintiff argues that the patentee meant for the calculation of the barrier coating to be a percentage of the pre-coated resin complex because the only written description of "about 20% to about 50% range" relates to a measurement of the barrier coating as a percentage of the pre-coated resin complex and claim 1 uses that exact range. (D.I. 54 at 7); *Markman* Hr'g Tr. 9:11–20.

Defendant contends that Plaintiff improperly requests that the court limit the claim's construction to one embodiment in the specification. *See Phillips*, 415 F.3d at 1323 (cautioning against importing limitations from the specification). Defendant reasons that "about 20% to about 50% range" only references "one embodiment" among

2. The phrase "**therapeutically effective extended release profile,**" as used in the '012 patent, is construed to mean "an extended release profile associated with a therapeutic effect that lasts for a period of at least about 12 hours."[2]

"other suitable ranges [that] can be determined by one of skill in the art, having been provided with the information herein." '399 patent, col. 12, ll. 8–15. This argument, however, misinterprets the specification. The language used to describe the barrier coating as a percentage of the pre-coated resin complex was not just in one embodiment, but appeared in every described embodiment that related to the measurement of the barrier coating. '399 patent, col. 12, ll. 4–15; *See Medicines Company v. Mylan, Inc.,* 853 F.3d 1296, 1309 (Fed. Cir. 2017) (limiting a claim term to an example in a patent that was the only embodiment of the term and the only description that cast light on what the term meant to a person of ordinary skill in the art). Thus, the court finds that a person of ordinary skill in the art would conclude that the "w/w %" measurement is a ratio of the barrier coating to the pre-coated resin complex.

[2] The parties dispute what the '399 patent teaches as "last[ing] for a period of at least about 12 hours"—the active component's therapeutic effect or the release of the active without a therapeutic effect. The court finds that the claim phrase should be construed as "an extended release profile associated with a therapeutic effect that lasts for a period of at least about 12 hours."

Plaintiff argues that neither the claim language nor the specification suggests that the twelve-hour time limit is associated with the therapeutic effect. *Markman* Hr'g Tr. 32:6–17; (D.I. 54 at 9–10.) Plaintiff reads the claim phrase as having two separate components: a therapeutic effect and an active release. *See* (D.I. 54 at 8–10.) Plaintiff argues that the abstract supports its contention. The abstract states that "(1) a therapeutically effective amount of MPH is reached in about 20 minutes, and (2) the composition provides a 12 hour extended release profile." '399 patent, Abstract; (D.I. 51 at 11.) Plaintiff suggest that "extended release" does not refer to the therapeutic effect, but only refers to the release of the active component for at least twelve hours. (D.I. 50 at 9); '399 patent, col. 4, ll. 20–27. According to Plaintiff, this means that the specification does not require the active component to produce a therapeutic effect over a period of at least twelve hours, but only that the active is released for a period of twelve hours. (D.I. 56 at 13.) This reading of the claim language and specification is grammatically incorrect and finds no support in the intrinsic record. A plain reading of the claim language suggests that the phrase "extended release profile" modifies "therapeutically effective." Plaintiff's construction is also improper because it requires the court to accept that a patient would experience a therapeutic effect during the first twenty minutes of the active release of the resin complex, but not while the drug continued to be released into the patient's system over the remaining eleven hours and forty minutes. *Markman* Hr'g Tr. 41:11–15, (D.I. 50 at 9.) Such construction seems nonsensical and ignores the purpose of the drug and the intrinsic record.

Defendant argues—and the court agrees—that the overall purpose of the invention and the specification make clear that the therapeutic effect must last over at least a twelve-hour period. First, the patented tablet was specifically made to be administered to school-aged children during the school day to offer them twelve hours of effective ADHD therapy. (D.I. 51 at 1.) Nothing in the patent or the specification suggests that, after the therapeutic effect is reached in twenty minutes, that the therapeutic effect of the active component does not continue for at least twelve hours. Indeed, the patent notes that "a therapeutically effective amount of methylphenidate is reached in less than about 20 minutes and the composition provides a twelve-hour extended release profile." '399 patent, Abstract; (D.I. 51 at 11.) The specification, in fact, repeatedly suggests that the therapeutic efficacy of the claimed extended release tablets lasts for twelve-hour intervals. *See* '399 patent, col. 1., ll. 48–50 ("The chewable tablet can be divided into portions and these tablet portions retain the fast onset and 12 hour release profile."); *see also* '399 patent, col. 2, ll. 66–67 ("the formulation provides an extended release profiles to at least about 12 hours"); *see also* '399 patent, col. 4, ll. 20–23 ("'extended release' ("ER") refers to compositions which are characterized by having at least one of the active components . . . having a release over a period of about 12 hours"); *see also* '399 patent, col. 19, ll. 44–51 ("prov[ing] a method of treating one or more of the above disorders for a period of at least twelve hours by administering a MPH extended release chewable tablet"). Therefore, the court will construe the claim as "an extended release profile associated with a therapeutic effect that lasts for a period of at least about 12 hours."

