UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, **Plaintiff,** **v.** **FERA PHARMACEUTICALS, LLC, et al.,** **Defendants.**	No. 15–cv–3654 (KM)(MAH) **OPINION** **(*Markman*)**
FRESENIUS KABI USA, LLC, **Plaintiff,** **v.** **INNOPHARMA LICENSING, LLC, et al.,** **Defendants.**	

KEVIN MCNULTY, U.S.D.J.:

This Opinion contains the Court's construction of key patent terms following a *Markman* hearing. This patent infringement case is brought by the plaintiff, Fresenius Kabi USA, LLC, against the defendants, Fera Pharmaceuticals, LLC and Oakwood Laboratories, LLC (collectively, "Fera") and InnoPharma, Inc. and InnoPharma Licensing, LLC (collectively, "InnoPharma").[1] The patents-in-suit are Patent Nos. 9,006,289 ("the '289 patent"), 9,168,238

[1] The suit against InnoPharma was originally filed under the docket number 15–3655, but the cases were consolidated for pretrial purposes upon request of the parties. (*See* ECF No. 79) A third suit, docket number 15–3853, was originally consolidated with these two, but those defendants settled with Fresenius after the opening briefs were filed. (*See* ECF No. 120)

("the '238 patent"), and 9,168,239 ("the '239 patent"). All three patents describe formulations of levothyroxine, a hormone produced by the thyroid. These patents claim a form of lyophilized (i.e. freeze-dried) levothyroxine that can be reconstituted and injected into patients who lack a properly functioning thyroid. (Pl. Opening 1)[2]

The Food and Drug Administration approved Fresenius's New Drug Application ("NDA") on June 24, 2011. (3AC Fera ¶ 15) The '289 patent was issued on April 14, 2015, and is due to expire on October 3, 2032. (3AC Fera ¶¶ 10, 16) The '238 and '239 patents were issued on October 27, 2015, and are due to expire on August 29, 2032. (3AC Fera ¶¶ 11–12, 16) Fera and InnoPharma filed Abbreviated New Drug Applications ("ANDA") that sought

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[2] Citations to the record will be abbreviated as follows:

"3AC Fera" — Third Amended Complaint of Fresenius against Fera (ECF No. 83).

"Fera Answer" — Fera's Answer to 3AC Fera (ECF No. 84).

"InnoPharma Answer" — InnoPharma's Answer to the Second Amended Complaint of Fresenius against InnoPharma (ECF No. 85).

"Joint Br." — Parties' Joint Claim Construction and Prehearing Statement (ECF No. 92).

"Pl. Opening" — Plaintiff's Opening Markman Brief (ECF No. 101).

"Pl. Ex." — Plaintiff's Exhibits (ECF Nos. 101–2 to 101–5), attached to the Declaration of Justin T. Quinn (ECF No. 101–1).

"Pl. Response" — Plaintiff's Responsive Markman Brief (ECF No. 171).

"Def. Opening" — Defendants' Amended Opening Markman Brief (ECF No. 157).

"Def. Ex."— Defendants' Exhibits (ECF Nos. 102–2 to 102–19), attached to the Certification of Christina L. Saveriano (ECF No 102–1).

"Def. Response" — Defendants' Responsive Markman Brief (ECF No. 170).

"'289 Patent" — United States Patent No. 9,006,289, Pl. Ex. 1 (ECF No. 101–2).

"'238 Patent" — United States Patent No. 9,168,238, Pl. Ex. 2 (ECF No. 101–3).

"'239 Patent" — United States Patent No. 9,168,239, Pl. Ex. 3 (ECF No. 101–4).

"Remington" — *Remington: The Science and Practice of Pharmacy*, (Alfonso R. Gennaro et al. eds. 20th ed. 2000), Def Ex. G (ECF No. 102–8).

approval to commercially market generic versions of Fresenius's patented levothyroxine injections. (InnoPharma Answer ¶ 1; Fera Answer ¶ 17) This lawsuit followed.

I. CLAIM CONSTRUCTION

A. Standard

"The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996)). "[T]he words of a claim are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks and citations omitted). Courts interpret claim terms according to an objective standard: "[T]he ordinary and customary meaning of a claim term 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." *Id.* at 1313. To make this determination, courts may consider evidence intrinsic to the patent, *i.e.*, "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," as well as "extrinsic evidence, which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* at 1314, 1317 (internal quotation marks and citations omitted).

