NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEPOMED, INC., Plaintiff, v. BANNER PHARMACAPS INC. and WATSON LABORATORIES, INC., Defendants.	Civil Action No. 13-04542 (JLL) (JAD) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way an application for claim construction by Plaintiff Depomed, Inc., ("Plaintiff") and Defendants Banner Pharmacaps Inc., and Watson Laboratories, Inc. (Collectively "Defendants"). The parties seek construction of certain language contained in claim 13 of United States Patent No. 7,662,858 (the " '858 Patent") and claim 12 of United States Patent No. 7,884, 095 (the " '095 Patent"); and claim 15 of the '095 Patent. The Court held a Markman hearing on March 3, 2015. The Court has considered the parties' written and oral arguments and sets forth herein its construction of the disputed claim terms.

I. BACKGROUND

This is a Hatch Waxman Litigation involving a generic version of Plaintiff's brand name drug "Zipsor". Zipsor is used in the treatment of pain, including bunionectomy pain. Buionectomy is surgical procedure which removes a bunion. Zipsor is a 25mg, liquid filled, diclofenac capsule that allows diclofenac to stably remain in suspension and quickly disperse

upon release in the stomach to prevent aggregation. Diclofenac is a nonsteroidal anti-inflammatory drug used to treat pain and inflammation associated with arthritis. Zipsor is protected by 7 patents listed in the Orange Book. The seven patents in suit can be divided into two groups: two composition patents which cover the composition of the liquid filled, diclofenac capsules and five method patents which describe the method of using the diclofenac tablets for the treatment of pain conditions. Only the '858 and the '095 method patents raise a specific claim construction dispute other than the general dispute that unconstrued claims should be given their plain and ordinary meaning.

While the parties have agreed to constructions of a number of claim terms, the parties dispute the interpretation of language in claims 13 and 12 of the '858 Patent and the '095 Patent, respectively; as well as language in claim 15 of '095 patent. The parties ask the Court to give the proper construction of "NPRS" and "average 48 hour NPRS score" within the meaning of method claims 13 of the '858 Patent and claim 12 of the '095 patent and the proper construction of "Clinically significant", within the meaning of claim 15 of the'095 patent.

II. LEGAL STANDARD

A court's analysis of a patent infringement claim is two-fold. *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1365 (Fed.Cir.2002). The court must first define the meaning and scope of the patent claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The court then engages in a comparison of the claims as construed to the alleged infringing product (or method). *Tate*, 279 F.3d at 1365. At this stage, the Court must only engage in the first step.

Claim construction is a matter of law to be determined solely by the court. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005), *cert. denied*, 546 U.S. 1170, 126 S.Ct. 1332, 164 L.Ed.2d 49 (2006). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Id. at 1312 (quotations omitted). In construing the terms of a patent, a court should look first to the language of the claim itself. *Vitronics Corp. v. Conceptronic*, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The terms in the claim "are generally given their ordinary and customary meaning." *Id.* at 1582.5 "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. A court "must look at the ordinary meaning in the context of the written description and the prosecution history." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed.Cir.2005). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed.Cir.2004).

To this end, the court should first examine the intrinsic record-the patent itself, including the claims, the specification and, if in evidence, the prosecution history. *Vitronics*, 90 F.3d at 1582 (*citing Markman*, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. Indeed, the Federal Circuit has explained that the specification is " 'usually ... dispositive ... [and] the single best guide the meaning of a disputed term.' " *Phillips*, 415 F.3d at 1315 (*quoting Vitronics,* 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317. The

specification is also an important guide in claims construction as it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." Id. at 1316.

Additionally, the court should consult the patent's prosecution history as it "provides evidence of how the PTO and the inventor understood the patent." *Id.* Courts should be circumspect in reviewing a prosecution history as it represents "an ongoing negotiation between the PTO and the applicant, rather than the final product of the negotiation ...." *Id.* A district court may also examine extrinsic evidence: "all evidence external to the patent and prosecution history." *Markman,* 52 F.3d at 980; *Phillips,* 415 F.3d at 1317–18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. *Markman,* 52 F.3d at 980. In particular, a court may find reference to technical dictionaries useful "in determining the meaning of particular terminology." *See Phillips,* 415 F.3d at 1318. However, extrinsic evidence is generally thought to be less reliable than the patent and prosecution history, *id.* at 1318–19; in essence, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language," *C.R. Bard, Inc. v. U.S. Surgical Corp.,* 388 F.3d 858, 862 (Fed.Cir.2004) (quotation omitted). With this framework in mind, the Court now turns to the disputed claim language.

