IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD and IROKO PHARMACEUTICALS, LLC,	)	
Plaintiffs,	)	
v.	)	Civ. No. 14-1515-SLR
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 29th day of February, 2016, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. 8,679,544 ("the '544 patent"), 8,999,387 ("the '387 patent"), and 9,017,721 ("the '721 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"A pharmaceutical composition containing 18 mg of diclofenac acid"**[1] **and "a pharmaceutical composition containing 35 mg diclofenac acid."**[2] Consistent with the parties' proposed constructions, the plain and ordinary meaning of the limitation will apply. The specification states that "[t]he present invention relates to

[1] Found in claim 1 of the '544 patent, claim 1 of the '387 patent, and claim 1 of the '721 patent.
[2] Found in claim 6 of the '544 patent, claim 11 of the '387 patent, and claim 8 of the '721 patent.

methods for producing particles of diclofenac using dry milling processes as well as compositions comprising diclofenac, medicaments produced using diclofenac in particulate form and/or compositions, and to methods of treatment . . . using a therapeutically effective amount of diclofenac administered by way of said medicaments." (1:5-11)[3] The specification generally describes "methods of making finely divided or sized drugs" such as dry milling, wet grinding/milling, and airjet milling, as well as the limitations of such methods. *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1336 (Fed. Cir. 2009) (the Federal Circuit "recognizes that disparaging comments alone do not necessarily show a manifest or express disavowal of the criticized subject matter"). The specification presents dry milling of the biologically active material[4] (3:56-62; 31:39-32:22), the biologically active material (32:23-67), and methods of administering pharmaceutical compositions (18:14-22). The claims at issue are directed to compositions and do not recite a specific process (i.e., dry milling) for manufacturing the diclofenac acid particles. The court concludes that the specification does not support defendants' additional language limiting the claims to "dry-milled diclofenac acid." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (if a patent describes only a single embodiment, the claims of the patent must not necessarily be construed as being limited to that embodiment "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction'").

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[3] As the three patents-in-suit share a specification, references are to the '544 patent.
[4] Indeed, during prosecution of the original application, the patentee selected the process claims to prosecute, resulting in U.S. Patent No. 8,735,450 (not at issue here), which discloses and claims compositions made by the dry-milling process.

2. **"Wherein the unit dose when tested in vitro by USP Apparatus I (Basket) method of U.S. Pharmacopoeia at 100 rpm at 37ºC in 900 ml of 0.05% sodium lauryl sulfate in citric acid solution buffered to pH 5.75 has a dissolution rate of diclofenac acid such that at least [X]%, by weight, is released by [X] minutes"**[5] **and "wherein the unit dose has a dissolution rate of diclofenac acid such that at least [X]%, by weight, is released by [X] minutes:"**[6] "Wherein at least [X]%, by weight, of diclofenac acid is released from the unit dose by [X] minutes as determined by USP Apparatus I (Basket) method of U.S. Pharmacopeia at 100 rpm at 37ºC in 900 ml of 0.05% sodium lauryl sulfate in citric acid solution buffered to pH 5.75" and "using the methodology prescribed in the independent claims, the unit dose has a dissolution rate such that at least [X]%, by weight, of diclofenac acid is released from the unit dose by [X] minutes." According to the specification "[t]he process results in the biologically active material having an improved dissolution profile[, which] has significant advantages including the improvement of bioavailability of the biologically active material in vivo." (24:35-39) The specification describes how to carry out the testing method. (24:35-25:22, 54:12-67, example 14)

3. **"The particles of diclofenac acid have a median particle size on a volume average basis of"**[7] **and "the diclofenac acid has a median particle size, on a volume average basis, of:"**[8] "The diclofenac acid particles have a particle size

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[5] Found in claims 1 and 6 of the '544 patent, claims 1 and 11 of the '387 patent, and claims 1 and 8 of the '721 patent.
[6] Found in claims 2-5 and 7-10 of the '544 patent, claims 6-8 and 16-18 of the '387 patent, and claims 3-5 and 10-12 of the '721 patent.
[7] Found in claims 1 and 6 of the '544 patent.
[8] Found in claims 1-4 and 11-14 of the '387 patent and claims 1-2, 8-9, 15-18 and 23-24 of the '721 patent.

diameter that divides the population in half such that 50% of the population is greater than or less than said particle size diameter as determined on an equivalent spherical particle volume basis measured after particle size reduction but before preparing the unit dose." The specification defines "median particle size" "as the median particle diameter as determined on an equivalent spherical particle volume basis. Where the term median is used, it is understood to describe the particle size that divides the population in half such that 50% of the population is greater than or less than this size." (22:2-8) The specification explains that the "median particle size" is determined on a particle volume basis. (16:39-40, 17:52-53, 33:12-13) Further, "laser diffraction . . . is commonly used to measure particle size from 100 nm to 2000 micron, by calculat[ing] a volume distribution of equivalent spherical particles . . . ." (21:44-50) Contrary to defendants' argument that the language "volume average basis" in the claims renders them indefinite, the court concludes that the entire limitation, viewed in light of the specification, would "inform those skilled in the art about the scope of the invention with reasonable certainty."[9] *Nautilus, Inc. v. Biosig Instruments, Inc.*, ___ U.S. ___, 134 S.Ct. 2120, 2129 (2014) (citations omitted).

4. **"Perceptible pain relief"[10] and "peak pain relief:"**[11] "An observable decrease in pain by a patient" and "the maximum observable decrease in pain by a patient." The specification describes efficacy studies for the treatment of pain. (61:32-

[9] **Extrinsic evidence**. Indeed, the parties' experts agree that measurements calculated on a volume basis are known to one of skill in the art. (D.I. 108 at ¶¶ 27-39; D.I. 125 at ¶¶ 9-12)

[10] Found in claims 21-22 of the '544 patent, claims 23 and 24 of the '387 patent, and claims 19-22 of the '721 patent.

[11] Found in claims 23-24 of the '544 patent.

69:28, example 16) The court acknowledges defendants' argument that perception of pain is dependent on the individual enrolled in the study. However, the methods described in the specification are standardized approaches used in industry.[12] (61:35-39) Plaintiffs' expert[13] explained that:

> [P]hysicians in the field have been using the terms "perceptible pain relief" and "peak pain relief" consistently in this manner for years. These pain relief terms are not novel to Plaintiffs' clinical study of the Zorvolex® drug products. In fact, many clinical studies of nonsteroidal anti-inflammatory drugs, like diclofenac acid, utilized the terms "perceptible pain relief" and "peak pain relief" to assess the pain relief of patients undergoing treatment. The use of "peak pain relief" and "perceptible pain relief" in the field is consistent with their description in the clinical efficacy study disclosed in the specification of the patents-in-suit.

(D.I. 109 at ¶ 32)

5. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

United States District Judge

[12] "[A] Phase 2, Phase 2, Randomized, 35 Double-Blind, Single-Dose, Parallel-Group, Active- and Placebo-Controlled Study of Diclofenac Nanoformulation Capsules for the Treatment of Pain After Surgical Removal of Impacted Third Molars."

[13] **Extrinsic evidence**.