IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., Plaintiff, v. XELLIA PHARMACEUTICALS APS and XELLIA PHARMACEUTICALS INC., Defendants.	Civil Action No. 14-199-RGA

MEMORANDUM OPINION

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January 6, 2015

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction for claim 1 of U.S. Patent No. 5,952,300 ("the '300 patent").

I. BACKGROUND

Merck Sharp & Dohme Corp. ("Plaintiff") filed a patent infringement action against Xellia Pharmaceuticals ApS and Xellia Pharmaceuticals Inc. ("Defendants") on February 14, 2014. (D.I. 1). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 50). The Court held oral argument on the disputed claim term on December 18, 2014. (D.I. 72).

II. LEGAL STANDARD

"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) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a matter of law, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the 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." *Phillips*, 415 F.3d at 1315 (internal quotation marks and citations omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [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." *Phillips*, 415 F.3d at 1312–13 (internal quotation marks and citations omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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." *Id.* at 1314 (internal citations omitted).

A court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in order to assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* at 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *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) (internal quotation marks and citation omitted).

III. JUDICIAL ESTOPPEL

Defendants argue that Plaintiff is judicially estopped from proposing its present construction. (D.I. 50 at p. 18). Plaintiff was engaged in prior litigation involving the '300 patent. *See Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. 2:10-1625 (D.N.J). In that case, Plaintiff was granted summary judgment of non-obviousness. (D.I. 51 at Ex. 2-C). The case

ultimately settled. (D.I. 50 at p. 13). Defendants argue that Plaintiff took an inconsistent claim construction position from the one it now argues and should therefore be estopped from making its current argument. (*Id.* at p. 19).

The doctrine of judicial estoppel bars a party that has previously asserted a legal position from asserting an inconsistent or contrary legal position in a later proceeding. *Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 419 (3d Cir. 1988). This equitable remedy is applied to preserve the integrity of the system. Its focus is on the relationship between the litigant (*i.e.*, Merck) and the judicial system. *Id.* The elements of judicial estoppel in the Third Circuit are: (1) the party to be estopped is taking two irreconcilably inconsistent positions; (2) the party to be estopped has changed his or her position in bad faith; and (3) the use of judicial estoppel is tailored to address the harm identified and no lesser sanction would adequately remedy the damage done. *Montrose Med. Group Participating Savings Plan v. Bulger*, 243 F.3d 773, 777-78 (3d Cir. 2001).

Defendants argue that in *Sandoz*, Plaintiff took the position that the acetate buffer is added as a separate component, not formed in situ.[1] (D.I. 50 at p. 21). Defendants maintain that bad faith is shown because Plaintiff is "playing fast and loose with the court" by now arguing that the buffer can be formed in situ. (*Id.*) Defendants did not discuss whether a lesser sanction would remedy the damage. (*Id.*). Defendants' argument that Plaintiff took a different position in *Sandoz* is not based on previous claim construction arguments. (*Id.* at p. 35). In that case, there was no claim construction dispute about subpart c) of claim 1, the language now in dispute. (*Id.*). Rather, Defendants base their argument on excerpts of testimony from Plaintiff's expert in the *Sandoz* case, Dr. Byrn. (*Id.* at pp. 16-19). Defendants argue that Plaintiff overcame

[1] *See infra* Section IV.

obviousness by arguing that no one would have thought to add an additional acetate buffer. (D.I. 72 at 42:9-13). Defendants maintain that this non-obviousness argument gives rise to an implied claim construction which requires a separate acetate buffer to be added. (D.I. 72 at 42:14). Defendants argue that the previous implied construction contradicts Plaintiff's position that the buffer can be formed in situ. (D.I. 50 at p. 19).

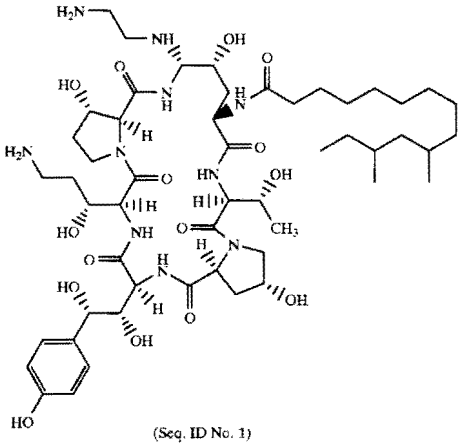
The Court does not find Plaintiff's proposed construction to be inconsistent with its position in the *Sandoz* case. Subsection c) was not a disputed term in the *Sandoz* litigation, and it therefore had its plain and ordinary meaning. (*Id.* at 27). At oral argument in this case, Plaintiff asserted that its position was essentially the plain and ordinary meaning. (D.I. 72 at 47:2-4). While Plaintiff may have made different arguments in the previous case because the case focused on different issues, its claim construction position remains the same. The Court is not convinced that out-of-context statements from Plaintiff's previous expert give rise to an implied claim construction. The Court will therefore not apply judicial estoppel.

