NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NAUTILUS NEUROSCIENCES, INC., et al.,	:	**Civil Action No. 11-1997 (ES)**
	:	**Civil Action No. 12-1243 (ES)**
Plaintiffs,	:	
	:	**OPINION**
v.	:	
WOCKHARDT USA LLC, et al.,	:	
Defendants.	:	

SALAS, DISTRICT JUDGE

I. Introduction

Before the Court is the parties' request for claim construction of certain disputed terms in these patent infringement actions. The Court held a *Markman* hearing on January 17, 2013. This Opinion sets forth the Court's construction of the disputed claim terms.

II. Background

Plaintiffs Nautilus Neurosciences, Inc. ("Nautilus") and APR Applied Pharma Research SA (collectively, "Plaintiffs") brought these Hatch-Waxman Act patent infringement actions against Defendants Wockhardt USA LLC and Wockhardt Ltd. (collectively, "Defendants") relating to Nautilus's Cambia® product used in the treatment of migraine. (D.E. No. 67, Plaintiffs' Opening *Markman* Brief ("Pl. Opening Br.") at 2).

Specifically, these actions arise from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"). (D.E. No. 68, Defendants' Opening *Markman* Brief ("Def. Opening Br.") at 4). Pursuant to its ANDA,

Defendants seek FDA approval to market a generic version of Cambia® before expiration of the four patents listed for Cambia® in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). (*See id.* at 4-6; *see also* Pl. Opening Br. at 2). These four patents are: United States Patent Nos. 6,974,595 (the "'595 patent"); 7,482,377 (the "'377 patent"); 7,759,394 (the "'394 patent"); and 8,097,651 (the "'651 patent"). (Pl. Opening Br. at 2; Def. Opening Br. at 4). Nautilus is the exclusive licensee for these four patents that are owned by APR Pharma Research SA. (Def. Opening Br. at 4).

In its ANDA, Defendants certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the four patents were invalid, unenforceable and/or would not be infringed by Defendants' generic version of Cambia®. (*Id.* at 4-6). Plaintiffs accordingly brought these two patent infringement suits against Defendants, claiming that Defendants' generic version of Cambia® would infringe the '595 patent, the '377 patent, the '394 patent, and the '651 patent. (Pl. Opening Br. at 2).

As detailed below, the parties have asked the Court to construe two terms from the '595 patent and two terms from the '651 patent.

III. 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) (internal quotations omitted). Claim construction is a matter of law to be determined solely by the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

"[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." *Phillips*, 415 F.3d at 1312-13 (internal quotations omitted). To determine the ordinary and customary meaning of disputed claim language that has a "particular meaning in a field of art," the court must look to "those sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean." *Id.* at 1314 (internal quotations omitted).

Thus, the court must "look to the claim language, the specification, the prosecution history, and any relevant extrinsic evidence." *Meyer Intellectual Properties Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1368 (Fed. Cir. 2012); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (*e.g.*, the patent specification and file history) and extrinsic evidence (*e.g.*, expert testimony).").

With respect to intrinsic evidence, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

Importantly, the specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). "[T]he specification may reveal a special definition given to a claim term by the patentee" or "may reveal an intentional disclaimer, or disavowal, of claim scope by

the inventor." *Phillips*, 415 F.3d at 1316. Indeed, "the specification necessarily informs the proper construction of the claims" and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1316-17.

Notably, however, the court may "not read limitations from the specification into claims." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Specifically, the Federal Circuit has "repeatedly warned against confining the claims to . . . embodiments" described in the specification. *Phillips*, 415 F.3d at 1323.

The court must also consider the patent's prosecution history—"the complete record of the proceedings before the PTO . . . includ[ing] the prior art cited during the examination of the patent." *Id.* at 1317. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* Although the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," it can nevertheless "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Therefore, in sum, "[c]laim terms are given their ordinary and customary meaning—the meaning that they would have to a person of ordinary skill in the art in light of the specification and prosecution history at the time of the invention." *Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1283 (Fed. Cir. 2012). And "[c]laim terms are properly construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Id.* (internal quotations omitted).

Finally, the court may also rely on extrinsic evidence—"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 v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995)). But, extrinsic evidence "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319.

IV. Construction of Disputed Claim Terms

A. The '595 Patent

1. "diclofenac formulation comprises diclofenac in acid and/or salt form"[1]

The parties dispute the meaning of this term from claim 28 of the '595 patent. Claim 28 is as follows (with emphasis on the disputed claim language):

> *A method for obtaining an average T_{max} of diclofenac in a human patient between 5 and 30 minutes after administration comprising orally administering a diclofenac formulation to said patient, wherein said* ***diclofenac formulation comprises diclofenac in acid and/or salt form****, and wherein said diclofenac formulation is selected from:*
>
> *a. a powder formulation dissolved or dispersed in water; and*
>
> *b. a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.*

Plaintiffs' Proposed Construction: "a pharmaceutical formulation containing diclofenac in the free acid and/or salt form"

Defendants' Proposed Construction: "a formulation of diclofenac that contains an alkali metal carbonate or bicarbonate"

[1] Defendants initially proposed the term to be construed as "diclofenac formulation." (Def. Opening Br. at 3, 13). At the *Markman* hearing, however, Defendants agreed that using the term "diclofenac formulation comprises diclofenac in acid and/or salt form," as Plaintiffs had proposed, would not affect the claim construction analysis. (Tr. at 60:15-62:1).

