IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAVELIN PHARMACEUTICALS, INC., HOSPIRA, INC. and JANSSEN PHARMACEUTICA N.V.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 16-224-LPS
MYLAN LABORATORIES LIMITED, MYLAN INC. and MYLAN PHARMACEUTICALS INC.,	:	
Defendants.	:	

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MEMORANDUM OPINION

October 10, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Javelin Pharmaceuticals, Inc., Hospira, Inc., and Janssen Pharmaceutica N.V. (collectively, "Javelin") filed suit against Defendants Mylan Laboratories Limited, Mylan Inc., and Mylan Pharmaceuticals Inc. ("Mylan"), which submitted an Abbreviated New Drug Application to market a generic version of Javelin's Dyloject®, an injectable diclofenac sodium product in a 37.5 mg dose injected with 1 mL of liquid. Javelin asserts Orange Book–listed U.S. Patent Nos. 6,407,079 and 8,946,292, which generally describe pharmaceutical compositions of diclofenac and beta-cyclodextrin and methods of providing analgesia with such compositions. Presently before the Court is the issue of claim construction.[1] The parties submitted briefs (*see* D.I. 48, 49, 51, 53) and the Court held a claim construction hearing on August 7, 2017.

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . .

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[1]Mylan has stipulated to infringement of the asserted claims of the '079 patent. (*See* D.I. 43) The parties do not seek construction of any terms of the '079 patent.

[which 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." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent 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).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven

when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d

at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. "wherein the method achieves at least about 82% of maximum observable total pain relief assessed by a Visual Analog Scale"[2]

1. "about 82% of maximum observable total pain relief"

Javelin "about 82% of the sum of pain relief resulting from administration of a pharmaceutical composition comprising about 75 mg of a diclofenac compound and a beta-cyclodextrin compound"
Mylan Indefinite Alternatively, "the area under the curve as measured on a Visual Analog Scale of 0-100 mm over the specified Visual Analog Scale time intervals, that is at least 82% of the area under the curve for pain relief over the time interval"
Court "about 82% of the sum of pain relief resulting from administration of a pharmaceutical composition comprising about 75 mg of a diclofenac compound and a beta-cyclodextrin compound"

2. "Visual Analog Scale"

Javelin plain meaning
Mylan Indefinite Alternatively, "measurement of peak pain relief at 5, 15, 30 and 45 minutes, and at 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 10, 12, and 24 hours on a scale of 0-100 mm that is associated to the dose of analgesic formulation administered"
Court plain meaning

[2]This term appears in claims 1-3 and 5 of the '292 patent.

3. "total pain relief"

Javelin plain meaning, i.e. "sum of pain relief over time"
Mylan Indefinite Alternatively, "sum of pain relief as measured on a Visual Analog Scale of 0-100 mm over the specified Visual Analog Scale time intervals; also referred to as 'TOTPAR'"
Court "sum of pain relief over time"

The parties' claim construction disputes center on various aspects of the wherein clause of claim 1. Because the parties' arguments regarding each specific claim term overlap to a significant degree, the Court will consider them together.

Mylan first contends that the wherein clause must be read as a positive limitation. Javelin counters that the clause is merely the intended result of practicing the claimed method and, therefore, should not be considered a limitation.

Claim language that "is only a statement of purpose and intended result" that "does not result in a manipulative difference in the steps of the claim" is generally not limiting. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001); *see also Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1378 (Fed. Cir. 2005) (finding clause that "simply describes the intended result" of following the steps in claimed method was not limiting). Thus, in general, "[a] whereby [or wherein] clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003). "However, when the 'whereby' [or 'wherein'] clause states a condition that is material to patentability, it cannot be

ignored in order to change the substance of the invention." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329-30 (Fed. Cir. 2005) (finding clause limiting where it "is more than the intended result of a process step," "is part of the process itself," and is "integral part of the invention").

