IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, ASTRAZENECA UK LIMITED, Plaintiffs, v. LANNETT HOLDINGS, INC. and LANNETT COMPANY, INC., Defendants.	Civil Action No. 14-984-RGA

MEMORANDUM OPINION

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December 1, 2015

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of several terms in U.S. Patent Nos. 6,750,237 ("the '237 patent") and 7,220,767 ("the '767 patent"). The Court has considered the parties' Joint Claim Construction Brief. (D.I. 49). The Court heard oral argument on November 16, 2015. (D.I. 59 [hereinafter, "Tr."]).

I. BACKGROUND

On July 25, 2014, Plaintiffs Impax Laboratories, Inc. and AstraZeneca AB filed this action against Defendants Lannett Holdings, Inc. and Lannett Company, Inc., alleging infringement of the '237 and '767 patents. (D.I. 1). On July 30, 2014, Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited filed an action against Defendants alleging infringement of the same patents. (C.A. No. 14-999 D.I. 1). On December 10, 2014, this Court consolidated the two cases. (D.I. 33). The patents at issue are addressed to pharmaceutical formulations containing zolmitriptan, an intranasal administration device containing a pharmaceutical formulation containing zolmitriptan, and an aqueous solution of zolmitriptan. (D.I. 50-1 at 5, 10).

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 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."

Id. 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).

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of 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 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* 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. PATENTS AT ISSUE

Claims 1 and 9 are representative of the asserted claims in the '237 patent. They read:

1. A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is in the range 4.5 to 5.5.

9. A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 7.0, wherein the formulation is buffered by a mixture of citric acid and disodium phosphate.

('237 patent, 5:4–7; 5:22–6:2).

Claims 1 and 5 are representative of the asserted claims in the '767 patent. They read:

1. A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 6.0.

5. A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 6.0, wherein the formulation is buffered by a mixture of citric acid and disodium phosphate.

('767 patent, 5:8–11; 5:18–22).

IV. CONSTRUCTION OF DISPUTED TERMS

1. preambles

   a. *Plaintiffs' proposed construction*: limiting

   b. *Defendants' proposed construction*: not limiting

c. *Court's construction*: limiting

The parties dispute whether the claim preambles that state "[a] pharmaceutical formulation suitable for intranasal administration" are limiting. (D.I. 49 at 6).

A preamble should be construed as a claim limitation if it gives "life, meaning, and vitality to the claim." *Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks and citation omitted). A preamble gives "life, meaning, and vitality to the claim" if, for example, it provides antecedent basis for claim language, recites structural elements that the specification highlights as important, or discloses a fundamental characteristic of the claimed invention. *See id.*; *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004). A preamble should not be construed as limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Poly-Am., L.P.*, 383 F.3d at 1310 (quoting *Rowe v. Dror,* 112 F.3d 473, 478 (Fed. Cir. 1997)) (internal quotation marks omitted). Whether to treat a preamble as limiting should be "resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

Plaintiffs argue that the preambles are limiting because they provide antecedent basis for a term in the claim bodies. (D.I. 49 at 7). Plaintiffs also argue that the preambles describe structural elements that the specifications highlight as important. (*Id.* at 7–8). Defendants respond that the preambles are non-limiting statements of intended use because they do not recite any chemical composition or structure and the patentees did not rely on the preambles during prosecution to distinguish the claims from prior art. (*Id.* at 11–14). Defendants also argue that

the preambles do not provide antecedent basis because, although the term "formulation" appears in the bodies of the claims as well as the preambles, that term is not a structural limitation. (*Id.* at 11). Defendants contend that "formulation" is merely a descriptive name for the structurally complete set of limitations in the bodies of the claims. (*Id.*).

The preamble language "pharmaceutical formulation" provides antecedent basis for the language "the formulation" in the bodies of the claims. Because none of the preamble language "suitable for intranasal administration" appears in the claim bodies, however, that language plainly does not provide antecedent basis for terms in the claim bodies. Still, the preamble language "suitable for intranasal administration" does more than state an intended use for the formulations. It informs the meaning of those formulations—they must possess features making them appropriate for intranasal use. Further, that the patentees did not rely on the preambles to distinguish prior art during prosecution does not suggest that the preambles are non-limiting because the patent examiner cited only intranasal art. (D.I. 50-1 at 24). That the examiner cited only intranasal art is some indication that he or she acknowledged that the patents claim intranasal formulations.

