NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, Defendants.	**Civil Action No. 15-3324 (SRC)** **OPINION & ORDER** (consolidated for discovery purposes with Civil Action Nos. 16-4918, 16-9035, 15-3327, 16-4921, 15-3326, and 16-4920)
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC., Defendants.	
HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., Defendants.	

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc. (collectively, "Horizon") and Defendants Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "DRL"), Mylan Inc., Mylan Laboratories Limited, and Mylan Pharmaceuticals Inc. (collectively, "Mylan"), and Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Lupin"). In this patent infringement suit involving eleven pharmaceutical patents related to the drug Vimovo®, the parties seek construction of claims in three patents. Horizon, DRL and Lupin seek construction of terms in U.S. Patent No. 8,945,621 ("the '621 patent"). All parties seek construction of terms in U.S. Patent Nos. 9,220,698 ("the '698 patent") and 9,393,208 ("the '208 patent"). The Court held a Markman hearing on November 7, 2017.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> 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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to

> 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

> The Federal Circuit has established this framework for the construction of claim language: We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the 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. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks 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. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

A. The '621 patent

The parties had originally briefed three terms in the '621 patent: "coordinated release," "more effective," and "reducing the incidence." Just before the Markman hearing, the parties agreed that: 1) "coordinated release" should have the same construction as previously established

in regard to the ’907 patent; and 2) “reducing the incidence” need not be construed. This leaves only “more effective” at issue.

The phrase “more effective” appears toward the end of claim 1 in the ’621 patent:

> . . . wherein said pharmaceutical composition in unit dose form reduces the incidence of NSAID-associated ulcers in said patient and wherein administration of the unit dose form is more effective at reducing the incidence of the NSAID-associated ulcers in patients taking LDA than in patients not taking LDA who are administered the unit dose form.

At the hearing, it became clear that the parties have no actual dispute about the meaning of the phrase, “more effective,” and they agree that it should have its ordinary meaning. The dispute between the parties instead concerned Defendants’ argument that the claim is nonsensical and therefore indefinite, but these are not issues to address at claim construction. “More effective” has its ordinary meaning.

B. The ’698 and ’208 patents

The parties dispute the construction of three terms in the ’698 and ’208 patents: “±20%,” “target,” and “mean area under the plasma concentration-time curve.” The parties seek construction of these terms in the two patents, but focused on the ’698 patent in briefing and at the hearing. The ’698 patent has one independent claim:

> 1. A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to a patient in need thereof an AM unit dose form and, 10 hours (±20%) later, a PM unit dose form, wherein:
>
> the AM and PM unit dose forms each comprises:
>
> naproxen, or a pharmaceutically acceptable salt thereof, in an amount to provide 500 mg of naproxen, and
>
> esomeprazole, or a pharmaceutically acceptable salt thereof, in an amount to provide 20 mg of esomeprazole;
>
> said esomeprazole, or pharmaceutically acceptable salt thereof, is released from said AM and PM unit dose forms at a pH of 0 or greater,

the AM and PM unit dose forms target:

> i) a pharmacokinetic (pk) profile for naproxen where:
> a) for the AM dose of naproxen, the mean C_{max} is 86.2 ng/mL (±20%) and the median T_{max} is 3.0 hours (±20%); and
> b) for the PM dose of naproxen, the mean C_{max} is 76.8 ng/mL (±20%) and the median T_{max} is 10 hours (±20%); and
> ii) a pharmacokinetic (pk) profile for esomeprazole where:
> a) for the AM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the AM dose is administered to 10 hours (±20%) after the AM dose is administered ($AUC_{0\text{-}10,am}$) is 1216 hr*ng/mL (±20%),
> b) for the PM dose of esomeprazole, the mean area under the plasma concentration-time curve from when the PM dose is administered to 14 hours (±20%) after the PM dose is administered ($AUC_{0\text{-}14,pm}$) is 919 hr*ng/mL (±20%), and
> c) the total mean area under the plasma concentration-time curve for esomeprazole from when the AM dose is administered to 24 hours (±20%) after the AM dose is administered ($AUC_{0\text{-}24}$) is 2000 hr*ng/mL (±20%); and
>
> the AM and PM unit dose forms further target a mean % time at which intragastric pH remains at about 4.0 or greater for about a 24 hour period after reaching steady state that is at least about 60%.