III. DISCUSSION

A. "NPRS" and "Average 48 hour NPRS score"

The claim terms "NPRS" and "average 48 hour NPRS pain score", appear in claim 13 of the '858 Patent which is dependent upon claim 12 which in turn, is dependent upon claim 1. The claim language for the '858 patent, with the disputed terms indicated by emphasis, is as follows:

1. A method of treating acute post-bunionectomy pain in a patient in need of such treatment, said method comprising orally administering to the patient a dose of between about 13 to about 25 mg of diclofenac potassium in a dispersible liquid formulation about every 4 hours to about 8 hours over a period of at least 24 hours, wherein the daily total amount of diclofenac potassium administered is less than or equal to about 100 mg.

12. The method according to claim 1, wherein the amount of the diclofenac potassium in the dispersible liquid formulation comprises about 25 mg of diclofenac potassium.

13. The method according to claim 12, wherein the administration of diclofenac potassium in the dispersible liquid formulation results in an *average 48 hour NPRS pain score* of about 2.49.

Moreover, the claim terms "NPRS" and "average 48 hour NPRS pain score" appear in claim 12 of the '095 Patent which is dependent upon claim 11 which in turn, is dependent upon claim 1. The relevant claim language for the '095 patent is:

1. A method of treating acute post-osteotomy pain in a patient in need of such treatment, said method comprising orally administering to the patient a dose of between about 13 to about 25 mg of diclofenac potassium in a dispersible liquid formulation about every 4 hours to about 8 hours over a period of at least 24 hours, wherein the daily total amount of diclofenac potassium administered is less than or equal to about 100 mg, wherein the osteotomy is correction of a bone deformity.

11. The method according to claim 1, wherein the amount of the diclofenac potassium in the dispersible liquid formulation comprises about 25 mg of diclofenac potassium.

12. The method according to claim 11, wherein the administration of diclofenac potassium in the dispersible liquid formulation results in an *average 48 hour NPRS pain score* of about 2.49.

"NPRS" stands for "Numerical Pain Rating Scale". Plaintiff's proposed definition of NPRS is "an 11 point numerical pain rating scale from 0-10". Alternatively, Defendants' proposed definition of NPRS is "a pain intensity rating scale that uses a numerical rating such as

0-10, 0-5, 0-4 or a visual scale with both words and numbers". For the term "average 48 hour NPRS pain score", Plaintiff proposes the term be constructed as, "the average pain intensity over a 48 hour multiple dose period using an NPRS pain score". Defendants' proposed construction reads, "the average 48 hour pain intensity score on a pain rating scale that uses numerical rating such as 0-10, 0-5, 0-4, or a visual scale with both numbers and words".

Plaintiff argues that the claim language expressly supports their construction. Plaintiff states that the claim's limitation of an "average 48 hour NPRS pain score of about 2.49" pain score requires that the NPRS limitation itself have a definite range, rather than several possible ranges. Plaintiff contends that because the language refers to a specific average score of 2.49 over 48 hours, the score would lose meaning if used on a different scale. (Tr. Of Proceedings, March 3, 2015 ["Hr'g Tr."], 10:10-23). Plaintiff also asserts that the claim language is tied into the specification. Plaintiff points to a specific example, example 2, in the specification which uses 2.49 as the score taken over a 48 hour period by using an 0 to 10 scale. (Hr'd Tr., 11:10-12:1).

Defendants in turn argue that their proposed construction largely tracks the definition of NPRS as set forth in the specification: "the numerical pain rating scale refers to a numerical rating of 0-10 or 0-5 or to a visual scale with both words and numbers." Defendants state that during the prosecution of both patents, the applicants explained that the clinical study of example 2 used a primary efficacy endpoint, "determined by ***an*** NPRS of 0-10 where 0 represents no pain and 10 represents the worst possible pain". By the using the word "an" rather than "the", Defendants contend that both the applicants and the expert who used the same phrase acknowledged that there is more than one kind of numerical pain rating scale.

Defendants state that Plaintiff's proposed construction is too constrictive and contrary to the open-ended definition for NPRS in the specification which states: "The numerical pain rating scale (NPRS) refers to an numerical rating of 0-10 or 0-5 or to a visual scale with both words and numbers." (Def's Opening Brief at 8-9). Defendants state that Plaintiff's proposed construction improperly deletes the second and third alternatives in this definition. Defendants counter Plaintiff's argument by stating that while example 2 in the specification of the '858 and '095 patents used the 0-11 scale to determine the efficacy of the claimed methods of treatment, this data is merely exemplary. (*Id.* at 9). Defendant contends that it does not state anywhere in the specification that the NPRS used in example 2 is limited only to the scale used in example 2.