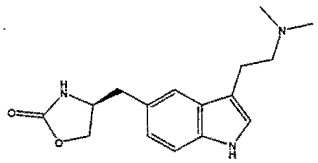
More importantly, review of the patents as a whole demonstrates that the entire preamble gives "life, meaning, and vitality" to the pharmaceutical formulation claims. First, the patents repeatedly refer to the invention as a pharmaceutical formulation for use in intranasal administration. ('767 patent, 1:17–19, 2:8–10, 2:18–19, 2:23–24, 2:28, 2:40–42, 2:64–65, 3:22–24, 3:48–50, 3:62–63; '237 patent, 1:16–17, 2:7–8, 2:18–19, 2:23–25, 2:28, 2:40–42, 2:66, 3:22–23, 3:44–46, 3:58–59). Second, the specifications identify issues with prior art formulations and explain that the "inventors devised an intranasal formulation of zolmitriptan that provided effective and improved fast relief for migraine sufferers." ('767 patent, 1:33–38, 2:8–10; '237

patent, 1:31–36, 2:7–9). Third, Examples 1–8 of the patents are directed to intranasal formulations and Example 9 of both patents describes a method for administering such intranasal formulations. ('767 patent, 4:1-67, 5:1–6; '237 patent, 3:65–67, 4:1–67, 5:1–2). These disclosures demonstrate that the claimed formulation is an improved pharmaceutical formulation of zolmitriptan suitable for intranasal administration. Indeed, the specifications nowhere suggest that the invention relates to formulations not suitable for intranasal use.

I therefore conclude that the preambles of the pharmaceutical formulation claims ("[a] pharmaceutical formulation suitable for intranasal administration") are necessary limitations of those claims.

2. "zolmitriptan"

a. *Plaintiffs' proposed construction*: compound having the chemical name (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone and chemical structure:



b. *Defendants' proposed construction*: compounds containing the basic structure as depicted in Figure 1 below, as well as ionic and covalently bonded forms thereof that preserve the pharmaceutical activity of the structure

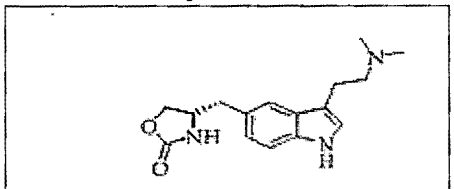
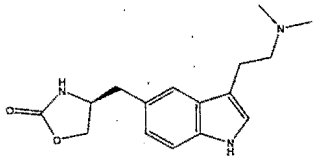


Figure 1

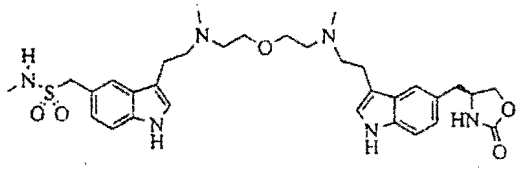
c. *Court's construction*: compound having the chemical name (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone and chemical structure:



The parties agree that the term "zolmitriptan" encompasses a compound having the chemical name and basic chemical structure depicted above. (D.I. 49 at 18, 20). Further, there is no dispute that the ordinary and customary meaning of "zolmitriptan" includes ionically bonded forms of zolmitriptan. (*Id.* at 21; Tr. at 27–28). The parties disagree regarding whether "zolmitriptan" also includes covalently bonded forms of that structure that preserve the pharmaceutical activity of the structure. (D.I. 49 at 20, 24).

Plaintiffs contend that covalently bonded "forms" of zolmitriptan are in fact different molecules and therefore not "zolmitriptan." (*Id.* at 20). Plaintiffs argue that a covalent bond, unlike an ionic bond, is an intramolecular bond that forms a new molecule with a different name, formula, structure, and molecular weight than its component parts. (*Id.* at 26). According to Plaintiffs, the molecule formed by a covalent bond between zolmitriptan and some other molecule would thus not fall within the plain and ordinary meaning of "zolmitriptan" to one of skill in the art at the time of invention. (*Id.*). Plaintiffs further argue that no isolated part of such a molecule would be "zolmitriptan" because it would have a different structure than that depicted above. (*See id.* at 28; Tr. at 30).

Defendants argue that Plaintiffs' attempt to distinguish ionically and covalently bonded forms of zolmitriptan is arbitrary. (Tr. at 39). Defendants rely on the Marquess reference to demonstrate that one of ordinary skill in the art would have understood "zolmitriptan" to encompass the portion of covalently bonded molecules that correspond to the "basic structure" of zolmitriptan. (D.I. 49 at 23). Defendants argue that Marquess Figure 21 below discloses a covalently bonded version of zolmitriptan as "zolmitriptan." (*Id.* at 23; *see* D.I. 50-2 at 63–64).



(I)

Sumatriptan Zolmitriptan

FIGURE 21

Defendants' reliance on Marquess is unavailing. Defendants do not dispute that the molecule depicted in Marquess Figure 21 is a molecule with a different name, formula, structure, and molecular weight than zolmitriptan. Thus, the entire Figure 21 molecule cannot be "zolmitriptan." Further, the Figure 21 molecule does not contain "zolmitriptan," notwithstanding that the term appears under the right-hand portion of the figure. The portion of Figure 21 labeled "zolmitriptan," which has one methyl (CH_3) group and one CH_2 group attached to the nitrogen atom, does not comport with the chemical name and structure disclosed in the specifications, which has two methyl groups attached to the nitrogen atom. (D.I. 50-4 at 63). I conclude that one of ordinary skill in the art would therefore not understand "zolmitriptan" to include covalently bonded forms of the chemical structure disclosed in the specifications as zolmitriptan.

For the reasons stated above, I adopt Plaintiffs' proposed construction.[1]

3. "buffer," "buffered," "in a buffer"

a. *Plaintiffs' proposed construction*: systems of (1) weak acids and their conjugate bases, (2) weak bases and their conjugate acids, and (3) certain acid-base pairs that can function in the manner of System 1 or 2.[2]

[1] As Plaintiffs point out (D.I. 49 at 19 n.2), the chemical name for zolmitriptan in their proposed construction differs slightly from that stated in the specifications. Defendants conceded at oral argument that a person skilled in the art, seeing the word "zolmitriptan," and seeing the description in the specifications, would understand that there were typographical errors in the name. (Tr. at 36). The construction I now adopt thus corrects the errors in the specifications' statement of the chemical name of zolmitriptan.

[2] Plaintiffs explained at oral argument that "(3) certain acid-base pairs that can function in the manner of System 1 or 2" is meant to encompass weak acid-weak base pairs that "function the same way" as pairs of weak acids and their conjugate bases or weak bases and their conjugate acids but in which the paired acids and bases are not "conjugates." (Tr. at 49).

b. *Defendants' proposed construction*: formulations or material(s) that are contained in formulations that tend to allow the formulation to resist change in pH on adding acid or alkali or on dilution with solvent

c. *Court's construction*: formulations or material(s) therein that resist change in pH on adding acid or alkali or on dilution with solvent

Plaintiffs argue that the terms "buffer," "buffered," and "in a buffer" refer to an aqueous solution consisting of a mixture of a weak acid and a weak base. (D.I. 49 at 33). Plaintiffs contend that Defendants' proposed construction unreasonably broadens the terms' scope to encompass strong acids, strong bases, and single-component pH adjusting agents. (*Id.* at 34). Plaintiffs cite the absence of a strong acid, strong base, or single-component pH adjusting agent in any of the examples of buffers disclosed in the specifications as reason to limit the terms to weak acids and bases and their respective conjugate acids and bases. (*Id.* 49 at 33–34). Plaintiffs also rely on extrinsic evidence to support their contention that their proposed construction comports with the plain and ordinary meaning of the terms. (*Id.* at 34 (citing D.I. 50-5 at 4, 33–34, 38–39), 38 (citing D.I. 50-4 at 65–67; D.I. 50-5 at 48)).

Defendants propose a functional definition addressed to resistance to change in pH upon adding acid or alkali or on dilution with solvent. (*Id.* at 34). Defendants contend that Plaintiffs' proposed construction is too narrow because it excludes application to acids and bases that are within the ordinary and customary meaning of the terms. (*Id.*). Defendants argue that the intrinsic evidence does not shed light on the proper construction of "buffer" and that limitations in examples in a specification, without more, should not be read into the claims. (*Id.* at 35, 37). Defendants thus rely on extrinsic evidence that indicates that a person of ordinary skill in the art would understand "buffer" to include strong acids and bases and single-component agents that resist changes in pH. (*Id.* at 34).

The patent specifications do not expressly define the term "buffer" and the parties do not point to anything in the prosecution history that bears on this dispute. That the examples of buffers in the specifications are all combinations of weak acids and bases does not settle the question of the appropriate scope of the term. *See Nazomi Commc'ns, Inc. v. ARM Holdings, PLC,* 403 F.3d 1364, 1369 (Fed. Cir. 2005) (claims may embrace "different subject matter than is illustrated in the specific embodiments in the specification"). Thus, it is proper to consult extrinsic evidence to ascertain the ordinary meaning of "buffer."