Court's Construction: "a formulation of diclofenac that contains an alkali metal carbonate or bicarbonate"

Plaintiffs argue that the claim language is clear and unambiguous such that the Court need not look any further to construe this term. (Pl. Opening Br. at 9-10; D.E. No. 73, Plaintiffs' Responsive *Markman* Brief ("Pl. Resp. Br.") at 17). Plaintiffs also argue that, unlike the other independent claims in the '595 patent, there is no indication that the patentee intended to directly or indirectly include an alkali metal carbonate or bicarbonate limitation in claim 28. (*See* Pl. Opening Br. at 10-11). Finally, Plaintiffs contend that Defendants' proposed construction improperly reads a limitation from the specification into claim 28. (*Id*. at 11).

Defendants argue that the intrinsic evidence must be examined. (Def. Opening Br. at 13). Defendants contend that a person of ordinary skill in the art, reading the entire patent, would understand the disputed claim language as referring to diclofenac formulations that contain an alkali metal carbonate or bicarbonate. (*Id.*). Defendants cite several portions of the specification, including the abstract, that allegedly show that the invention of the '595 patent is diclofenac combined with an alkali metal carbonate or bicarbonate. (*Id.* at 14-17). Defendants also argue that the prosecution histories for the '595 patent and the related '377 patent demonstrate that an alkali metal carbonate or bicarbonate feature is critical to the '595 patent. (*Id.* at 17-25).

The Court disagrees with Plaintiffs that it need not look beyond the claim language. *See Phillips*, 415 F.3d at 1314-15. As such, "the specification is always highly relevant to the claim construction analysis" and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1315, 1317 (internal quotations omitted).

Here, the specification provides that "[i]t has now been found that, by adding alkali metal bicarbonates or mixtures thereof to the Diclofenac in its acid and/or salt form . . . pharmaceutical compositions can be obtained." ('595 Patent at 2:20-25). In fact, "[t]he first object of the present invention is . . . represented by a pharmaceutical formulation for oral use containing Diclofenac ill [sic] acid and/or [s]alt form *together with* alkali metal bicarbonates or mixtures thereof and customary excipients and adjuvants." (*Id.* at 2:26-30 (emphasis added)).

The specification further provides that "[i]t has in fact been surprisingly demonstrated that the use of alkali metal bicarbonates . . . permits to achieve constant, reproducible and foreseeable blood levels of the active ingredient." (*Id.* at 2:33-37). The specification explains that "it has also been found that the combined use of Diclofenac *together with* alkali metal bicarbonates yields Diclofenac-based pharmaceutical compositions in which the active ingredient is released more rapidly compared with normal formulations, bringing about higher blood levels and therefore a more immediate therapeutic effect." (*Id.* at 2:38-44 (emphasis added)). The specification describes "immediate release formulations for oral use of the *present invention*" as "containing from 10 to 60 mg of Diclofenac in acid and/or salt form *together with* alkali metal bicarbonates or mixtures thereof." (*Id.* at 3:11-15 (emphasis added)). Similarly, the '595 patent abstract provides that "[n]ew pharmaceutical compositions for oral use containing Diclofenac *together with* alkali metal bicarbonates . . . are described." (*Id.*, Abstract (emphasis added)).

In addition, as Defendants correctly note, every example from the '595 patent uses a formulation containing diclofenac in combination with an alkali metal carbonate or bicarbonate. (Def. Opening Br. at 16). For instance, in a comparative test disclosed in Example 4 of the '595 patent, the formulation disclosed in Example 1 is specifically compared with formulations "not

containing alkali metal carbonates and bicarbonates." *See Phillips*, 415 F.3d at 1323 (recognizing that, in certain situations, "it will become clear . . . [that] the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive").

The specification therefore emphasizes that the contemplated diclofenac formulation or composition[2] of the '595 patent is diclofenac "together with" with alkali metal carbonates or bicarbonates. The Court must read the language of claim 28 in view of these characterizations in the '595 patent specification. *See Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1324 (Fed. Cir. 2008) ("The claims of the patent must be read in light of the specification's consistent emphasis on [the] fundamental feature of the invention."); *Phillips*, 415 F.3d at 1316 ("[T]he specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. . . . [T]he inventor's intention, as expressed in the specification, is regarded as dispositive."); *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("[W]here the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.").

The Court is not persuaded that other portions of the specification—those that Plaintiffs argue show that the invention involves diclofenac pharmaceutical compositions more generally—compel a construction that does not involve an alkali metal carbonate or bicarbonate. (*See* '595 Patent at 1:8-11; '595 Patent at 2:12-16; Tr. at 51:1-12). As Plaintiffs conceded at the *Markman* hearing, the patent "does not speak to any other combination" to achieve the results claimed in claim 28 but the combination of diclofenac *and* an alkali metal carbonate or bicarbonate. (*See* Tr. at 51:11-52:6).

[2] The parties agree that, for claim construction, there is no difference between the terms formulation and composition. (Tr. at 59:13-14; 64:7-12).