Additionally, Defendants assert that the dispute presented by "average 48 hour NPRS score" is whether it should be construed to require a multiple dose period and whether it should be construed to require a dose period lasting 48 hours. Defendants argue that Plaintiff's proposed construction would create a "multiple dose period requirement", which Defendants contend is unnecessary because the claims already require more than one dose of diclofenac to be administered (claim 1 of each patent requires diclofenac to be administered at least every 8 hours over 24 hours). Defendants contend that Plaintiff's proposed construction unnecessarily limits the methods of claim 13 in the '858 patent and claim 12 in the '095 patent by requiring that diclofenac be dosed over a 48 period. Defendants state that, as written, both claims allow dosing to cease after at least 24 hours, and the patent provides no reason why 48-hour average NPRS score cannot include NPRS scores taken after dosing ceases.

After due consideration of Defendants' and Plaintiff's arguments, the Court concludes that Plaintiff's proposed construction is proper. In construing the terms of a patent, this Court looks first to the language of the claim itself. *Vitronics*, 90 F.3d 1576, 1582 (Fed.Cir.1996). In

the case at bar, while the language of the claim itself does not expressly indicate that a scale of 0-10 should be used when determining the average pain intensity over a 48 hour multiple dose period using an NPRS pain score, it does clearly state that the administration of diclofenac "results in an *average 48 hour NPRS pain score* of about 2.49." "The context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms." *ACTV,* 346 F.3d 1082, 1088 (Fed. Cir. 2003). With that principle in mind, the Court is compelled to adopt Plaintiff's argument regarding the context of the 2.49 score. Were the Court to adopt Defendants' proposed construction, the 2.49 NPRS score would become inappropriately ambiguous when considering the surrounding context. The meaning of a score of 2.49 takes on a significantly different implication when considered in the context of 0-10 scale, as opposed to the context of a 0-4 scale. While a score of 2.49 on a scale of 0-10 may indicate to a person of ordinary skill in the art that the patient was reporting a low pain rating, that score results in an entirely different connotation when offered using a different scale, such as the 0-4 scale proposed by Defendants.

Moreover, the Federal Circuit explains that the specification is "'usually ... dispositive ... [and] the single best guide to the meaning of a disputed term.' " *Phillips*, 415 F.3d at 1315 (*quoting Vitronics*, 90 F.3d at 1582). Here, Plaintiff has tied the patents' specifications to the relevant claim language in a manner sufficient to convince the Court that it is appropriate to adopt its proposed construction. The Court is cognizant, as Defendants note, that language in the specification includes a 0-5 scale. However, as Plaintiff correctly argues, Defendants ignore the very next sentence in the specification, which states, "the patient is being asked to rate the pain with 0 being no pain and 10 being the worst possible pain". Therefore, looking at the specification in its entirety, this previously cited sentence gives significance and context to the

2.49 NPRS score included the claim term. Were the Court to only consider the first sentence Defendants cite in the specification, the claim term would not only lose its intended inference, as demonstrated by the following sentence in the specification, but the Court's analysis would run afoul of the holding in *Phillips. 415 F.3d, 1313.* ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.") *See also Merck & Co. v. Teva Pharms. USA, Inc.,* 347 F.3d 1367, 1371 (Fed.Cir.2003)("[C]laims must be construed so as to be consistent with the specification, of which they are a part.")

The Court also adopts Plaintiff's proposed construction of the disputed term "average 48 hour NPRS pain score", which is, "the average pain intensity over a 48 hour multiple dose period using an NPRS pain score". As Plaintiff argued in its briefs and at the March 3, 2015 Markman hearing, in Table 2, Column 17 of the '858 Patent, a score of 2.49 was recorded over a 48 hour multiple dose period, using an 11 point NPRS, 0-10 scale. ('858 Patent, 17:47-50.) While the Court is mindful and has considered Defendants' argument that Plaintiff's proposed construction may seek to import limitations from example 2 into the disputed claims, the Court is nevertheless satisfied that this is not the case. The express claim language makes reference to an average score of 2.49 over a 48 hour period, which is achieved by giving a patient multiple doses over 48 hours, as evidenced in example 2 of the specification. Throughout the Patents' specifications, it is taught that the 48-hour pain score is the average taken *over* a 48 hour period, using an 11 point, 0-10 NPRS scale. (*See e.g.* '858 Patent, 16:28-34; 17:1-3; 17:62-66; 11:48-51.)(Emphasis added). This language in the specification explains how the claim element "48 hour multiple dose period" is to be determined. As noted above, when analyzing the specification in its entirety, this previously cited language in the specification gives significance and context to the

language, "48 hour multiple dose period" included the claim term. Therefore, based upon this analysis, the Court adopts Plaintiff's proposed claim construction for the disputed claim terms "NPRS" and "average 48 hour NPRS pain score".