In *Phillips*, the United States Court of Appeals for the Federal Circuit, sitting en banc, explained that its prior case law had "attempted to explain why, in general, certain types of evidence are more valuable than others." *Id.* at 1324 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). *Phillips* assigned significant value to intrinsic evidence and less weight to extrinsic evidence, holding extrinsic evidence useful only to the extent

that "those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id.*

Thus, a court "first look[s] to the actual words of the claims and then read[s] them in view of the specification." *Profectus Tech. LLC v. Huawei Techs. Co.*, 823 F.3d 1375, 1380 (Fed. Cir. 2016). "[C]laims must be read in view of the specification, of which they are a part" because the specification "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. "[I]f the specification reveals a special definition given to a claim term by the inventor, then the inventor's lexicography governs, even if it differs from the term's ordinary meaning." *David Netzer Consulting Eng'r LLC v. Shell Oil Co.*, 824 F.3d 989, 994 (Fed. Cir. 2016) (citing *Phillips*, 415 F.3d at 1316). The court may also consider, where relevant, the patent's prosecution history, "which consists of the complete record of the proceedings before the PTO and [] the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. Extrinsic evidence, considered in the context of the intrinsic evidence, may "help educate the court regarding the field of the invention and [] help the court determine what a person of ordinary skill in the art would understand claim terms to mean." *Phillips*, 415 F.3d at 1319.

B. Levothyroxine

The specification section of the patents[3] provides some background information on levothyroxine:

> A healthy thyroid produces hormones that regulate multiple metabolic processes and that play important roles in growth and development, in maturation of the central nervous system and bone including augmentation of cellular respiration and thermogenesis, and in metabolism of proteins, carbohydrates and lipids. The thyroid accomplishes its regulation functions by producing the hormones L-triiodothyronine (liothyronine; T3) and L-thyroxine (levothyroxine; T4).

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[3] The three patents all contain the same specification, so a citation to the specification of the '289 Patent applies equally to all. (*See* Pl. Opening 7 n.4)

...

...

> A patient who has had their thyroid gland removed, or whose thyroid gland functions at an undesirably low level (hypothyroidism), may be treated by administration of a daily maintenance dose of 50-100 micrograms (μg) of levothyroxine sodium. A patient in need of additional intervention may be treated by administration of an initial dose of 200-500 μg or 300-500 μg of levothyroxine sodium and/or with a 2nd day dose of 100-300 μg of levothyroxine sodium.

('289 Patent 1:13–47) The drug at issue in this suit is a lyophilized, or freeze-dried, formulation of levothyroxine that is later reconstituted and injected into patients. (Pl. Opening 1)

Levothyroxine injections have been available in the United States since 1969. (Def. Opening 3) Fresenius's newly patented formulations contain levothyroxine, a buffer, and a specific amount of a bulking agent called mannitol. The mannitol provides bulk to the "cake" that remains after the formulation is freeze dried. Fresenius's patents are based on the discovery that, contrary to expectation, a reduction in the proportion of mannitol improved the stability of the freeze dried cake. (Pl. Opening 1–2)

C. Disputed Claims

The parties presented charts that jointly summarize their positions as to the eleven disputed claims. I will present the charts in groups of related terms as I consider the claim construction arguments.

1. "Buffer" and "Phosphate Buffer"

While Fresenius "does not believe that the construction of any disputed term will be most significant to the resolution of the case" (Joint Br. 5), both Fera and InnoPharma consider construction of the term "buffer" to be potentially case dispositive. (*Id.* at 5–6) As to the "buffer" term, the parties summarize their positions as follows:

Term	Fresenius	InnoPharma	Fera
"buffer" ('289 Patent: 1, 4, 9, 14, 16; '238 Patent: 1, 10, 11, 20, 21, 30; '239 Patent: 1, 7, 8)	Plain and ordinary meaning "A system that resists changes in pH when acid or base is added."	"A compound that resists changes in pH when an acid or base is added, and is present in an amount not exceeding 800 µg total mass."	"A *buffer* is a solution of a weak acid and its conjugate base, the base being provided by one of its soluble salts."
"phosphate buffer" ('289 Patent: 1, 4, 9, 14, 16; '238 Patent: 10, 20, 30; '239 Patent: 7, 8)	Plain and ordinary meaning "A buffer comprising a phosphate."	"A buffer (as otherwise construed) comprising one or more phosphate groups."	This term does not require a separate construction from "buffer"; its meaning should be consistent with the Court's construction of "buffer."

