NOT FOR PUBLICATION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

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