IV. CONSTRUCTION OF DISPUTED TERM

Claim 1 of the '300 patent is the only disputed claim, and it reads:

A pharmaceutical composition for intravenous administration to a patient comprising
a) a pharmaceutically effective amount of a compound having the formula

(I)



(Seq. ID No. 1)

and the pharmaceutically acceptable salts thereof,

b) a pharmaceutically acceptable amount of an excipient effective to form a lyophilized cake; and

c) a pharmaceutically acceptable amount of an acetate buffer effective to provide a pharmaceutically acceptable pH.

1. *"a pharmaceutically acceptable amount of an acetate buffer effective to provide a pharmaceutically acceptable pH"*

a. *Plaintiff's proposed construction*: "A pharmaceutically acceptable amount of an acetate buffer is present such that the resulting composition has a pharmaceutically acceptable pH"

b. *Defendants' proposed construction*: "A pharmaceutically acceptable amount of an acetate buffer that is added to the composition as a separate component to provide a pharmaceutically acceptable pH, and which is distinct from the acetate that may be present due to dissociation of the caspofungin salt of element a)"

c. *Court's construction*: Plain and ordinary meaning

The parties' dispute boils down to two elements of subpart c). First, whether "effective to provide" means that the acetate buffer is the sole contributor to the composition's pH or just

one factor affecting pH. Second, whether the acetate buffer must be added as a separate component or can be formed in situ. The Court will address these elements in turn.

Plaintiff argues that the acetate buffer contributes to the pH, but it is not solely responsible for controlling the composition's pH. (D.I. 50 at p. 25). Plaintiff further argues that the specification teaches that the acetate buffer need not be the only buffer. (*Id.* at 31). Defendants respond that Plaintiff's construction reads out the "effective to provide" claim language by requiring only that the buffer be present. (D.I. 50 at p. 24). Defendants argue that Plaintiff's construction does not require the buffer to have any causative effect on the pH.

The Court agrees in part with both parties. Despite its position in the papers and at oral argument that the acetate buffer contributes to the pH, Plaintiff's proposed construction reads out that requirement. I agree that the buffer must have some causative effect on the pH and need not merely be present. The Court does not find, however, that "effective to provide" requires that the acetate buffer be the sole cause of the composition's pH. Neither proposed construction captures that the buffer must have some effect on the pH, but not solely control the pH. The customary usage of "effective to provide" is not a term of art that the Court needs assistance in understanding. *See Abbott Labs. v. Baxter Pharm. Products, Inc.*, 334 F.3d 1274, 1277-78 (Fed. Cir. 2003) (holding that the customary usage of "effective amount" was an amount sufficient to achieve the claimed effect). The plain and ordinary meaning therefore applies.

The second dispute is whether the acetate buffer must be added separately, or can be formed in situ by adding ingredients that react and form the buffer within the composition. Defendants argue that the claim language requires that the acetate buffer be separately added, and must be distinct from any acetate present as a result of "the pharmaceutically acceptable salts" of subsection a). (D.I. 50 at p. 14). Because the salts of subsection a) and the buffer of

subsection c) are claimed separately, Defendants argue that the buffer cannot be formed by the salts. (*Id.*). Defendants further argue that the specification teaches that the acetate buffer must be separately added because it refers to "switching to an acetate buffer." (D.I. 50 at p. 15). They argue that the inventors could not "switch" to an acetate buffer if the buffer were formed by the salts of subsection a). (D.I. 50 at p. 43). Finally, Defendants argue the acetate buffer is separately added in every example in the specification. (D.I. 50 at p. 41).[2]

Plaintiff argues that Defendants are improperly importing process limitations into a composition claim. (D.I. 50 at pp. 7-8). Plaintiff notes that in the prosecution history the applicants emphasized the importance of the buffer's presence, not how the buffer was added to the composition. (D.I. 50 at p. 9). Plaintiff argues that "switching" refers only to how the inventors discovered the composition and does not limit the invention. (D.I. 50 at p. 30). Finally, Plaintiff argues that the examples in the specification enable the invention, and an enablement cannot be converted into a limitation. (D.I. 72 at 48:19-21).

The Court agrees that Defendants' construction reads a process limitation into a composition claim. The requirements that the buffer "is added to the composition as a separate component" and "is distinct from the acetate that may be present due to dissociation of the caspofungin salt of element a)" are process limitations, and should not be read into a composition claim. *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 345 F. App'x 594, 597-99 (Fed. Cir. 2009). The '300 patent has a separate process claim and a product-by-process claim. ('300 patent, claims 7, 8, col. 10 l. 43 – col. 12 l. 5). Defendants' proposed construction essentially converts

[2] Defendants also argue that Merck's previous expert believed that the acetate buffer needed to be separately added. (D.I. 50 at pp. 16-19). For the reasons discussed above, the Court does not find that Dr. Byrn offered an implied claim construction. *See supra* Section III.

the composition claim into a product-by-process claim. The Court therefore does not believe that Defendants' construction is correct.

The Court does not find that either proposed construction captures the claim requirements. Plaintiff's proposed construction reads out the requirement that the acetate buffer have some causative effect on the composition's pH. Defendants' proposed construction imports process limitations into a composition claim. The Court finds that the plain and ordinary meaning applies.