(Pl. Opening 6–7; Def. Opening 7)

Claim 1 of each of the three patents describes the "buffer" as part of the "lyophilized solid composition" and does not state an amount or mass of the buffer.[4] (*See, e.g.*, '289 Patent Claim 1; '238 Patent Claim 1; '239 Patent Claim 1) Other dependent claims in the '289 and '239 Patents designate the "buffer" as "dibasic sodium phosphate," and give a fixed measurement for it of between 400 and 600 µg. ('289 Patent Claims 4, 9, 16; '239 Patent Claim 8) Dependent claims of the '238 Patent simply refer to the "phosphate buffer" without stating any particular amount. ('238 Patent Claims 10, 20, 30

The specifications of all three patents contain the following language discussing "buffers":

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[4] The '289 Patent specifies a "phosphate buffer." ('289 Patent Claim 1)

> A solid composition that includes levothyroxine sodium and mannitol may include one or more other substances. Non-limiting examples of other substances include bulking agents, carriers, diluents, fillers, salts, **buffers**, stabilizers, solubilizers, preservatives, antioxidants, and tonicity contributors. Substances that may be useful in formulating pharmaceutically acceptable compositions, and methods of forming such compositions, are described for example in Remington: The Science and Practice of Pharmacy, 20th Ed., ed. A. Gennaro, Lippincott Williams & Wilkins, 2000, and in Kibbe, "Handbook of Pharmaceutical Excipients," 3rd Edition, 2000.
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> A solid composition that includes levothyroxine sodium and mannitol may be prepared by forming a liquid mixture containing a solvent, levothyroxine sodium and mannitol, and lyophilizing the liquid mixture. Forming a liquid mixture for use in preparing the solid composition may include combining ingredients including the solvent, levothyroxine sodium and mannitol. The ingredients used to form the liquid mixture may include a phosphate **buffer**; however the ingredients preferably do not include tribasic sodium phosphate. In one example, the ingredients used to form the liquid mixture include a phosphate **buffer** other than tribasic sodium phosphate, such as dibasic sodium phosphate (Na_2HPO_4) or monobasic sodium phosphate (NaH_2PO_4). The amount of phosphate **buffer** in the ingredients may be an amount sufficient to provide a beneficial pH **buffering** effect in the liquid mixture. Preferably the ingredients used to form the liquid mixture include from 100 to 800 µg, from 200 to 700 µg, from 300 to 700 µg, or from 400 to 600 µg dibasic sodium phosphate. Dibasic sodium phosphate may be added as a hydrate, such as dibasic sodium phosphate heptahydrate.

('289 Patent 4:24–55 (emphasis of each occurrence of the word "buffer" added))

To support their construction of "buffer," Fresenius and Fera both quote the Remington textbook. (Def. Opening 11; Pl. Response 5–6) Remington is cited in the specification itself, albeit rather generally as a reference for "[s]ubstances that may be useful" and "methods" of formulation. (*See* first paragraph of passage quoted immediately above.)

Fresenius derives its functional construction of the term "buffer" from page 240 of Remington, which is the opening sentence of that textbook's discussion of buffers: "The terms *buffer, buffer solution,* and *buffered solution,* when used with reference to 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." (Remington 240)[5] Fera quotes a brief reference from page 380 of Remington. The entire quotation at page 380 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. Refer to Chapter17 for an extensive discussion of pH and buffers." (Remington 380)

Fera's proposed construction, whether plausible or not, contradicts the language of the claims and specification. In addition, it is based on a textbook definition that declares itself to be incomplete and cross-references a more complete discussion elsewhere in the Remington treatise.

