

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER
PHARMACEUTICALS INC., RB
PHARMACEUTICALS LIMITED, and
MONOSOL RX, LLC,

Plaintiffs,

v.

WATSON LABORATORIES, INC.,

Defendant.

Civil Action No. 13-1674-RGA

RECKITT BENCKISER
PHARMACEUTICALS INC., RB
PHARMACEUTICALS LIMITED, and
MONOSOL RX, LLC,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.,
INTELGENX TECHNOLOGIES CORP.

Defendant

Civil Action No. 14-0422-RGA

MEMORANDUM OPINION

Dana Severance, Esq., Wilmington, DE, Womble Carlyle Sandridge Rice; Dan Ladow, Esq. (argued), New York, NY, Troutman Sanders LLP; Magnus Essunger, Esq., New York, NY, Troutman Sanders LLP; Andrew Regan, Esq., New York, NY, Troutman Sanders LLP; Cassandra Adams, Esq., New York, NY, Steptoe & Johnson LLP; Attorneys for Plaintiffs

Kate Lester, Esq., Wilmington, DE, Richards, Layton & Finger, PA; Daniel Brown, Esq. (argued), New York, NY, Latham & Watkins LLP; Michelle Ma, Esq., Menlo Park, Latham & Watkins LLP; Jack Phillips, Esq., Wilmington, DE, Phillips, Goldman & Spence, P.A.; Attorneys for Defendants

June 26, 2015


ANDREWS, U.S. DISTRICT JUDGE:

Before this Court is a supplemental claim construction of a single term of U.S. Patent No. 8,475,832 (“the ‘832 Patent”). The Court previously construed other disputed terms submitted by the parties. (D.I. 156). In the present matter, the Court has considered the parties’ claim construction briefing (D.I. 237, 239, 243, 253) and held a *Markman* hearing. (D.I. 294).

I. 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).

II. CONSTRUCTION OF DISPUTED TERM

A. The '832 Patent

Claim 1 of the '832 patent reads:

A film dosage composition comprising:

- a. A polymeric carrier matrix;
- b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
- c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
- d. A *buffer* in an amount to provide a local pH for said composition of a value sufficient to optimize absorption of said buprenorphine, wherein said local pH is from about 3 to about 3.5 in the presence of saliva.

('832 Patent, Claim 1) (relevant term italicized).

1. "buffer"

a. *Plaintiffs' proposed construction:* "Buffer" as used in the claims has its plain and ordinary meaning as used in the pharmaceutical sciences: "buffer" means one or more components that function to help resist changes to pH when small amount of an acidic or basic agent are added.

b. *Defendants' proposed construction:* A combination of a weak acid and its conjugate base present in the composition, the base being provided by one of its soluble salts, in a sufficient amount to [*provide a local pH for the composition sufficient to optimize absorption of said buprenorphine wherein said local pH is about 3 to about 3.5 in the presence of saliva in the mouth, where local pH refers to the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves, for example, in the mouth of the user*]

c. *Court's construction:* a buffer is a component in the composition that functions to resist changes to pH when an acid or base is added to the composition.

The crux of this dispute is whether a buffer must include both a weak acid and a conjugate base, or whether a buffer need only include one of a weak acid or a conjugate base. In other words, whether a buffer must be a combination, or whether one or more components will suffice.

Plaintiffs provide useful definitions from specialized dictionaries but appear to recite from them selectively. Merriam-Webster's Medical Desk Dictionary, cited by Plaintiffs, describes a buffer as "a substance or mixture of substances (as bicarbonates and some proteins in biological fluids) that in solution tends to stabilize the hydrogen-ion concentration by neutralizing within limits both acids and bases." (D.I. 239 at p. 2; D.I. 239-1 at 3).¹ Similarly, Plaintiffs quote from the Oxford Dictionary of Biochemistry and Molecular Biology: "any substance or mixture of substances that, when dissolved (usually in water), will maintain its solution at approximately constant pH despite small additions of acid or base." (D.I. 239 at p. 2; D.I. 239-2 at 5). The very next sentence of that definition, however, reads, "The commonest examples are moderately strong solutions containing both a weak acid and its conjugate base (or a weak base and its conjugate acid)." (D.I. 239-2 at 5). Defendants question the use of these definitions as not coming from pharmaceutical references. (D.I. 243 at p. 3). Instead, Defendants point to Remington's as an authority on pharmaceutical science. Remington's states: "Buffers are used to maintain the pH of a medicinal at an optimal value. A *buffer* is a solution of a weak acid and its conjugate base, the base being provided by one of its soluble salts." (D.I.

¹ Notably, part of the definition for "buffer solution," the next entry in the same dictionary, appears to comport with Defendants' definition of "buffer": "a solution that usu[ally] contains ... a weak acid (as carbonic acid) together with one of the salts of this acid ... and that by its resistance to changes in hydrogen-ion concentration on the addition of acid or base is useful in many ... processes." (D.I. 239-1 at 3).

245-1 at 12). Defendants argue that there is no compelling reason to deviate from what it believes is the ordinary meaning of buffer. (D.I. 243 at p. 4).

Even though the definitions strongly suggest that a buffer often—or in its “commonest example”—contains both a weak acid and a conjugate base, that does not appear to always be the case. Instead, the fundamental characteristic of a buffer is that it buffers, or resists changes to, pH. The definitions offered by the parties suggest that more often than not this is done with both an acid and a base. But even so, the combination is not required. The Court’s construction, unlike Plaintiffs’ proposal, makes clear that the buffer must function to resist changes to pH—not merely “help” resist changes. Similarly, Plaintiffs’ inclusion of “small amounts” of an acid or base does not add meaning to buffer.

The claims, as Plaintiffs argue, by themselves demonstrate buffer may refer to a single component or combination. (D.I. 239 at p. 3). For example, claim 7 of the patent reads, “The film dosage composition of claim 1, wherein said buffer comprises sodium citrate, citric acid, and combinations thereof.” (’832 Patent, Claim 7). The fact that the claim explicitly contemplated “combinations” of sodium citrate and citric acid suggests that, by themselves, sodium citrate and citric acid could act as the said buffer. If sodium citrate or citric acid could be buffers by themselves, it would not be correct that a combination of components, as Defendants assert, is required.

The specification also demonstrates that a buffer is not limited to a combination of an acid and base. Plaintiffs argue that the specification states in several places that “any buffer” may be used. (D.I. 239 at p. 4). Defendants argue that the examples in the patent that the buffer “may include” or “comprise” sodium citrate, citric acid, or combinations do not demonstrate that the buffer is citric acid or is sodium citrate. (D.I. 243 at p. 8; *see, e.g.*, ’832 Patent at 13:7-10

(“Any buffer system may be used as desired. In some embodiments, the buffer may include sodium citrate, citric acid, and combinations thereof.”)). Defendants overstate their claim. This “include” or “comprise” language does not by itself demonstrate that a buffer is only citric acid or sodium citrate. But the language does suggest that an expansive view of a buffer system was contemplated to cover “any” buffer system. Similarly, as with the claim language, the fact that the buffer could also include “combinations” of sodium citrate and citric acid suggests that it could also include the components by themselves—else there would be no need to call out combinations explicitly.

Defendants do point to persuasive examples in the specification, but it would be improper to limit the claim language to these examples. Defendants argue that the specification demonstrates that the invention functions by requiring both a weak acid and conjugate base. (D.I. 243 at p.5; *see* ‘832 Patent, Table 5). For example, in describing three test film formulations, the specification says that the “first film did not include any buffer,” and in the corresponding column of Table 5, that test film contains neither citric acid nor sodium nitrate. (‘832 Patent at 18:37-38). In contrast, the two other test formulations are described as “buffered” and contain a mix of citric acid and sodium citrate. (‘832 Patent at 18:38-40). More specifically, Defendants point out that the claim specifies that the buffer provides a local pH from about 3 to 3.5 in the presence of saliva and that the second test formulation of Table 5, which has a “pH = 3-3.5,” contains 2.96 mg of citric acid and 2.34 mg of sodium citrate. (D.I. 243 at p. 5; ‘832 Patent, Table 5). Defendants argue that this is consistent with the construction of a buffer as a conjugate base and weak acid. (D.I. 243 at p. 6). Defendants are correct that this is consistent with a construction of buffer that contains both a conjugate base and weak acid, but

it does not prove anything. A combination of acid and base counts as a buffer, but that does not foreclose an individual component, such as citric acid or sodium citrate, also being a buffer.

Both parties cite to the prosecution history and prior art cited in the patent to illuminate the meaning of buffer, but the Court does not find this evidence particularly persuasive either way. Plaintiffs have cited cases of other courts construing “buffering agent,” but it is challenging to draw much from constructions of this term within the context of entirely different patents and intrinsic records. (D.I. 239 at p. 7).

For the above reasons, a buffer is a component in the composition that functions to resist changes to pH when an acid or base is added to the composition.