The prosecution history for the '595 patent also supports limiting the disputed term to a formulation that contains an alkali metal carbonate or bicarbonate. In the first line of the "remarks" portion of the amendment adding claim 28, the applicants stated that the "*present invention is premised* on the discovery that alkali metal carbonates and bicarbonates potentiate the analgesic effect of diclofenac by increasing the rate at which orally administered diclofenac enters the bloodstream." (Def. Opening Br. at 22-23 (citing Ex. 11, 12/20/04 amendment, at W002235) (emphasis added)). In these "remarks," the applicants also stated that the asserted prior art reference "does not disclose the claimed diclofenac/metal bicarbonate combination," characterizing the "combination claimed in [the] application" as "diclofenac/alkali metal carbonate/bicarbonate." (Def. Opening Br. at 23 (citing Ex. 11, 12/20/04 amendment, at W002238)).

The Court therefore finds that, in view of the specification and prosecution history, the alkali metal carbonate or bicarbonate feature is an inherent limitation in the claim language "diclofenac formulation comprises diclofenac in acid and/or salt form." *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342-44 (Fed. Cir. 2001) (finding disclaimer of subject matter and construing claim language accordingly). The Court need not consider any extrinsic evidence for construction of this claim term. *See Vitronics*, 90 F.3d at 1583 ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.").

2. "means for enhancing said average T_{max}"

The parties ask the court to construe this term from claim 34 of the '595 patent. Claim 34 is as follows (with emphasis on the disputed claim language):

> *A method for obtaining an average T_{max} of diclofenac in a human patient between 5 and 30 minutes after administration comprising orally administering a diclofenac formulation to said patient, wherein said diclofenac formulation comprises diclofenac in acid and/or salt form and* ***means for enhancing said average T_{max}*** *of said diclofenac, and wherein said diclofenac formulation is selected from:*
>
> *a. a powder formulation dissolved or dispersed in water; and*
>
> *b. a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.*

By statute, a patentee may express a claimed element as a "means or step for performing a specified function without the recital of structure, material, or acts in support thereof." 35 U.S.C. § 112 ¶ 6. The statute thus "establishes a *quid pro quo* whereby a patentee may conveniently claim an element using a generic 'means' for performing a function, provided the patentee's specification discloses structure capable of performing that function." *Lighting Ballast Control LLC v. Philips Electronics N. Am. Corp.*, No. 12-1014, 2013 WL 11874, at *3 (Fed. Cir. Jan. 2, 2013). "If the word 'means' appears in a claim element in association with a function, th[e] court presumes that § 112, ¶ 6 applies." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1257 (Fed. Cir. 1999). Here, the parties agree that this term invokes a means-plus-function analysis under 35 U.S.C. § 112. (Pl. Opening Br. at 11; Def. Opening Br. at 25).

Claim construction of this term therefore involves two steps. "First, the court must identify the claimed function." *Lighting Ballast Control LLC*, 2013 WL 11874, at *6. Once the

function is identified, the court "construe[s] the meaning of the words used to describe the claimed function, using ordinary principles of claim construction." *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1319 (Fed. Cir. 2003).

Here, the parties agree that the function is "means for enhancing said average T_{max}." (Pl. Opening Br. at 11-12; Def. Opening Br. at 25-26). Thus, the Court must construe the meaning of these words used to describe the claimed function.

> *Plaintiffs' Proposed Construction of the Function:* "the use of an agent to shorten the time to maximum plasma concentration of diclofenac in the blood of a human patient"
>
> *Defendants' Proposed Construction of the Function:* "lowering the mean time to peak plasma concentration of diclofenac in more than one patient"
>
> *Court's Construction of the Function:* "the use of an agent to shorten the time to maximum plasma concentration of diclofenac in the blood of a human patient"

At the *Markman* hearing, Defendants agreed to adopt Plaintiffs' proposed construction of the claimed function. (Tr. at 86:3-87:7 ("[I]t is okay if the Court wants to adopt the function as described by [P]laintiffs . . . . We are fine with the function as stated by the [P]laintiff[s].")). Indeed, Plaintiffs' construction accounts for the definition of T_{max} from the specification—i.e., "the time to the maximum plasma concentration." ('595 Patent at 2:17-18). And the specification supports using the "shorten" language in Plaintiffs' proposal. (*See* '595 Patent at 3:37-42 ("[T]he presently claimed Diclofenac-based formulations permit to achieve a higher C_{max} in a *shorter* T_{max} . . . .") (emphasis added)).

In their briefing, Defendants cite no intrinsic or extrinsic evidence in support of the "more than one patient" portion of their proposal. (Def. Opening Br. at 25-26; D.E. No. 71, Defendants' Responsive *Markman* Brief ("Def. Resp. Br.") at 13-18). The Court therefore construes the function, "means for enhancing said average T_{max}," as "the use of an agent to

shorten the time to maximum plasma concentration of diclofenac in the blood of a human patient."

Next, "the court must identify the structure described in the specification that performs the claimed function." *Lighting Ballast Control*, 2013 WL 11874, at *6.