B. "Clinically Significant"

The claim term "clinically significant" appears in claim 15 of the '095 patent, which is dependent upon claim 11, which in turn, is dependent upon claim 1. Plaintiff's proposed construction defines "clinically significant" as a 30% reduction in pain intensity as compared to a placebo. Defendants offer no construction of the term. The relevant claim language for the '095 patent is as follows, with the disputed term indicated by emphasis:

> "The method according to claim 11, wherein the administration of diclofenac potassium in the dispersible liquid formulation provides *clinically significant* analgesic efficacy for about 6 hours."

Plaintiff maintains that the claim term "clinically significant" modifies the term "analgesic efficacy" and requires that such clinically significant "analgesic efficacy" be maintained for 6 hours. Moreover, Plaintiff argues, the claim language does not require that the efficacy begin with the first treatment nor that it initiate at the beginning of the 6 hour window. Plaintiff contends that the specification defines it using their proposed construction: "30% reduction in pain intensity" is defined as "clinically significant analgesic efficacy". Plaintiff further notes that no other portion of the specification uses the express claim language "clinically significant analgesic efficacy," except at the outset where it refers to an embodiment. Plaintiff states that this embodiment defines "clinically significant analgesic efficacy" as a 30% reduction in pain intensity.

Defendants argue that the term "clinically significant" does not need to be construed because a person of ordinary skill in the art would understand and be able to apply this phrase without further elaboration. Defendants' expert states that the term is an omnibus term used to refer to anything deemed by the patient, the caregiver, or the investigator as having practical impact on the quality of medical care, patient experience, and/or the overall outcome of treatment. Defendants argue that Plaintiff's proposed construction does not clarify the meaning of "clinically significant," but rather, it improperly narrows the general phrase to a specific quantitative value.

Defendants point to the specification, which states that "pain is highly subjective to the individual experiencing it" and "the goal of post-surgical pain management is to provide a quick onset of analgesic or pain relief" and "educe or modulate the quality and intensity of pain a patient experiences". Defendants argue that the specification also distinguishes between an embodiment involving a 30% pain reduction and an embodiment providing "clinically significant analgesic efficacy". The specification also suggests that an analgesic effect can be clinically significant if it reduces opioids, therefore, Defendants contend, to a POSA, reducing or delaying reliance on opioids in treating acute pain is a clinically significant analgesic effect

Defendants state that Plaintiff's proposed construction seems to rely on language from the clinical study reported in example 2 of the '858 patent. Example 2 describes a clinical study that evaluated analgesic efficacy of a diclofenac treatment regimen. The study employed several measures to assess efficacy, including pain intensity, pain relief on a scale, time to meaningful pain relief, time to perceptible pain relief, and a global assessment of the study of medication. The specification explains for purposes of the study, "clinically significant analgesic analysis efficacy was defined as both, greater than or equal to 30% reduction from baseline pain intensity

using NPRS, and meaningful relief as indicated by a stopwatch method." To determine meaningful relief using the stopwatch method, subjects were handed a stopwatch shortly after receiving medication (diclofenac or placebo) and instructed to "stop the stopwatch when you have meaningful pain relief, that is, when the relief from pain is meaningful to you." Defendants argue that even if the definition of clinically significant analgesic efficacy" in example 2 is found to define the meaning of "clinically significant" in claim 15 of '095 patent, Plaintiff's proposed construction is still at odds because: 1) Plaintiff's proposed construction ignores the latter half of the definition ("meaningful relief"), and 2) the first half of the study compares pain intensity to baseline where Plaintiff's proposed definition compares pain intensity to placebo which Defendants contend are entirely different.