The claims and specification repeatedly discuss the buffer as a component of a solid composition. (*See, e.g.*, '289 Patent Claim 1, 2:53–58, 4:36–55; '238 Patent Claim 1; '239 Patent Claim 1) The specification explains:

> A solid composition ... is formed by a method that includes combining ingredients to form a liquid mixture, and lyophilizing the liquid mixture.... The term "lyophilizing" means removing from a solution or an emulsion one or more substances having the lowest boiling points by freezing the solution or emulsion and applying a vacuum to the frozen mixture.

(*E.g.*, '289 Patent 2:53–3:2) The patents do not limit the definition of a buffer to a liquid solution; rather, they explicitly use the term "buffer" to delineate the component in the lyophilized *solid* composition that performed and would perform the buffering action when the composition is in a liquid state.[6]

The specification's general citation to the Remington textbook as a whole is not a license to extract passages from that work in derogation of the clear

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[5] InnoPharma appears to agree with Fresenius that the definition should be derived from this part of Remington.

[6] In this plain-language way, it is like referring to a substance as a "sweetener," although it has that effect only when it chemically stimulates the taste receptors. *E.g.*, Purves D, Augustine GJ, Fitzpatrick D, et al., eds., *Neuroscience* (2d ed., Sunderland (MA): Sinauer Associates, 2001), excerpted at ww.ncbi.nlm.nih.gov/books/NBK11148.

language in the specification and claims. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1207 (Fed. Cir. 2013) ("We see no reason for such a non-specific reference to trump the clear disclaimer in the specification...."); *cf. Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) ("To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.").

At any rate, the cited page 380 of Remington directs the reader to chapter 17, where on pages 240–42 there is a detailed discussion of buffers. That discussion includes Fresenius's proposed definition, as well as a section that discusses the "buffer action" of certain "strong acids and bases." (Remington 242) Thus a buffer, even taking Fera's approach, would not necessarily be a liquid containing acids or bases that are weak. Fera's proffered definition of buffer, which limits the term to such a solution, is neither consistent with the meaning given in the patent by the inventor nor with the ordinary meaning. *See Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc.*, Civ. No. 13–1674, 2015 WL 3978883, at *3 (D. Del. June 26, 2015) ("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.").

InnoPharma does not go along with Fera's position as to the term "buffer"; it generally agrees with Fresenius's definition. InnoPharma, however, would insert a mass limitation: "an amount not exceeding 800 µg total mass." (Def. Opening 7) There is no language in the patent to support this limitation. Dependent claims in two of the patents do assign the buffer component a fixed mass between 400 and 600 µg. ('289 Patent Claims 4, 9, 16; '239 Patent Claim 8) Further, the specification gives exemplars of mass ranges for one buffer, dibasic sodium phosphate: "Preferably the ingredients used to form the liquid mixture include from 100 to 800 µg, from 200 to 700 µg, from 300 to 700 µg, or from 400 to 600 µg dibasic sodium phosphate." ('289 Patent 4:51–54) But as

a preface to those examples, the specification states: "The amount of phosphate buffer in the ingredients may be an amount sufficient to provide a beneficial pH buffering effect in the liquid mixture." ('289 Patent 4:48–51)

These patent claims do not impose a clear mass limitation on the term "buffer". A specification may shed light on the meaning of a claim, but a court must be cautious in extrapolating a claim limitation from particular examples or preferred amounts in a specification: "When consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specification." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009). The claim itself is paramount.[7]

A mass limit is not a standard feature of, or a concept inherent in, the ordinary meaning of the word buffer, and the patent never defines buffer in this way. The examples in the specification are prefaced with the term "[p]referably" and they address one specific type of buffer, dibasic sodium phosphate. ('289 Patent 4:51–54) Even if that were not the case, specifying an *amount* of an ingredient would not ordinarily limit the *definition* of the ingredient. If an inventor did want to limit a component's definition it would have to do so clearly and specifically. "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal quotations marks and citation omitted) Ascribing an arbitrary mass limit to "buffer" plucked from examples in the specifications neither accords with the plain and ordinary meaning or the term nor identifies an idiosyncratic definition within this patent.