Here, the Court is persuaded that although the wherein clause recites a result of the claimed method, it is also material to patentability. The specification indicates that the invention is ultimately a formulation (and method of using that formulation) that allows for lower dosing of diclofenac without sacrificing efficacy. *See* col. 5 ll. 34-36 ("A significant advantage of the invention results from the ability to achieve efficacy with lower doses and overall daily dosing of diclofenac."); col. 2 l. 62 - col. 3 l. 2 ("These formulations unexpectedly provide for significant efficacy and duration of pain relief at a lower dose than the current recommended doses of the diclofenac."). Consistent with this view of the invention, the applicants relied on the formulation's efficacy in responding to the examiner's rejection for obviousness. (*See* D.I. 46 Ex. D at 6) For example, the applicants explained that "one skilled in the art would not have expected that a diclofenac dose lower than the minimum approved dose could provide a maximum observable therapeutic effect." (*Id.* at 6) Applicants argued that it was, therefore, "surprising and unexpected that the claimed compositions, *e.g.*, a 37.5 mg of a diclofenac compound and a beta-cyclodextrin compound, act as effective as the recommended diclofenac dose, 75 mg, for providing analgesia to a patient." (*Id.* at 7) These statements demonstrate that efficacy – i.e., what is described by the disputed wherein clause – was used to define the claimed invention and distinguish it from the prior art. Accordingly, the wherein clause is limiting.

Having decided that the wherein clause is limiting, the Court considers the parties' proposed constructions for the disputed terms. These disputes primarily concern whether

specific test measures used in the specification should be incorporated into the Court's constructions. Mylan contends that the claims require use of a particular Visual Analog Scale (a scale of 0-100 mm) that must be used to take measurements at specific time points (5, 15, 30, and 45 minutes and 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 10, 12, and 24 hours after administration). (*See* D.I. 53 at 6) Relatedly, although the parties agree that "total pain relief" is the sum of pain relief over time, Mylan contends that total pain relief – and determining whether the pain relief achieved is at least 82% of that achieved with a 75 mg dose of diclofenac – must be calculated from measurements at the particular time points using the specified 0-100 mm scale. (*See id.* at 7-8)

The Court disagrees with Mylan's contentions. The Visual Analog Scale is a general tool commonly used in the art for measuring patient pain (*see* D.I. 53 Ex. A at S240), and the claims do not suggest any timing limitation with respect to when to use the Visual Analog Scale or that a particular version of the scale is required. While the '292 patent uses a particular version of the Visual Analog Scale at specific time intervals to collect the data presented in the patent, the Court sees no indication in the patent or otherwise that the patentee intended to narrow the claims as suggested by Mylan. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1346-47 (Fed. Cir. 2015) ("caution[ing] against limiting the claimed invention to preferred embodiments or specific examples in the specification"). Moreover, the prosecution history cited by Mylan shows that there were at one time limitations about the timing and method of measuring pain relief, but those limitations were removed during prosecution. (*See* D.I. 46 Ex. H at 2) Mylan provides no persuasive reason to read those limitations back into the claims. *See Hill-Rom*, 755 F.3d at 1372. Thus, the Court finds that Javelin's proposed constructions adequately capture the meaning of the claim terms.

Finally, Mylan contends that unless its proposed constructions are adopted, the claims are indefinite. Mylan specifically argues that "while a skilled artisan would understand that the claims require observation of a minimum amount of total pain relief, one would have a range a methodologies from which to select to attempt the analysis." (D.I. 48 at 18) Mylan further asserts that "neither the claim nor the specification provide[s] sufficient notice as to when and how to measure the 'observable total pain relief.'" (*Id.* at 19)

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).[3] A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

The Court is not persuaded on the present record that the claims are indefinite. As discussed above, the Visual Analog Scale is a common tool for measuring patient pain, and Mylan has not proven that a skilled artisan would lack knowledge about how to use it to determine how much maximum observable pain relief a method achieves. As Mylan points out, the patent describes one set of testing conditions that – even if not required by the claims – a person of skill in the art could use. *See* col. 6 ll. 61-66. Further, Mylan itself cites articles about

[3]The parties do not address the identity of a person of ordinary skill in the art.

the Visual Analog Scale indicating that it "is widely used due to its simplicity and adaptability to a broad range of populations and settings. Its acceptability as a generic pain measure was demonstrated in the early 1970s." (D.I. 53 Ex. A at S241) Although there are variations in how a Visual Analog Scale may be presented (e.g., horizontally or vertically, in units of cm or mm, with different pain descriptors, etc.), Mylan presents no evidence or expert testimony to support its position that an ordinarily skilled artisan would not understand how to select an appropriate Visual Analog Scale, use it to perform measurements on pain relief, and then calculate the percentage of pain relief achieved.

Accordingly, the Court will adopt Javelin's proposed constructions.

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.