The parties cite treatises, technical dictionaries, and expert reports in support of their proposed constructions. *Medical Biochemistry* and *Hawley's Condensed Chemical Dictionary*, 12th Edition, both comport with Plaintiffs' proposed construction and define "buffer" as either a mixture of a weak acid and its conjugate base or a weak base and its conjugate acid. (D.I. 50-5 at 4, 33). Plaintiffs also point to the declaration of their expert witness, Dr. Smyth, who states "that a person of ordinary skill would have understood the terms "buffer," "buffered," and "in a buffer" to refer to systems of (1) weak acids and their conjugate bases, (2) weak bases and their conjugate acids, and (3) certain acid-base pairs that can function in the manner of System 1 or 2." (D.I. 49 at 34 (citing D.I. 50-4 at 65)). In addition, Plaintiffs cite *Dictionary of Biotechnology*, 2d Edition, which defines "buffer" as follows: "A chemical solution which is resistant to change in pH on the addition of acid or alkali. Buffer solutions commonly consist of a mixture of a weak acid and its conjugate base . . . or a weak base and its conjugate acid. . . ." (*Id.* (citing D.I. 50-5 at 38–39)). This *Dictionary of Biotechnology* definition, however, supports Defendants' proposed construction over Plaintiffs'. After stating a definition quite similar to Defendants' proposed construction, *Dictionary of Biotechnology* says only that buffers "commonly" consist of a mixture of a weak acid and its conjugate base or a weak base and its

conjugate acid. (D.I. 50-5 at 38–39). Defendants also rely on the expert report of Dr. Gizurarson, submitted in an inter partes review of the '237 patent. (D.I. 49 at 35, 36). In that report, Dr. Gizurarson states his opinion that one of ordinary skill would have understood "buffer" in the '237 patent as "referring to the ability of a pharmaceutical formulation . . . to resist a change in pH on adding acid or alkali or on dilution with solvent." (D.I. 50-2 at 41–42).

The evidence discussed above favors each party's proposed construction nearly equally. The proper construction therefore turns on the meaning of *Remington: The Science and Practice of Pharmacy*, a recognized authority on pharmaceutical science. (D.I. 49 at 35, 39; *see* D.I. 50-5 at 41–48). The parties agree that the Remington treatise sets forth the plain and ordinary meaning of "buffer." (D.I. 49 at 35, 38). Each party argues, however, that Remington supports its proposed construction. (*Id.*). Defendants argue that "the Remington reference indicates unequivocally that strong acids and strong bases are recognized as being capable of acting as buffers." (*Id.* at 36). Plaintiffs respond that Remington supports their proposed construction because it indicates that, although strong acids and bases are capable of exhibiting buffer-like action, they are not "buffers" as that term would have been understood by one of ordinary skill in the art. (*Id.* at 38).

Review of the entire discussion of buffers in Remington suggests that Defendants' proposed construction reflects the plain meaning to one of ordinary skill. First, the first sentence under the heading "Buffers" states that "[t]he terms *buffer*, *buffer solution* and *buffered solution*, when used with reference to a hydrogen-ion concentration or pH, refer to the ability of a system, particularly an aqueous solution, to resist a change of pH on adding acid or alkali, or on dilution with a solvent." (D.I. 50-5 at 46). Second, Remington characterizes "unbuffered" solutions as those that "lack ability to resist change in pH on adding acid or base," which suggests that a

person of ordinary skill in the art would understand both "unbuffered" and "buffered" functionally, as Defendants propose. (*Id.*). Third, in discussing "Strong Acids and Bases as 'Buffers,'" Remington states that "[t]he ability to resist change in pH on adding acid or alkali is possessed also by relatively concentrated solutions of strong acids and strong bases." (*Id.* at 48). This discussion indicates that combinations or weak acids and their conjugate bases and weak bases and their conjugate acids do not exhaust the full scope of what one skilled in the art would have understood "buffer" to mean.

Notwithstanding the above, there are two aspects of the discussion of buffers in Remington that support Plaintiffs' proposed construction: (1) Remington states that the nature of "buffer action" for strong acids and bases "is quite different from that of the true buffer solutions" and (2) the heading "Strong Acids and Bases as 'Buffers'" employs quotation marks around "Buffers." (*See id.* at 48). Nevertheless, that the mechanism of the buffering action is different for different types of buffers does not negate the clear implication of the overall discussion in Remington: that one of ordinary skill would understand "buffer" functionally as a solution that resists changes in pH. I conclude that the Remington reference demonstrates that Defendants' functional understanding of "buffer," "buffered," and "in a buffer" would have been the understanding of one of ordinary skill in the art at the time of invention.

For the reasons stated above, I adopt Defendants' functional definition and therefore construe "buffer" as "formulations or material(s) therein that resist change in pH on adding acid or alkali or on dilution with solvent." The Court's construction is expressed differently than Defendants' proposed construction for clarity.

V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.