IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN LTD and PERNIX THERAPEUTICS, LLC, Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., Defendant.	)	C.A. No. 16-138 (GMS)
PERNIX IRELAND PAIN LTD and PERNIX THERAPEUTICS, LLC, Plaintiffs, v. ALVOGEN MALTA OPERATIONS LTD., Defendant.	)	C.A. No. 16-139 (GMS)

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 9,265,760, 9,326,982, 9,333,201, 9,339,499, 9,421,200, and 9,433,619

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 9,265,760 (the "'760 Patent"), 9,326,982 (the "'982 Patent"), 9,333,201 (the "'201 Patent"), 9,339,499 (the "'499 Patent"), 9,421,200 (the "'200 Patent"), and 9,433,619 (the "'619 Patent"):

1. The term "administering" is construed to mean "delivering into the body."[1]

[1] Plaintiffs ask the court to construe "administering" as "prescribing, dispensing, giving or taking (such that what is prescribed, dispensed, given or taken is actually taken into the patient's body)." (D.I. 60 at 7). Plaintiffs

2. The phrase "starting dose is not adjusted relative to a patient without hepatic impairment" is construed to mean "[t]he dose prescribed to a patient with mild or moderate hepatic impairment when initiating treatment is not reduced due to that hepatic impairment relative to the dose prescribed to a patient without hepatic impairment when initiating treatment."[2]

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argue that the plain meaning, the specification, and prior case law clearly counsel in favor of a broad construction. (D.I. 60 at 7). The court disagrees.

The patentees explicitly use the term "prescribing" elsewhere within the patent: "[C]hanges in pharmacokinetic parameters . . . can lead to many problems, including . . . complications for physicians in prescribing." '760 patent, col. 4 ll. 30–34. If the term "administering" was meant to encompass the physician "prescribing" the drug to the patient, then the patentees' would not have differentiated between the two terms in the specification.

Further, Defendants' proposed construction of "administering" is consistent with the patent. The patent describes how "[t]he drug seeps out over a period of time starting at about 1 hour after administration and continues until about 10-12 hours after administration." *Id.* col. 7 ll. 50–52. The patent also explains that "Zohydro ER capsules exhibit peak plasma concentrations occurring approximately 5 hours after dose administration." *Id.* col. 18 ll. 22–23. In fact, the specification is replete with such examples. On the contrary, there are only two instances where substituting the plaintiffs' construction of either "prescribing" or "dispensing" for administration would make contextual sense: (1) "[ER] morphine sulfate . . . should be administered with caution, and in reduced dosages in . . . patients with severe . . . hepatic insufficiency," *Id.* col. 4 ll. 27–29; and (2) "[t]he blood levels of the drug do not become dangerously high to a patient even when the patient is hepatically impaired and a government approved label packaged with the drug indicated the dosage can be administered to patients with and without hepatic impairment." *Id.* col. 7 ll. 52–57. Defendants first citation to the specification is found in the part of the patent discussing a prior art drug, KADIAN®. The court, therefore, does not find that evidence to be relevant to the construction of "administering" in the context of the '760 invention. As for the second citation, the court does not see how such a disclosure undermines Defendants' construction. Thus, the patent does not support Plaintiff's broad construction.

Plaintiffs argue that Defendants cite to parts of the specification that use the term "administration," instead of the claim term, "administering." (D.I. 60 at 9). Plaintiffs believe that because "administering" and "administration" are different parts of speech, the use of "administration" cannot influence the construction of "administering." *Id.* The court does not find that argument persuasive because there exists no plausible reason—and Plaintiffs do not offer one—to give the noun form a different meaning than the verb form.

The court also does not find Plaintiffs' citations to case law persuasive. "[T]he determination of the meaning of a particular term in one patent will not necessarily bear on the interpretation of the same term in a subsequent patent . . . ." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1333 (Fed. Cir. 2005) (Mayer, J., dissenting). The cases Plaintiffs cite to construe the term "administering" in the context of completely different patents. This is not a situation where the patents in the other cases all derive from the same parent application. *See Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning."). Accordingly, the court declines to adopt Plaintiffs' broad construction, which finds no support in the patent.

[2] The phrase "starting dose is not adjusted relative to a patient without hepatic impairment" appears in the wherein clause of claim 1 of the '760 patent. The parties dispute whether the phrase is a claim limitation. The court finds that the disputed phase is a limitation, and, therefore, adopts Plaintiffs' construction.

To support their contention that the disputed phrase is not a limitation, Defendants cite to caselaw evidencing that statements of purpose and result cannot be considered limitations. (D.I. 74 at 14); *Bristol-Myers*

3. The terms "subject" and "average [or mean]" in the phrases "[average/mean] hydrocodone [$AUC_{0\text{-}inf}/C_{max}$] . . . [in/dosed to] subjects . . .," and "[average/mean]

Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375–77 (Fed. Cir. 2001). Defendants also argue that claim phrases producing no manipulative difference in how the steps of the claims are carried out cannot be considered limitations. (D.I. 74 at 14); *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1380–81 (Fed. Cir. 2003) (finding that the phrase "whereby the security is traded efficiently" did not inform the "mechanics" of how the trade was executed, but instead, characterized the result of the claim step, "executing a trade of the security"). The court is not persuaded by Defendants' citations because it finds that adjusting the starting dose relative to a patient without hepatic impairment is, in fact, a manipulative difference over the prior art, not merely a statement of purpose or result.

The Background of the Invention describes the treatment of hepatic impairment with opioids prior to the invention of the patents-in-suit. It states that opioids "generally require reduced dosing in patients with hepatic impairment, because the liver is the source of most opioid metabolism." '760 patent, col. 2 l. 42–44. Because the liver regulates the effects of opioids in the body, a hepatic impairment makes it difficult for the liver to sufficiently control the effects of opioids. As a result, if patients with a hepatic impairment are not given a controlled, reduced dose of opioids that their liver can manage, there is a risk of "excessive or persistent sedation, coma or death." *Id.* col. 2 l. 47. Receiving a reduced dose of the opioids, however, diminishes some of the benefits of the drug. Therefore, there was a need in the prior art for an opioid that could safely, yet effectively, manage the pain of those with hepatic impairments. For that reason, the ability of a patient with a hepatic impairment to gain the same benefits from the opioid that a non-hepatically impaired patient receives in just one dose differs from the prior art. This is not a situation where a "whereby clause in a method claim . . . simply expresse[s] the intended result of a process step positively recited." *Minton*, 336 F.3d at 1381. The disputed phrase does have an effect on how the administering step is performed—contrary to Defendants' argument—because patients with hepatic impairment ingest a different dose than they normally would, given the prior art. As such, the claim phrase explaining that hepatically and non-hepatically impaired patients get the same starting dose "is 'necessary to give life, meaning and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). That fact is further supported by the prosecution history.

During prosecution of the '760 patent, the applicants referenced an Office Action from the prosecution of the grandparent application, U.S. Pat. Appl. No. 13/950,969 ("the '969 Application"). (D.I. 79 at A-155–57). In that Office Action, the Examiner acknowledged that having the same initial dose for both types of patients does change the method of administering the drug. *Id.* In the '969 application, the Examiner stated that, although there is no compositional difference over the prior art, the patent differs from prior art "in the method of using that composition." *Id.* at A-156. Because the '969 patent disclosed a "kit," as opposed to a method of use, the claimed invention was not novel over the prior art. *Id.* The '760 patent does, however, disclose a method of use. After initial rejections, the '760 patent was allowed with the "wherein the starting dose is not modified" claim phrase unchanged. (D.I. 79 at A-138). In the Notice of Allowance, the Examiner also recognized that the prior art would not lead a skilled artisan to give the same starting dose to impaired and unimpaired patients. *See id.* ("Thus, the predictability of producing an extended release with only hydrocodone bitartrate as the active appears to be unpredictable in the art and would thus not lead the skilled artisan to start the dosage at a dose similar to a normal patient. Further, given the use of hydrocodone is well known in the art, the skilled artisan would understand that the starting dose would be based on the common dosing practice for normal patients."). As the Examiner pointed out, a physician would *not* normally give a hepatically impaired patient the same dose as a patient without a hepatic impairment. Since the method of treating pain in the hepatically impaired patient is different than the prior art's method of treating pain in that same patient, having a patient ingest the same initial dose regardless of their hepatic impairment is not just a mental step. Accordingly, the court adopts Plaintiffs' proposed construction of the term because that construction effectuates the court's finding that the phrase is a limitation. Defendants' indefiniteness argument with regard to this claim phrase is preserved for trial.

hydrocodone [AUC0-inf/Cmax] . . . [in/dosed to] subjects . . . relative to subjects," are construed to have their plain and ordinary meanings.[3]

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UNITED STATES DISTRICT JUDGE

[3] Plaintiffs construed "subject" and "average [or mean]" to have their plain and ordinary meanings. Defendants do not offer an alternative construction for these terms. Instead, Defendants argue that the terms are indefinite. The court does not typically address indefiniteness arguments at the claim construction stage. As such, Defendants have preserved that argument for trial.