Plaintiffs' Proposed Corresponding Structure: "alkali metal carbonates or bicarbonates"

Defendants' Proposed Corresponding Structure: "potassium bicarbonate or sodium bicarbonate"

Court's Identification of the Corresponding Structure: "alkali metal bicarbonates"

Plaintiffs argue that the specification supports their proposal that the corresponding structure is "alkali metal carbonates or bicarbonates." (Pl. Opening Br. at 13-14). Plaintiffs also argue that Defendants' proposal is improperly narrow because dependent claim 38 indicates that the means for enhancing T_{max} comprises one or more alkali metal carbonates or bicarbonates. (*Id.* at 14). Finally, Plaintiffs argue that, although potassium and sodium bicarbonates are mentioned in the context of a preferred embodiment, the specification does not indicate that these two ingredients are the only ingredients capable of performing the claimed function. (*Id.* at 15).

Citing the examples from the '595 patent, Defendants argue that the only structures that correspond to the claimed function are "potassium bicarbonate and sodium bicarbonate." (Def. Opening Br. at 26). Defendants also argue that, during prosecution, the applicants overcame a rejection by amending their claims such that the language "alkali metal bicarbonates or mixtures thereof" was replaced with "alkali metal bicarbonate selected from the group consisting of sodium bicarbonate, potassium bicarbonate and mixtures thereof." (*Id.* at 26-27 (citing Ex. 11, 9/18/02 amendment, at W002125-28)). Finally, Defendants argue that Plaintiffs' own expert testimony shows that only sodium or potassium bicarbonates are practical and suitable for human

use, not the class of alkali metal carbonates or bicarbonates in general. (*See* Def. Resp. Br. at 15-16; Tr. at 95:17-97:4)

"The specification must be read as a whole to determine the structure capable of performing the claimed function." *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379 (Fed. Cir. 2001). Importantly, a "structure disclosed in the specification is corresponding structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1367 (Fed. Cir. 2012) (quoting *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003)).

Here, the Court finds that the specification plainly links or associates alkali metal *bicarbonates* to the function recited in claim 34, "means for enhancing said average T_{max}." For instance, the specification asserts that:

> [I]t has also been found that the combined use of Diclofenac together with alkali metal bicarbonates yields Diclofenac-based pharmaceutical compositions in which the active ingredient is released more rapidly compared with normal formulations, bringing about higher blood levels and therefore a more immediate therapeutic effect . . . .
>
> As it will be clear from the examples, the immediate release formulations for oral use of the present invention containing from 10 to 60 mg of Diclofenac in acid and/or salt form together with alkali metal bicarbonates or mixtures thereof in amounts of from 20 to 80% by weight based on the weight of Diclofenac permit to generate in human patients an average C_{max} of Diclofenac comprised between 400 and 2500 ng/ml . . . . Secondly, the formulations according to the present invention permit to obtain in humans an average T_{max} of Diclofenac after 5÷30 minutes since administration . . . .

('595 Patent at 2:37-43 & 3:12-24; *see also* '595 Patent at 2:32-42).

The Court finds, however, that alkali metal *carbonates* are not linked or associated with the claimed function in the specification or prosecution history. Rather, as Plaintiffs acknowledged at the *Markman* hearing, alkali metal carbonates are only *disclosed* in Examples 1 through 3 in the '595 patent. (Tr. at 89:14-17; *see also* '595 Patent, Examples 1-3). Moreover, as Plaintiffs also acknowledged, alkali metal carbonates in these examples are only disclosed in combination with alkali metal bicarbonates. (Tr. at 89:14-17; *see also* '595 Patent, Examples 1-3). Therefore, notwithstanding dependent claim 38, the Court is not persuaded that alkali metal carbonates qualify as corresponding structure. *See Icon Health & Fitness, Inc. v. Octane Fitness, LLC*, Nos. 11-1521 & 11-1636, 2012 WL 5237021, at *5 (Fed. Cir. Oct. 24, 2012) ("[C]laim differentiation cannot override the effect of section 112(6). . . . [T]he scope of the limitation literally covers structures described in the specification and equivalents thereof notwithstanding the existence of dependent claims.").

Conversely, the Court is not persuaded that the corresponding structure is limited to only potassium bicarbonate or sodium bicarbonate. As noted above, the specification indicates that the class of alkali metal bicarbonates is tied to the claimed function. It is this generic structure that is linked to the claimed function, not only the specific alkali metal bicarbonates disclosed in the examples. *See Mettler-Toledo, Inc. v. B-Tek Scales, LLC*, 671 F.3d 1291, 1296 (Fed. Cir. 2012) (explaining that one of the patents-in-suit linked a generic structure to the claimed function and therefore the corresponding structure was not limited to a specific subset of that class).

The Court is also not persuaded that extrinsic evidence compels adopting Defendants' proposed structure. At the *Markman* hearing, Defendants confirmed that nothing in the intrinsic record suggests that potassium bicarbonates or sodium bicarbonates are the only bicarbonates practical and suitable for human consumption. (*See* Tr. at 98:8-11). The Court rejects

Defendants' invitation to "look at practicality," (*id.* at 96:8-9), and narrowly identify the corresponding structure in view of extrinsic evidence. *See DESA IP, LLC v. EML Technologies, LLC*, 211 F. App'x 932, 936-37 (Fed. Cir. 2007) ("Expert testimony in conflict with the intrinsic evidence . . . should have been accorded no weight. . . . Because the intrinsic evidence clearly sets forth the corresponding structure . . . it was improper to rely upon contrary extrinsic evidence to construe this term.").[3]

B. The '651 Patent

1. "a buffering or alkalizing agent"

The parties dispute the meaning of this term from claims 1, 3, 6, 8, and 13 of the '651 patent. By way of illustration, independent claims 1, 6, and 13 are as follows (with emphasis on the disputed claim language):

> *1. A method of treating phonophobia and photophobia in a human patient in need thereof comprising: a) providing an oral formulation comprising one or more pharmaceutically acceptable excipients and 50 mg. of diclofenac or a pharmaceutically acceptable salt thereof, wherein said one or more pharmaceutically acceptable excipients comprises* ***a buffering or alkalizing agent****, further wherein said formulation has been shown to achieve a* C_{max} *of from about 1500 to about 2500 ng/ml and* t_{max} *in from about 10 to about 25 minutes; and b) orally administering said formulation to a patient suffering from phonophobia and photophobia wherein said* t_{max} *and* C_{max} *are mean values obtained from a plurality of human patients.*
>
> *6. A method of treating recurrent migraine in a human patient in need thereof suffering from migraine comprising: a) providing an oral formulation comprising one or more pharmaceutically acceptable excipients and 50 mg. of diclofenac or a pharmaceutically acceptable salt thereof, wherein said one or more pharmaceutically acceptable excipients comprises* ***a buffering or alkalizing agent****, further wherein said formulation has been shown to achieve a* C_{max} *of from about 1500 to about*

[3] Initially, Defendants asked the Court to identify "structural equivalents" at the *Markman* stage of this action. (Def. Opening Br. at 27-30; Def. Resp. Br. at 17-18). At the *Markman* hearing, however, Defendants withdrew this request. (Tr. at 91:23-92:9).

> *2500 ng/ml and t_{max} in from about 10 to about 25 minutes; and b) orally administering said formulation to a patient requiring sustained migraine relief for at least 24 hours.*
>
> *13. A method of treating headache pain, nausea, photophobia and phonophobia in a human patient in need thereof comprising: a) providing an oral formulation comprising one or more pharmaceutically acceptable excipients and 50 mg. of diclofenac or a pharmaceutically acceptable salt thereof, wherein said one or more pharmaceutically acceptable excipients comprise* ***a buffering or alkalizing agent*** *wherein said formulation has been shown to achieve a C_{max} of from about 1500 to about 2500 ng/ml and t_{max} in from about 10 to about 25 minutes; and b) orally administering said formulation to a patient suffering from headache pain, nausea, photophobia and phonophobia.*

Plaintiffs' Proposed Construction: "an agent that controls, maintains, or raises the pH of a solution"

Defendants' Proposed Construction: "carbonates or bicarbonates of the metals of Group 1A of the Periodic Table"

Court's Construction: "an agent that controls, maintains, or raises the pH of a solution"

As an initial matter, the parties agree that Defendants' proposal, "carbonates or bicarbonates of the metals of Group 1A of the Periodic Table," is effectively a proposal to construe the disputed claim term to mean alkali metal carbonates or bicarbonates. (*See* Def. Opening Br. at 31 ("[T]he claim term 'buffering or alkalizing agent' should be construed to mean alkali metal carbonates or bicarbonates, which the parties agree means 'carbonates or bicarbonates of the metals of Group 1A of the Periodic Table.'"); Pl. Resp. Br. at 3 n.1 ("Defendants' proposed construction is . . . 'carbonates or bicarbonates of the metals of the [sic] Group 1A of the Periodic Table' which is merely another way of saying alkali metal carbonates or bicarbonates.").

Plaintiffs argue that their proposed construction is consistent with the claim language and the specification of the '651 patent. (Pl. Opening Br. at 24-25). Plaintiffs contend that the '651

patent was clearly intended to be broader than the parent '394 patent, which specifically claims diclofenac formulations that have an alkali metal carbonate or bicarbonate. (*Id.* at 24). Citing expert testimony and a medical dictionary, Plaintiffs argue that the extrinsic evidence confirms that "buffering" and "alkalizing" have a plain and ordinary meaning to one of ordinary skill in the art. (*Id.* at 25-26). Plaintiffs argue that Defendants' proposal is incorrect for three reasons: (1) Defendants improperly rely on the claims of the parent '394 patent; (2) Defendants' proposal violates the prohibition against limiting claims to specific preferred embodiments; and (3) the patentee has not deliberately redefined this claim term. (*Id.* at 27-28).

Defendants argue, however, that the disputed term has no plain and ordinary meaning and one of ordinary skill in the art would examine the entire patent to ascertain the term's meaning. (Def. Opening Br. at 30). Defendants argue that the specification supports their proposal because the only examples of buffering agents disclosed in the specification are alkali metal carbonates or bicarbonates, specifically potassium bicarbonate. (*Id.* at 30-31). Indeed, Defendants contend that, throughout the '651 patent, alkali metal carbonates or bicarbonates are identified as buffering agents. (*Id.* at 31).

Defendants further contend that the prosecution history supports their construction because, in the statement of reasons for allowance, the examiner characterized the disputed term to mean carbonates or bicarbonates and stated that buffering from carbonates or bicarbonates was a novel aspect of the claims. (*Id.* at 31-32). To further support their proposed construction, Defendants cite the prosecution history of the related '394 patent. (*Id.* at 32-33). Finally, Defendants argue that the prosecution history of the unrelated '377 patent, as extrinsic evidence, supports their proposed construction. (*Id.* at 34).

"Claim terms are given their ordinary and customary meaning—the meaning that they would have to a person of ordinary skill in the art in light of the specification and prosecution history at the time of the invention." *Woods*, 692 F.3d at 1283. To ascertain the meaning of a term that has a "particular meaning in a field of art," such as "a buffering or alkalizing agent," the Court must examine the intrinsic evidence and any relevant extrinsic evidence. *See Phillips*, 415 F.3d at 1314, 1318. Indeed, construing the term "a buffering or alkalizing agent" does *not* reflect a situation where the "ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent" and construction involves "little more than the application of the widely accepted meaning of commonly understood words." *See id.* at 1314.

Here, the intrinsic evidence provides minimal guidance on the meaning of "a buffering or alkalizing agent." For instance, beyond the claims themselves, the term "alkalizing agent" is not referenced in the patent. Nevertheless, Plaintiffs' proposal is consistent, at least in part, with the follow description in the specification:

> *[b]uffering agents* are not critical to the invention, but are preferably used to provide a rapid rate of onset for the final pharmaceutical product. In a preferred embodiment for powder sachets, the buffering agent *controls the pH of the formulation* when dissolved in water, and preferably yields a pH greater than about 6.8, 7.0, 7.2, or 7.4, and less than about 7.8, 7.7 or 7.6, when mixed with 50 mL or 100 or 200 ml[] of water at 25 degrees Celsius. Particularly preferred buffering agents are alkali metal carbonates and bicarbonates . . . .

('651 Patent at 9:4-13 (emphasis added)). Indeed, the applicants relied on this description during prosecution, in part, to support the buffering or alkalizing agent limitation. (Tr. at 132:15-133:4 (citing Def. Opening Br., Ex. 13 at W025036)).

Although Defendants argue that the only examples of buffering agents provided in the specification are alkali metal carbonates or bicarbonates, this does not amount to lexicography or

disavowal of claim scope. *See Thorner*, 669 F.3d at 1365-66 ("It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term. . . . Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal. . . . It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation.") (internal quotations omitted); *see also Phillips*, 415 F.3d at 1323 ("[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.").

Defendants also cite the examiner's reasons for allowing the patent in which the examiner stated that:

> Examiner notes the extensive additional set of references kindly cited by applicant . . . . Most of the references cited are directed to analgesic formulation technologies relevant to the subject matter area disclosed herein. However, said references have not provided any identifiable teaching or teachings which individually, or in combination, render the instant claimed method, a method directed to the effective and rapid alleviation of the symptoms of migraine headaches by the administration of small, *bicarbonate or carbonate buffered*, doses of diclofenac potassium, either anticipated or obvious, respectively.

(Def. Opening Br. at 32 (citing Ex. 13, Examiner's Statement of Reasons for Allowance, at W025311) (emphasis added)). Defendants argue that, since the applicants did not file a response to the examiner's statement of reasons, the "silence indicates their assent to the [e]xaminer's characterization of the invention." (Def. Opening Br. at 32).

At the *Markman* hearing, Defendants further clarified that they are *not* arguing that any such silence reflects "surrender" or "clear disavowal." (Tr. at 122:10-123:16). Rather, Defendants contend that, since there is no plain and ordinary meaning to "a buffering or

alkalizing agent," the Court need not find clear disavowal but nevertheless should use the examiner's stated reasons to construe the disputed term. (*See* Tr. at 123:8-15 ("My understanding of the case law[], clear disavowal you get into when there is a plain and ordinary meaning. Did they surrender it. We are not arguing that. We are arguing there is no plain and ordinary meaning. So the statement by the examiner, it is not a surrender or a clear disavowal. It is part of claim construction.")).

The Court finds that that the examiner's reasons for allowance do not limit the scope of the term "a buffering or alkalizing agent." Defendants cite *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.* to support their reliance on the examiner's reasons for allowance to construe this term. (Def. Opening Br. at 31). There, however, the Federal Circuit asserted that "[s]tatements made during prosecution which clearly disclaim a particular claim interpretation will limit the scope of the claims" and, in the reasons for allowance, the "examiner simply repeated the arguments that the patentee had presented." *ACCO Brands, Inc.*, 346 F.3d 1075, 1078-79 (Fed. Cir. 2003). Here, Defendants do not rely on any such statement that clearly limits the scope of "a buffering or alkalizing agent." Rather, Defendants concede that the reasons for allowance do *not* reflect clear disavowal. (Tr. at 140:7-8 ("Court: It is not a clear disavowal; [Defendants' Counsel]: That's correct.")). Furthermore, Defendants concede that the "bicarbonate or carbonate buffered" portion of the examiner's reasons for allowance was *not* the only reason for allowability cited by the examiner. (Tr. at 114:24-115:1 ("So according to the [P]laintiffs, that is why the claims were allowed, because [the applicants] filed a disclaimer, and *yes, that is one of the reasons*.") (emphasis added)).