A note about terminology: in the art, "PK profile" refers to a pharmacokinetic profile, basically statements of characteristics of levels of the active ingredient in blood plasma, showing the absorption of the active ingredient by the body. "PD profile" refers to a pharmacodynamic profile, basically statements of the resulting effect on the body, such as raising the stomach pH a certain amount. Claim 1 states targets in terms of certain PK characteristics (plasma levels of active ingredients) and certain PD characteristics (levels of intragastric pH).

1. "±20%"

The parties dispute whether "±20%" in claim 1 has its ordinary arithmetic meaning (plus or minus 20%), or is a "coefficient of variation" ("CV"), as defined in the specification. The term "±20%" appears in claim 1 in 10 places: half are time values (hours ±20%), and half are plasma

concentration values (C_{max} or AUC ±20%). Defendants propose that "±20%" has its ordinary arithmetic meaning when modifying time values, but a special meaning (CV) when modifying plasma concentration values. There is no dispute that, as to the time values, "±20%" has its ordinary arithmetic meaning.

On first blush, Defendants seem to make a strong case for the CV construction: Defendants point out that, in a section which states principles of general applicability, the specification states: "With regard to the pharmacokinetic and/or pharmacodynamic values provided herein, the degree of variation is reflected in SDs and % CV values. The %CV = SD/mean x 100." '698 patent, col.5 ll.53-56. There is no dispute that C_{max} and AUC are pharmacokinetic ("PK") values.

Defendants, however, have overlooked the full context of that statement in the specification:

> With regard to the pharmacokinetic and/or pharmacodynamic values provided herein, the degree of variation is reflected in SDs and % CV values. The % CV=SD/mean x 100; the SD=(% CV x mean) divided by 100. It can be expected that approximately 68% of patients will be within one SD of the mean and approximately 95% of patients will be within two SDs of the mean. The pharmacokinetic and pharmacodynamic values presented herein are average values, rounded to the nearest whole number, and are based upon results obtained from multiple individuals. As a result, the values presented herein may vary from one patient to another. This variation is reflected in the term 'about.'

'698 patent, col. 5 ll.53-64. When the sentence quoted by Defendants is read in context, the context shows that this applies only "to results obtained from multiple individuals." '698 patent, col.5 ll.61-62. It therefore applies only to PK or PD values that state results from groups of patients, such as results of research studies. It does not apply to results from a single patient. The preamble of claim 1 states: "A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to *a* patient in need thereof . . ."

(emphasis added). The PK and PD limitations in claim 1 apply to that single patient, not to results from multiple individuals.[1]

Furthermore, as Plaintiffs point out, the prosecution history shows that the applicants substituted "±20%" in claim 1 (then claim 19) for the word "about." (Beel Dec. Ex. 5 at 5.) The applicants stated, in regard to this change: "This amendment is supported Applicants' specification [sic] at, for example, page 6, lines 17-18." (Id.) This citation refers to this statement in the draft specification: "For the values provided herein, the term 'about' indicates a given number may vary by at least 5%, with variations of 10%, 15% or 20% being possible." (Beel Dec. Ex.7 at 6.) Note that the applicants did not refer to the next paragraph in the draft specification which, like the specification in the issued patent, is the paragraph quoted above about PK values and the coefficient of variation. This statement in the prosecution history supports the understanding that the applicants intended "±20%" to mean a simple arithmetic percentage – roughly equivalent to "about" – , rather than a coefficient of variation.

Plaintiffs also point out that claim 1 uses "±20%" in reference not only to PK and PD values, but also in regard to time periods. In short, the CV concept has no applicability to – and, rather, makes no sense if applied to – time periods. "[T]he same word appearing in the same claim should be interpreted consistently." Dig. Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335,

[1] At the hearing, counsel for Plaintiffs argued that the PK and PD profile values in claim 1 are summary statistics for groups of patients. This position conflicts with the preamble language that specifies that what is claimed is a method of treatment for "a patient." Plaintiffs have not pointed to anything in the patent that shows that what the inventors actually invented was a method for treating a group of patients. See Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim.")