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[7] Adding an upper mass limit to the definition of this term is also arbitrary. Why only an upper limit? Why only this component? InnoPharma proffers no sufficient answer. Because InnoPharma is not really reasoning forward from the claims of the patent, I might infer that it is reasoning backward from its desire to market a compound containing over 800μg. Such an inference is not, however, central to my reasoning here.

Fresenius's proposed functional definition of a buffer as "[a] system that resists changes in pH when acid or base is added" is consistent with both the language of the patent and the plain and ordinary meaning of the term. In addition, I accept that as a construction of the term "buffer" because, from the context, I judge that the patent clearly uses that term in a functional sense.

The parties do not present additional argument about the meaning of "phosphate buffer." They do not dispute the meaning of "phosphate," so the only issue that divides them is the construction of "buffer," already discussed above. (*See, e.g.*, Def. Response 6 n.4.) Further construction of "phosphate buffer" is therefore unnecessary.

2. "Dibasic Sodium Phosphate"

Term	Fresenius	InnoPharma	Fera
"dibasic sodium phosphate" ('289 Patent: 4, 5, 9, 10, 16, 17; '239 Patent: 8)	Plain and ordinary meaning "A compound which includes Na_2HPO_4"	"A member of the family of sodium phosphates having two hydrogens that may be replaced by a monovalent metal or radical, *i.e.*, 'Na_2HPO_4.'"	No proposed construction

(Pl. Opening 9; Def. Opening 6)

This dispute between Fresenius and InnoPharma is over whether "dibasic sodium phosphate" refers only to the anhydrous form or includes the hydrate forms as well. (*E.g.*, Def. Opening 6; Pl. Response 7) The claims use the term "dibasic sodium phosphate" without further defining it. The specification provides:

> In one example, the ingredients used to form the liquid mixture include a phosphate buffer other than tribasic sodium phosphate, such as dibasic sodium phosphate (Na_2HPO_4) or monobasic sodium phosphate (NaH_2PO_4). The amount of phosphate buffer in the ingredients may be an amount sufficient to provide a beneficial

> pH buffering effect in the liquid mixture. Preferably the ingredients used to form the liquid mixture include from 100 to 800 µg, from 200 to 700 µg, from 300 to 700 µg, or from 400 to 600 µg dibasic sodium phosphate. Dibasic sodium phosphate may be added as a hydrate, such as dibasic sodium phosphate heptahydrate.

('289 Patent 4:44–55)

InnoPharma argues that the specification defines dibasic sodium phosphate as anhydrous because, immediately following the chemical name, it places the anhydrous chemical formulation in parentheses, thus: "dibasic sodium phosphate (Na_2HPO_4)." (Pl. Opening 7) But this proposed construction ignores the language three sentences later in the specification, which states that "[d]ibasic sodium phosphate may be added as a hydrate, such as dibasic sodium phosphate heptahydrate." ('289 Patent 4:54–55) InnoPharma argues that this separate mention of the hydrate form carries the negative implication that "dibasic sodium phosphate," as used earlier, referred only to the anhydrous form. That is not a natural reading of the language, which does not suggest a contrast. The first reference contains no language that tends to exclude hydrate forms. The second reference does not say that the hydrate form may be used in addition to, or as an alternative to, dibasic sodium phosphate; it says that dibasic sodium phosphate may be added "as a hydrate," implying that the hydrate form is encompassed by the definition of dibasic sodium phosphate. If, as InnoPharma urges, the term "dibasic sodium phosphate" excluded hydrate forms, then it would make little sense to immediately give a hydrate form as a specific example of it.[8]

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[8] Defendants also cite to a scientific and technical dictionary. (Def. Opening 6) The dictionary, however, does not specifically define "dibasic sodium phosphate." (*See* Def. Ex. F. (ECF No. 102–7)) Instead, defendants piece their definition together from "dibasic" and "sodium phosphate." But sodium phosphate is defined generally, and the dictionary definition does not specify whether both anhydrous and hydrate forms would be included in sodium phosphate compounds. (*See* Def. Ex. F. 1373) This extrinsic evidence does not undermine the strong intrinsic evidence.

I conclude that when the claims use the term dibasic sodium phosphate, they intend it as a general designation encompassing both the anhydrous and hydrate forms. On the other hand, however, Fresenius's proposed construction— "A compound which includes Na_2HPO_4"—is too broad and openended. For the reasons expressed above, in the context of the patent language, I find that "dibasic sodium phosphate" means anhydrous Na_2HPO_4 and the hydrate forms of Na_2HPO_4.