Even accepting Defendants' contention that "there is no plain [and] ordinary meaning" for the term "buffering or alkalizing agent," (Tr. at 122:10-15 & 123:7-16), the Court must look

to the specification for guidance. *See Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 991 (Fed. Cir. 2007) ("Without a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning."); *Phillips*, 415 F.3d at 1315 ("[T]he specification . . . is the single best guide to the meaning of a disputed term.") (internal quotations omitted). As discussed above, the specification does not support confining the disputed term to an alkali metal carbonate or bicarbonate. *See Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."). The patentee is thus entitled to the full scope of "a buffering or alkalizing agent."

In support of their proposal, Defendants also reference several portions of the prosecution history for the related parent '394 patent, including the following applicant and examiner statements:

- Examiner: "The instant claims are directed to the treatment of pain by administration of an oral dosage of diclofenac-bicarbonate composition . . . ." (Def. Opening Br., Ex. 14 at W003265));

- Applicant: "The action of the alkali metal bicarbonate in the current formulations differs drastically in its purpose and mechanism. In this case, the bicarbonate is used to improve solubility by creating pH conditions more favorable to dissolution of diclofenac potassium." (Def. Opening Br. at 33 (citing Ex. 14 at W003374));

- Examiner: "[T]he specification, while being enabled for the administration of diclofenac compositions comprising a bicarbonate salt as the critical additional additive, does not reasonably provide enablement for administration of any other diclofenac-containing composition wherein the critical 'dissolution enhancing' additive has <u>not</u> been specified but provides pharmacological performance, or the pH/solubility performance equivalents, of the bicarbonate-containing compositions." (Def. Opening Br., Ex. 14 at W003541 (emphasis in original));

- Applicant: "There is no disclosure in the Granger working examples of the use of diclofenac in combination with an alkali metal bicarbonate and, in particular, with sodium and/or potassium bicarbonate." (Def. Opening Br. at 33 (citing Ex. 14 at W003825)).

Defendants contend that the "claims of the '394 patent refer exclusively to an alkali metal carbonate or bicarbonate" and that, in the '394 patent prosecution history, the applicants had "repeatedly distinguished prior art on the basis of their invention requiring an alkali metal carbonate/bicarbonate." (Def. Opening Br. at 33). Defendants argue that the claims of the '651 patent "should be construed 'so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.'" (Def. Resp. Br. at 25 (quoting *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1368 (Fed. Cir. 2001))). Defendants contend that the applicants' reliance on alkali metal carbonates or bicarbonates to distinguish their claims in the prosecution of the '394 patent is "fully binding" on the '651 patent claims. (Def. Resp. Br. at 24 (citing *Alloc*, 342 F.3d at 1370)).

Although the alkali metal carbonate or bicarbonate limitation is present in the '394 patent, it is not present in the '651 patent. Indeed, the above-referenced statements from the '394 patent's prosecution history were not made in reference to the disputed claim language. The Court is therefore not persuaded that these statements limit the scope of "a buffering or alkalizing agent" to alkali metal carbonates or bicarbonates. *See Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) ("[T]he doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language."); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005) ("[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application."); *Alloc*, 342 F.3d at 1381 ("Statements . . . made during the prosecution of a parent application can only apply to continuation applications if the parent and child patents contain the same claim limitations.").

The Court finds that the extrinsic evidence is consistent with the intrinsic record and supports Plaintiffs' proposal. *Stedman's Medical Dictionary* provides the following definitions: (1) buffer as "to add a [buffer] to a solution and thus give it the property of resisting a change in pH when it receives a limited amount of acid or alkali," (Pl. Opening Br., Ex. E at NAU0797161)); and (2) alkalizer as "[a]n agent that neutralizes acids or renders a solution alkaline," (*Id.* at NAU0797160). The Court finds these definitions consistent with the intrinsic record and accordingly relies on *Stedman's Medical Dictionary* to construe "a buffering or alkalizing agent." *Phillips*, 415 F.3d at 1322-23 ("[J]udges are free to consult dictionaries and technical treatises 'at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'") (quoting *Vitronics*, 90 F.3d at 1584 n.6).

In addition, expert testimony is consistent with the intrinsic record and supports Plaintiffs' proposal. (D.E. No. 67-4, Decl. of William Curatolo in Support of Plaintiffs' *Markman* Brief ¶¶ 20, 22 ("Buffers control the pH of a solution and resist changes in pH when acids or bases are added to the solution or when dilution of the solution occurs. . . . Alkalizing agents neutralize acids and can raise the pH of solutions."); D.E. No. 73-1, Ex. 7 to Singh Decl., Deposition of Patrick Sinko ("Sinko Depo.") at 62:6-7 & 63:24-64:2 ("[T]he goal of a buffer is to resist changes in pH . . . . I think one of ordinary skill would expect that an alkalizing agent is going to elevate the pH.")).

In sum, the Court refuses to narrow the scope of "a buffering or alkalizing agent" to mean only alkali metal carbonates or bicarbonates because neither the specification nor the prosecution

history of either the ’651 patent or the ’394 patent provide lexicography or clear expressions of restriction or disavowal to that effect.