1345 (Fed. Cir. 1998).

Furthermore, in the specification, where the inventors meant to refer to the CV, they wrote out, "% CV" or "% coefficient of variation." See, e.g., '698 patent, Figure 7; col.8 ll.12-13; Tables 4, 5, 6. Defendants have not pointed to any place in the specification that "±20%" appears and has the meaning, "a CV of 20."

"±20%" has its ordinary meaning, "plus or minus 20 %."

2. "target"

Claim 1 contains the term "target" in two places: "the AM and PM unit dose forms target:" and "the AM and PM unit dose forms further target." Plaintiffs contend that "target" has its ordinary meaning, and that that ordinary meaning is "produce." At oral argument, the Court inquired as to how "produce" is the ordinary meaning of "target." In reply, Plaintiffs explained that what they meant is that "produce" is the meaning that would be understood by the skilled artisan in the context of this patent. In support, Plaintiffs point to the declaration of their expert, Dr. Taft, who states that opinion. (Taft Dec. ¶ 28.) Plaintiffs also cite this statement in the '698 specification: "This, and similar, formulations can be effective in improving NSAID tolerability through dosages of esomeprazole and naproxen that produce the desired pharmacodynamic response and pharmacokinetic values." '698 patent, col.1 ll.34-37. Plaintiffs also point to a place in the specification in which an embodiment is said to target a particular PD profile. '698 patent, col.6 ll.46-56.

The Court finds Plaintiffs' proposed construction unpersuasive. At the hearing, Plaintiffs offered nothing to counter the Court's suggestion that the ordinary meaning of "target" is not "produce," except for the argument, based on extrinsic evidence, that the skilled artisan would

understand it that way. Under Federal Circuit law, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court." Phillips, 415 F.3d at 1318. Dr. Taft's assertion is the kind of conclusory, unsupported assertion that, under Phillips, is not useful in claim construction.

The only intrinsic evidence cited by Plaintiffs is the specification passage in which the treatment method is described as producing certain PD and PK profiles, as well as one in which the treatment method is said "to target" a specific PD profile. The Court does not see how this supports Plaintiffs' position. For example, if the specification of a car suspension patent states that the design "delivers" a smooth ride, and also that the design "creates" a smooth ride, that is not evidence that "deliver" means "create."

It is certainly clear that the inventors believed that the patented method should, at some point and in some way, produce the stated PD and PK profiles – as Plaintiffs demonstrate, the specification makes that clear. But that does not resolve this issue. As the Federal Circuit has stated, "the claims, not the specification, provide the measure of the patentee's right to exclude." Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1052 (Fed. Cir. 2002). "It is the claims that define the metes and bounds of the patentee's invention." Kara Tech. Inc. v. Stamps.com Inc., 582 F.3d 1341, 1347 (Fed. Cir. 2009). Thus, an underlying concern in claim construction is ascertaining the metes and bounds of the patentee's invention that are stated in the claim. Plaintiffs' proposed construction does not appear to clarify how the patentees drew those boundaries.

During oral argument, this was apparent when Plaintiffs seemed to contend that the PK and PD profile values in claim 1 are average values that are obtained from some unspecified group

of patients. If this is Plaintiffs' position, it makes no sense. As already noted, the preamble of claim 1 states: "A method for treating osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis comprising orally administering to *a* patient in need thereof . . ." (emphasis added). Plaintiffs' position conflicts with this: how could the treatment of a single patient target PK and PD values that are averages from some unknown group?[2] Moreover, if this is the case, how does a skilled artisan determine whether or not a particular treatment of a particular individual patient has met the limitations of claim 1? Does one have to treat a group of patients and then compare the average values for the group to the values stated in claim 1? Is this a hypothetical group of patients? In terms of understanding the metes and bounds of the claims, this is a path to confusion.

In sum, Plaintiffs did not shed light on the meaning of "target" in claim 1.