3. The phrase **"the methylphenidate plasma concentration, as determined under fasted and fed conditions . . . is equivalent to the plasma concentration curve of FIG. 1 from about 0 to about 8 hours,"** as used in the '399 patent, is construed to mean "the methylphenidate plasma concentration, as determined under fasted and fed conditions . . . is equal to the plasma concentration curve of FIG. 1 from about 0 to about 8 hours."[3]

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[3] Plaintiff argues that "equivalent to" means "essentially the same," suggesting that the court must read variability into the claim language. Defendant disagrees and argues that "equivalent to" should be construed as "equal to." The court agrees with Defendant's construction.

Plaintiff argues that the specification and dependent claim 24 support its interpretation of "equivalent to" as requiring some variance. Plaintiff claims that "equivalent to" refers to the plasma concentration curves and whether they are "equivalent to" one another because the specification describes the treatments that used the patented tablet under either fasted or fed conditions had "similar maximum and peak absorptions characteristics." *Markman* Hr'g Tr. 46:13–15; '399 patent, col. 30, ll. 41–45. As a result, Plaintiff contends that the plasma concentration curves are not exactly the same because "if you give the same person the same medication on two different days, the two plasma concentration curves that you get will not likely be identical" and, thus, a person of ordinary skill in the art would understand that "equivalent to" implies for some variability. *Markman* Hr'g Tr. 47:6–9.

Contrarily, Defendant argues that Figure 1 does not include any error bars or other indications that would allow a person of ordinary skill in the art to infer variation and, thus, none should be included in the claim construction. (D.I. 57 at 14); *Markman* Hr'g Tr. 54:15–17. The court agrees.

The parties agree that administering the same drug to different people would result in some variation. That is, however, not what is represented by the curves in Figure 1. As Defendant argued at the *Markman* hearing, a person of ordinary skill in the art would understand that Figure 1 uses mean curves and not a curve for each individual person who is administered the tablet under fasted and fed conditions. '399 patent, fig. 1; *Markman* Hr'g Tr. 51:15–17. In other words, the curves already take into account the variation between individuals' reaction to the administered tablet, therefore, the inclusion of additional variation would be duplicitous. Thus, Figure 1 does not support Plaintiff's argument that a person of ordinary skill in the art would infer variation in the claim phrase "equivalent to."

Further, Defendant points out that the phrase "essentially the same" does not appear anywhere in the specification. (D.I. 57 at 14.) Instead, the specification uses the term "equivalent to" in a manner aligns with its proposed construction. For example, "equivalent to" was used to explain mesh particle size. '399 patent, col. 9, ll. 1–5. The specification explained that "[a]nother cation exchange resin having similar properties is Dowex® . . . 200-400 mesh particle size, which is *equivalent to* about 35 microns." '399 patent, col. 9, ll. 1–5 (emphasis added); *Markman* Hr'g Tr. 51:22–52:2. Thus, "equivalent to" was used to indicate the conversion of 200-400 mesh particle size as "equal to" 35 microns.

Plaintiff submitted a document during claim construction briefing that states that "[m]esh size is not a precise measurement of particle size" and, as a result, "equivalent to" must require variability. (JA 5082; D.I. 56 at 19.) Mesh size and mesh particle size refer to two different components—mesh size acts as a filter with holes and the mesh particles are the components that fall through those holes. *Markman* Hr'g Tr. 53:2–6. The statement Plaintiff relies is a comparison of mesh size to a measurement of size of the mesh particles that pass through the mesh, but the '399 specification discusses the conversion of mesh particles size to microns. *Id.* Therefore, Plaintiff's argument and the document used to support it are inapposite to the construction of this claim phrase.

Finally, Plaintiff argues that the language of claim 24 supports its construction that "equivalent to" means "essentially the same." Claim 24 explains that the plasma concentration, after administering a "dose equivalent to 40 mg racemic methylphenidate HCl," is "equivalent to the plasma concentration curve of FIG. 1 from about 0 to

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about 8 hours." '399 patent, col. 33, ll. 14–20. Plaintiff suggests that the plasma concentration curves, as indicated in Figure 1 of the specification, are not "materially different," but they are also not "equal to" one another. *Markman* Hr'g Tr. 48:1–2.

Alternatively, Defendant asserts that dependent claim 24 and the specification provide further support for its construction that "equivalent to" means "equal to." Defendant contends that claim 24 uses the term "equivalent to" as a reference to dose equivalency when it states "following a single oral administration of said chewable tablet at a dose equivalent to 40 mg racemic methylphenidate HCI in adults." '399 patent, col. 33, ll. 18–19, (D.I. 51 at 16.) This use of "equivalent to" does not suggest variation, but suggests that a specific dosage of racemic methylphenidate would be "equal to" a dosage of only the active enantiomer of the drug, which would be 20 milligrams. *Markman* Hr'g Tr. 50:1–8. (D.I. 51 at 16.) The court agrees with Defendant and finds that the specification and the claim language supports Defendant's construction of "equivalent to" as "equal to."