The Court agrees with Plaintiff. When attaching the claim term, "clinically significant" to the specification and the claim language itself, the Court finds it appropriate to adopt Plaintiff's proposed construction. While Defendants and their expert are correct in pointing out that "clinically significant" may have other possible meanings, this is not the case when this language read in the context of the specification as required by *Phillips. 415 F.3d, 1313.* ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.") Further, the fact that the definition might have several meanings demonstrates to this Court that the term should be construed using the language of the specification as required under *Phillips*, as it may clear any inappropriate ambiguity.

The specification expressly states that for, "[e]valuation of the frequency and timing (defined as time of meaningful pain relief) of obtaining *clinically significant analgesic efficacy* ***(defined as*** *a 30% reduction in pain intensity)* as compared to placebo in acute pain;". ('095

Patent, Col. 11, II. 64-67). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics*, 90 F.3d at 1582 (*citing Markman*, 52 F.3d at 979). Here, the specification is expressly defining what the claim term "clinically significant" means in the context of the '095 patent. The language of the claim calls for "clinically significant analgesic efficacy" to be achieved for 6 hours. The specification does not contain any other language in which the Court could reasonably infer that the clinically significant efficacy achieved for the 6 hours be defined as anything other than a reduction of pain intensity by 30%.

Moreover, while Defendants' argument regarding the multiple definitions for "clinically significant" offered in the specification is well-taken, but fails for several reasons. The specification states, "Evaluation evaluate the frequency of timing (defined as time of meaningful pain relief) of obtaining clinically significant analgesic efficacy (defined as a 30% reduction in pain intensity) as compared to *placebo* in acute pain." ('858 Patent, 11:61-64)(Emphasis added). Here, Plaintiff has shown how the specification demonstrates that the claim term at issue is compared to a patient who received a placebo, as opposed to a baseline comparison. Plaintiff furthered its point in this regard when it emphasized that Defendants' expert agreed that the specification used a placebo comparison. (Hr'g Tr., 29:15-30:9).

Similarly, as Plaintiff correctly reasoned, the example in the specification that Defendants call attention to did not deal with a 6 hour durational requirement as the claim language in question calls for. That example only asked a subject to stop a stopwatch when that person felt the onset of meaningful relief. It did not refer to the duration of pain relief, for which claim 15 of the '095 patent requires. Defendants' expert Dr. Loeser acknowledged as much when deposed by Plaintiff:

[Q:] Meaningful relief, as determined by the stopwatch method, that refers to the onset of meaningful relief; correct?

A. Yes.

Q. That does not refer to the duration of pain relief; correct?

A. Yes.

Q. And we can agree that Claim 15 of the '095 patent requires that there be meaningful clinically significant analgesic efficacy over six hours; correct?

MR. MADDOX: Object to form.

THE WITNESS: Yes.

BY MR. GAEDE:

Q. And that's a duration requirement; correct?

A. Yes.

(ECF No. 62-3; Loeser Depo. Tr.) at 67:14-68:4) In construing the terms of a patent, a court should look first to the language of the claim itself. *Vitronics*, 90 F.3d 1576, 1582. Within the claim language at issue, a 6 hour durational requirement is called for. The Court cannot construe the claim term at issue without considering that durational requirement that lies within the claim language. The section of the specification that Defendants rely on does not refer to a multiple dose period as Claim 15 requires. Defendants section refers to a "single dose test". This is outside the scope of Claim 15, which calls for a 6 hour, multi-dose period. "The context of the surrounding words of the claim also must be considered in determining the ordinary and

customary meaning of those terms." *ACTV,* 346 F.3d 1082, 1088 (Fed. Cir. 2003). In this case, the surrounding context of the claim term at issue is not tied into the specification language that Defendants rely on. Further, the section of the specification in which Plaintiff relies upon expressly defines what the claim term at issue is to mean within the scope of the claim. Therefore, based upon this analysis, the Court adopts Plaintiff's proposed claim construction for the disputed claim term "clinically significant".

IV. CONCLUSION

For the foregoing reasons, the Court construes the disputed terms of United States Patent Nos. 7,662,858 and 7,884,095 as follows:

1. The terms "NPRS" and "Average 48 Hour NPRS" as used in claim 12 of the '095 Patent and claim 13 of the '858 patent are construed to mean "an 11 point numerical pain rating scale from 0-10" and "the average pain intensity over a 48 hour multiple dose period using an NPRS pain score";

2. The term "clinically significant" as used in claim 15 of the '095 Patent is construed to mean "a 30% reduction in pain intensity as compared to a placebo."

An appropriate Order accompanies this Opinion.

Date: March 26, 2015

/s/ Jose L. Linares
Jose L. Linares
United States District Judge