2. “alkaline buffering agent or alkalizing agent”

The parties dispute the meaning of this term from dependent claims 5, 12, 17, and 19 of the ’651 patent. By way of illustration, claims 5 and 17 are as follows (with emphasis on the disputed claim language):

> *5. The method of claim 1, wherein said **alkaline buffering agent or alkalizing agent** is present relative to said diclofenac at a weight ratio of less than about 5:1.*
>
> *17. The method of claim 13 wherein said formulation comprises about 50 mg. of diclofenac potassium, and said **alkaline buffering agent or alkalizing agent** comprises greater than 20 wt. % of an alkali metal carbonate or bicarbonate based on the weight of the acid form of diclofenac.*

Plaintiffs’ Proposed Construction: “an agent that controls, maintains, or raises the pH of a solution”

Defendants’ Proposed Construction: “carbonates or bicarbonates of the metals of Group 1A of the Periodic Table”

Court’s Construction: “a basic agent that controls, maintains, or raises the pH of a solution”

The Court applies, in relevant part, the analysis above for “buffering or alkalizing agent” to the term “alkaline buffering agent or alkalizing agent.” In fact, Plaintiffs propose the *same* construction for this disputed term as they have for “a buffering or alkalizing agent,” namely “an agent that controls, maintains, or raises the pH of a solution.” (Pl. Opening Br. at 24). Similarly, Defendants propose the *same* construction for this disputed term as they have for “a buffering or alkalizing agent,” namely “carbonates or bicarbonates of the metals of Group 1A of the Periodic Table.” (Def. Opening Br. at 36). In effect, both parties agree that including the word “alkaline” in the claim language does not change the construction of “a buffering or alkalizing agent.” (*See*

Tr. at 136:23-25 ("Here both parties agree [that "a buffering or alkalizing agent" and "alkaline buffering agent or alkalizing agent"] don't deserve a separate meaning and ought to be given the same meaning.")). Furthermore, Plaintiffs ask the Court to delete "alkaline" from the disputed claim language. (*See* Pl. Resp. Br. at 11; Tr. at 135:5-136:5).

The Court "has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties." *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995). Furthermore, a "claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005).

Here, in the parent '394 patent's prosecution history, one of the inventors submitted a declaration asserting that "rapid pharmacokinetics" could be achieved "after incorporating and balancing a unique blend of *alkaline buffering agents*, hygroscopic excipients, water soluble excipients and wetting agents in the formulation." (Def. Opening Br., Ex. 14 at W003363 (emphasis added)).

As the intrinsic evidence provides no additional guidance for construing "alkaline" in this context, the Court considers extrinsic evidence. *Phillips*, 415 F.3d at 1322-23. *Stedman's Medical Dictionary* defines "alkaline" as "[r]elating to or having the reaction of an alkali" and defines "alkali" as "[a] strongly basic substance." (Pl. Opening Br., Ex. E at NAU0797160). Defendants' expert testimony is consistent with these definitions. (Sinko Depo. at 275:14 (testifying that "alkaline" means "a pH . . . above neutral")). Moreover, the parties agreed at the *Markman* hearing that, if the Court was to give "alkaline" meaning, then "basic" would be appropriate. (*See* Tr. at 138:7-8; 138:13-15).

The Court is not persuaded that it can delete "alkaline" from the disputed claim language because deleting "alkaline" does not reflect a minor or obvious correction. *See Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357-58 (Fed. Cir. 2003) ("The present case does not fall within the ambit of the district court's authority, for the nature of the error is not apparent from the face of the patent. . . . Under these circumstances, in order to make sense out of the patent, the district court was required to guess as to what was intended. That is beyond its authority."). Indeed, the phrase "alkaline buffering agents" is part of the intrinsic record. (*See* Def. Opening Br., Ex. 14 at W003363).[4]

The Court therefore construes "alkaline" as "basic." Applying the above analysis for "a buffering or alkalizing agent," in relevant part, the Court accordingly construes "alkaline buffering agent or alkalizing agent" to mean "a basic agent that controls, maintains, or raises the pH of a solution."[5]

V. Conclusion

For the reasons set forth above, the Court construes the disputed claim terms as indicated. An appropriate Order accompanies this Opinion.

s/Esther Salas
Esther Salas, U.S.D.J.

[4] Furthermore, the Court finds that any certificate of correction that may issue from the PTO would not apply to this action because Plaintiffs brought this action before the issuance of any such certificate. *See* 35 U.S.C. § 255; *Sw. Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1295 (Fed. Cir. 2000) ("[F]or causes arising before its issuance, the certificate of correction is not effective.").

[5] The Court notes that, in every claim that the disputed term "alkaline buffering agent or alkalizing agent" appears, the term is preceded by the word "said." (*See, e.g.*, '651 Patent, Claim 5 ("The method of claim 1, wherein *said* alkaline buffering agent or alkalizing agent is present relative to said diclofenac at a weight ratio of less than about 5:1.") (emphasis added)). The term "alkaline buffering agent or alkalizing agent," however, never actually appears before appearing in these dependent claims. The parties did not raise this issue and the Court does not find this material to its claim construction analysis.