3. Numerical Terms

Term	Fresenius	InnoPharma & Fera
"At most 0.20%" ('289 Patent: 6, 7, 8, 11, 12, 13)	Plain and ordinary meaning "0.20% or less	"not more than 0.20% (no nonzero number after the 2)"
"At most 0.15%" ('289 Patent: 18, 19, 20, 21)	Plain and ordinary meaning "0.15% or less."	"not more than 0.150% (no nonzero number after the 5)"
"Less than 0.20%" ('238 Patent: 2, 12, 22; '239 Patent: 2, 4)	Plain and ordinary meaning "Below 0.20%."	"less than or equal to 0.19999999%"

(Pl. Opening 11; Def. Opening 21)

Fresenius maintains that no construction of these terms is necessary. (Pl. Opening 12) I agree. "Less than" is a logical operator, encompassing all values below the stated value, but not the stated value itself. It has a fixed meaning in common parlance, as well as in mathematics, where it is represented symbolically as <. "At most", too, is a common, unambiguous phrase, encompassing all values below the stated value as well as the stated value itself. It means "less than or equal to", and is represented symbolically as

≤ or <=. [9] "Less than .20%", "at most 0.15%", and "at most 0.20%" are not terms that require further construction.

The defendants' alteration of the plain meaning, in which they substitute their own numbers for those in the patent, is inappropriate. Anyone might challenge a patent, I suppose, by suggesting that every number in it should be carried to additional decimal places. Before accepting this as a *Markman* issue requiring my intervention, I would have to be persuaded that the issue has some practical or chemical consequence. No such argument is made here. The repeating decimals here, moreover, seem to ignore obvious practical limits and inject a level of *faux* precision that can only create mischief. At oral argument, the parties acknowledged that this dispute was not substantial. I will construe these terms as-is.

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[9] *Wolfram Lang. & Sys. Documentation Center, Relational and Logical Operators, https://reference.wolfram.com/language/tutorial/RelationalAndLogicalOperators.html*

4. "Converted to liothyronine"

Term	Fresenius	InnoPharma & Fera
"Converted to liothyronine" ('289 Patent: 6, 7, 8, 11, 12, 13, 18, 19, 20, 21; '238 Patent: 2, 12, 22; '239 Patent: 2, 4)	Plain and ordinary meaning "Turned into liothyronine"	"Turned into liothyronine via a chemical reaction, cumulatively over a period of time"
"The composition of claim [X], where when the composition is stored at [X]°C., at most [X]% of the levothyroxine sodium is converted to liothyronine over a period of [X] months." ('289 Patent: 6, 7, 8, 11, 12, 13, 18, 19, 20, 21)	Plain and ordinary meaning	"The composition of claim [X], where when the composition is stored at [X] °C, not more than [X]% of the total levothyroxine sodium is turned into liothyronine via a chemical reaction, cumulatively over any [X] month period of storage."
"The lyophilized solid composition of claim [X], wherein when the lyophilized solid composition is stored at 25°C. for a predetermined time period, less than 0.20% of the salt of levothyroxine is converted to liothyronine." ('238 Patent: 2, 12, 22)	Plain and ordinary meaning	"The lyophilized solid composition of claim [X], wherein when the lyophilized solid composition is stored at 25°C, less than or equal to 0.19999999% of the total levothyroxine sodium is turned into liothyronine via a chemical reaction, cumulatively over any time period of storage equal to the predetermined time period."
"The lyophilized solid composition of claim [X], wherein when the lyophilized solid composition is stored at [X]°C. for a predetermined time period, less than 0.20% of the salt of levothyroxine is converted to liothyronine." ('239 Patent: 2, 4)	Plain and ordinary meaning	"The lyophilized solid composition of claim [X], wherein when the lyophilized solid composition is stored at [X] °C, less than or equal to 0.19999999% of the total salt of levothyroxine is turned into liothyronine via a chemical reaction, cumulatively over any time period of storage equal to the predetermined time period."

(Pl. Opening 12–15; