

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND
LIMITED, et al.,

1:15-cv-07742-NLH-AMD

1:16-cv-00645-NLH-AMD

Plaintiffs,

MARKMAN OPINION

v.

ACTAVIS LABORATORIES, UT,
INC., et al.,

Defendants.

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HILLMAN, District Judge

This is a Hatch-Waxman Act¹ action brought by Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.), which is the current owner and assignee of the patents-in-issue, and of the PENNSAID® 2% New rug Application ("NDA").² PENNSAID® 2% is the first FDA-approved

¹ The Third Circuit Court of Appeals has explained,

With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, Congress attempted to balance the goal of "mak[ing] available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement, see H.R.Rep. No. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714. The Act seeks to accomplish this purpose, in part, by encouraging "manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." S. Rep. No. 107-167, at 4 (2002).

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 394 (3d Cir. 2015).

²All rights under these patents were acquired from third parties.

twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis ("OA") of the knees.

Horizon has filed several Hatch-Waxman actions alleging patent infringement against generic companies seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents. Presently before the Court is Horizon's claims against defendant Actavis Laboratories UT, Inc. ("Actavis") related to U.S. Patent Nos. 9,168,304 ("the '304 patent"), 9,168,305 ("the '305 patent"), and 9,220,784 ("the '784 patent").³ Horizon brought these actions in response to Actavis' assertion that the generic copy of PENNSAID® 2% described in Actavis' Abbreviated New Drug Application No. 207238 ("ANDA"), if approved by the FDA, would not infringe these three Horizon patents, and Actavis' further assertion that it intends to market its FDA-approved generic copy of PENNSAID® 2% prior to the expiration of these Horizon patents.⁴

A claim construction hearing was held on July 21, 2016. This Opinion memorializes the Court's findings as to its

³ Horizon filed suit against Actavis relating to nine other patents covering PENNSAID® 2%. See Civil Action No. 14-7992 ("First Actavis Action"). Actavis declined Horizon's invitation to consolidate the actions.

⁴ This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

construction of three claims at issue pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).⁵

I. LAW OF CLAIM CONSTRUCTION

The ultimate question of the proper construction of a claim in a patent is a question of law for the court to determine. Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 837 (2015) (citing Markman v. Westview Instruments, Inc., 517 U.S. 370, 388-91 (1996)) (further explaining, "While we held in Markman that the ultimate issue of the proper construction of a claim should be treated as a question of law, we also recognized that in patent construction, subsidiary factfinding is sometimes necessary."). A patent claim is that "portion of the patent

⁵ The Markman hearing also included argument from Lupin Ltd. and Lupin Pharmaceuticals, Inc. in civil action numbers 15-3051, 15-5027, and 15-6935. The disputed claim terms in the Lupin actions overlap with the Actavis actions. This Opinion will address three disputed claim terms in the context of Actavis only, but the Court notes that Actavis has adopted Lupin's claim construction of the terms "improved absorption" and "effectively treat pain." Because the Lupin case involves additional disputed claim terms, the Court will issue a separate Markman decision in the Lupin actions directed to those additional terms.

In a related issue, the term "consists essentially of" is in dispute in all of the Actavis and Lupin actions. The Court has issued its construction of the term in the Horizon v. Actavis action, 14-7992. Horizon has indicated that it will ask that the Court reconsider that decision. Because how the Court resolves Horizon's motion for reconsideration on that term will affect the other Actavis actions and Lupin actions, that term will not be addressed now.

document that defines the scope of the patentee's rights.'" Id.
(quoting Markman, 517 U.S. at 372).

The Federal Circuit has set forth a "familiar approach to claim construction." In re Papst Licensing Digital Camera Patent Litigation, 778 F.3d 1255, 1261 (Fed. Cir. 2015). In construing a patent claim, which should be considered in the mindset of a person having ordinary skill in the art ("POSA"):

(1) a court should give words of a claim their ordinary meaning in the context of the claim and the whole patent document;

(2) the specification particularly, but also the prosecution history, informs the determination of claim meaning in context, including by resolving ambiguities;

(3) even if the meaning is plain on the face of the claim language, the patentee can, by acting with sufficient clarity, disclaim such a plain meaning or prescribe a special definition; and

(4) the court should apply the principle that "[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."

In re Papst, 778 F.3d at 1261 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc)) (explaining that claim terms should be given their ordinary and customary meaning

to a person having ordinary skill in the art at the time of the effective date of the patent application). Although intrinsic evidence is important in claim construction, district courts may also rely upon extrinsic evidence, which “`consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’” Phillips, 415 F.3d at 1317 (quoting Markman, 52 F.3d at 980).

In the context of an argument that a claim is indefinite, “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014) (interpreting 35 U.S.C. § 112, ¶ 2). “[T]he burden of proving indefiniteness remains on the party challenging validity and [] they must establish it by clear and convincing evidence.” Dow Chem. Co. v. Nova Chemicals Corp. (Canada), 809 F.3d 1223, 1227 (Fed. Cir. 2015).

II. DISPUTED TERMS

The Court has thoroughly considered the parties’ positions on their proposed construction of the three disputed claim terms as presented in their comprehensive briefs, certifications of experts, and oral argument at the Markman hearing. For all

three terms, the Court finds Horizon's construction to be proper.

A. "Wherein the Formulation is Administered Twice Daily"

Claim Term	Asserted Claims	Horizon's Proposed Construction	Actavis' Proposed Construction
"wherein the formulation is administered twice daily"	'304 patent, claims 1-5, 8-13	wherein the formulation is capable of being administered twice daily	wherein the user administers the formulation two times each day

Court's construction: "wherein the formulation is capable of being administered twice daily"

Horizon contends that the term should be construed that the formulation is capable of being administered twice daily to effectively treat pain. Actavis argues that the term unambiguously requires a user to administer the formulation because the present tense in the phrase "is administered" indicates that an actual administration is required, and not just that the formulation "can be" or "may be" administered.

The Court agrees with Horizon that the '304 patent refers to the nature of the formulation rather than the method of how the formulation is used. The language of the claim containing the term "wherein the formulation is administered twice daily" supports that construction. Claim 1 provides:

1. A topical formulation comprising: diclofenac sodium present at 2% w/w; DMSO present at 25% to 60% w/w; and a viscosity of 500-5000 centipoise, wherein the formulation is administered twice daily, to thereby effectively treat pain.

(Docket No. 43-2.)

This claim informs a POSA that PENNSAID® 2% is a topical formulation that is administered two times a day. The language of Claim 1, when considered in the context of the other claims, indicates that this patent concerns the composition of a topical formulation, as each of the 13 claims begin with "The topical formulation of . . .". It would not make any sense to assert thirteen claims about a topical formulation without including in the formulation's description how the formulation is used. The term "is administered twice daily" simply describes the nature of formulation.

The adoption of Actavis' construction of the term so that it provides an active instruction to the user on how to use the formulation would improperly turn all formulations that require the action of the user into method claims. Horizon's construction stays true to the claim language, and most naturally aligns with the patent's description of the invention, as understood by the appropriate person skilled in the art.

B. "Improved Absorption"

Claim Term	Asserted Claims	Horizon's Proposed Construction	Actavis' Proposed Construction
"improved absorption"	'304 patent, claim 12 '305 patent, claim 13 '784 patent, claim 13	Improved absorption as measured by the maximum plasma concentration (Cmax) and area under the curve (AUC) using scaled clinical doses.	Indefinite

Court's construction: "improved absorption as measured by the maximum plasma concentration (Cmax) and area under the curve (AUC) using scaled clinical doses"

Horizon contends that "improved absorption" refers to the absorption of compositions of the claimed invention compared to the "comparative liquid composition." To support its position, Horizon points to two specifications in the relevant patents that would instruct a POSA with reasonable certainty that "improved absorption" is referring to improved absorption of the inventive formulations compared to a comparative liquid composition as measured by the maximum plasma concentration (Cmax) and mean area under the curve (AUC) using scaled clinical doses.

Actavis argues that it is unclear which parameters should be used to determine if there has been "improved absorption," and the results of any comparison to the "comparative liquid formulation" may vary depending on the parameters chosen. Actavis contends that "improved absorption" may refer to either Cmax or AUC, only one of them, or both. Accordingly, Actavis argues that the term "improved absorption" is indefinite because it fails to inform a POSA, "with reasonable certainty," what combination of parameters disclosed in the specification should be used to determine if absorption is improved.⁶

As always, the starting point of claim construction is the language of the patent. Claim 12 of the '304 patent claims, "The topical formulation of claim 1, wherein the formulation has improved absorption on a per dose basis compared to a comparative liquid composition." (Docket No. 43-2 at 64.) Because the claim is silent as to what metrics should be used to

⁶ As noted above, Actavis incorporates by reference Lupin's arguments on the construction of this claim term. At the Markman hearing, Lupin emphasized that Horizon's change of its own claim construction from requiring consideration of only changes in the AUC to requiring the consideration of both the AUC and Cmax highlights the claim term's ambiguity. (Civ. A. No. 15-3051, Docket No. 86 at 41-42.) Horizon explained that it changed its construction to what it deems to be the most accurate construction. Whatever prompted the amended claim construction, the Court agrees with Horizon that its current construction is the proper one.

determine whether absorption has improved, the Court next looks to the specifications.

The "Characteristics of the Gel Formulation" section provides:

A comparison of the absorption of diclofenac sodium of compositions of the invention and a comparable composition from U.S. Pat. Nos. 4,575,515 and 4,652,557 was conducted in animals. The gels of the invention were shown to have improved absorption on a per dose basis than the comparative liquid compositions of these patents. In absolute terms, the clinical dose of the gels of the invention delivered a maximum observed plasma concentration (Cmax) at steady state of 81 ng/ml and an area under the curve (AUC) of 584 ng/ml. This compared to 12 ng/ml and 106 ng/ml for the comparator compositions.

(Docket No. 43-2 at 53.) This specification shows that Cmax and AUC are the parameters by which the gel formulation compares with the liquid formulation.

Actavis points to Example 7 to support its position that it is unclear to a POSA whether the metric for absorption is Cmax or AUC or both. Example 7 concerns the "Comparison of in Vivo Epicutaneous Absorption of Liquid Versus Gel Formulations," where a study was conducted to compare systemic absorption after topical application of a comparative solution with a gel of the invention. (Id. at 61.) The following pharmacokinetic parameters for diclofenac sodium were calculated:

AUC0_24 (Test Day 7)
AUC0_4 (Test Day 8)
AUC0_inf (Test Day 8)
Tmax (Test Days 7, 8) (time to reach Cmax)
Cmax (Test Days 7, 8) (maximum observed plasma concentration)

Cmin (Test Days 7, 8) (minimal observed plasma concentration)
C(trough) (Test Days 6, 7, and 8) (trough plasma concentration)
Kez (elimination half-life)
T1/2 (plasma elimination half-life).

(Id.)

Actavis points to a paragraph that comes after this list of testing parameters to support its position: "The data is shown in FIG. 12 and Tables 16 and 17. Compositions of the invention show significantly more absorption of diclofenac sodium as measured by the mean AUC. This result holds even when adjusting for dose." (Id. at 62.) Actavis argues that this paragraph's reference to only AUC, rather than both Cmax and AUC, would confuse a POSA as to the proper metrics for assessing improved absorption.

The Court agrees with Horizon that this paragraph does not cast a shadow of indefiniteness of the term "improved absorption" when it is considered in context with the rest of Example 7. The pharmacokinetic parameters list both Cmax and AUC, and Table 16 tracks the "PK profile at steady state on Day 7," and provides individual and mean data for Cmax and AUC. (Id. at 63.) Table 17, "Relative bioavailability and exposure to a comparative liquid formulation in comparison to the corresponding gel at steady state," shows the ratio for compositions of the invention versus the comparative liquid formulation for both Cmax and AUC parameters. (Id.) The Court

agrees with Horizon, and its supporting experts, that the specification and Example 7 as a whole would inform a POSA that in order to evaluate whether a formulation has "improved absorption" relative to the comparative liquid formulation, the POSA should compare Cmax and AUC using scaled clinical doses. Actavis has not met its burden of providing clear and convincing evidence to show indefinites of the "improved absorption" claim term.

C. "Effectively Treat Pain"

Claim Term	Claims	Horizon's Proposed Construction	Defendant's Proposed Construction
"effectively treat pain"	'304 patent, claims 1-5, 8-13 '305 patent, claims 1-5, 9-14 '784 patent, claims 1-5, 9-14	Effectively treat pain as measured by the WOMAC scale	Indefinite

Court's construction: "effectively treat pain as measured by the WOMAC scale"

Horizon argues that the term "effectively treat pain" would be understood by a person of ordinary skill in the art, after considering the intrinsic evidence, to mean "effectively treat pain as measured by the WOMAC scale." Actavis argues that the

term is inherently subjective and therefore indefinite. Actavis further argues that adding the WOMAC scale to the level of pain assessment does not cure the subjectivity problem.

This term is found in Claim 1:

1. A topical formulation comprising: diclofenac sodium present at 2% w/w; DMSO present at 25% to 60% w/w; and a viscosity of 500-5000 centipoise, wherein the formulation is administered twice daily, to thereby effectively treat pain.

(Docket No. 43-2.)

Similar to the term "wherein the formulation is administered twice daily," where Actavis' construction of the term would render indefinite the claims of all inventions that require the formulation to be administered to a person simply because the claim describes how the formulation is used, Actavis' construction of "effectively treat pain" would cause the same result. If Actavis' construction - that "effectively treat pain" is indefinite because pain is an inherently subjective and unquantifiable term - were credited, any invention that endeavored to reduce pain would be held indefinite because no true objective pain measurement scale exists.

Even though pain is subjective to each individual, whether the formulation effectively treats pain for each individual can be measured. Example 8 in the '304 patent describes a clinical study of topical diclofenac solution where pain was measured

according to the Western Ontario McMaster Universities LK3.1 Osteoarthritis Index ("WOMAC"). (Docket No. 43-2 at 63.) The specification teaches that in the clinical study, the "primary variables for assessment of efficacy will be the WOMAC LK3.1 pain and physical function and Patient Overall Health Assessment," and describes the WOMAC scale as a method of evaluating the effectiveness of pain treatment. The specification shows that "application of the gel formulations of the invention when applied topically will result in a reduction of pain or physical function on the WOMAC scale of at least 1 Likert scale unit over a 12 week period." (Id.)

Thus, when considering Claim 1 in the patent in tandem with Example 8, a POSA would understand that the efficacy of the formulation in treating pain is a reduction of pain or physical function on the WOMAC scale of at least 1 Likert scale unit over a 12 week period. Although one subject might experience knee pain as a 10 out of 10, while another subject might experience the "same" knee pain as a 2 out of 10, the patent teaches that a reduction of at least 1 unit on the WOMAC scale (from 10 to 9 for the first subject, and 2 to 1 for the second subject) is the measure of how the formulation "effectively treats pain." Consequently, the Court does not find that the term "effectively treats pain" to be indefinite, and instead construes the term to mean "effectively treat pain as measured by the WOMAC scale."

III. CONCLUSION

For the foregoing reasons, the disputed terms meet the definiteness requirement under 35 U.S.C. § 112, ¶ 2, and are construed as follows:

A. The term "wherein the formulation is administered twice daily" is construed as "wherein the formulation is capable of being administered twice daily"

B. The term "improved absorption" is construed as "improved absorption as measured by the maximum plasma concentration (Cmax) and area under the curve (AUC) using scaled clinical doses"

C. The term "effectively treat pain" is construed as "effectively treat pain as measured by the WOMAC scale."

An appropriate Order will be entered.

Date: August 17, 2016
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.