Defendants contend that "target" is indefinite. This Court considers indefiniteness arguments on summary judgment or at trial, and not at claim construction. Defendants propose, in the alternative, that if the Court does not find the term indefinite, it has its ordinary meaning, which is, "with the goal of obtaining."

Thus, both sides propose that "target" has its ordinary meaning, but they differ on what that ordinary meaning is. Defendants point to a number of dictionary definitions of target: "to establish as a target or a goal" (Beel Dec. Ex. 8), "establish as a goal" (Beel Dec. Ex. 9), and "to establish as a target, goal, etc.) (Beel Dec. Ex. 10). These three dictionary definitions agree that

[2] The Court recognizes that the specification states: "The pharmacokinetic and pharmacodynamic values presented herein are average values, rounded to the nearest whole number, and are based upon results obtained from multiple individuals." '698 patent, col.5 ll.59-62. This is clearly true as applied to research results, such as disclosed in Table 6. The parties did not address the question of whether this also applies to claim 1.

"target" means "to establish as a goal." Unlike Plaintiffs' proposed meaning, this fits with the Court's understanding of what "target" ordinarily means. This construction also fits with claim 1 and the patent as a whole: the PK and PD profiles in claim 1 appear to be goals for the treatment method of claim 1. If Plaintiffs are correct in their contention that the PK and PD values in claim 1 are averages for a group, the claim, using this construction, makes sense: one administers the method to an individual patient with the goal of obtaining these values, on average, for a group of patients. From this perspective, the PK and PD profiles in claim 1 do not serve as limitations for the method, but as statements of a goal aspired to, but not met, for every patient.[3]

This Court agrees with Defendants' proposed construction, "with the goal of obtaining." In the context in which "target" appears in claim 1, that exact wording has a poor grammatical fit (since "target" functions as a verb in claim 1, and "with the goal of obtaining" is a prepositional phrase.) To improve the grammatical fit, this Court construes "target" in claim 1 to mean: "set as a goal."

This Court recognizes the general canon of claim construction that claims should be construed so as to preserve their validity. While this Court today makes no determination about the validity of claim 1, at the same time, the Court recognizes that this construction of "target" could conceivably impact the validity of the claim. On this record, however, this Court sees no alternative. Plaintiffs' proposed construction makes no sense, and Defendants' proposed construction makes sense. Moreover, the Federal Circuit does not apply this canon of

[3] Defendants argued separately that the PK and PD values in claim 1 are non-limiting, offering a number of arguments in support, including one focused on the relationship between claim 1 and Table 6 in the specification. This Court need not reach any of these arguments at this juncture in order to construe the claim term, "target." The Court does not, today, decide the question of whether the PK and PD profiles in claim 1 are or are not limiting.

construction in every case, but limits it to certain circumstances:

> This court has frequently alluded to the familiar axiom that claims should be so construed, if possible, as to sustain their validity. At the same time, however, the court has admonished against judicial rewriting of claims to preserve validity. Accordingly, unless the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous, the axiom regarding the construction to preserve the validity of the claim does not apply.

Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004) (citations omitted). Because this Court does not find the term "target" to be ambiguous, it need not contemplate rewriting the claim to preserve its validity.

3. "mean area under the plasma concentration-time curve"

The parties dispute whether "mean area under the plasma concentration-time curve" ("mean AUC") is limited to a steady state value. Defendants seek to import a narrowing limitation from certain embodiments in the specification. There is no basis in the claim language for Defendants' proposed narrowing construction. "[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Phillips, 415 F.3d at 1323. Claim 1 contains a different limitation which specifies "after reaching steady state," and the specification includes examples in which the steady state characteristic is expressly stated, showing that the patentees knew how to state that characteristic when they intended it to apply. "Mean area under the plasma concentration curve" will be given its ordinary meaning, without the narrowing construction Defendants propose.

In conclusion, in claim 1 of the ’698 and ’208 patents, “±20%” and “mean area under the plasma concentration-time curve” have their ordinary meaning, while “target” means, “set as a goal.” In claim 1 of the ’621 patent, “more effective” has its ordinary meaning.

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: November 14, 2017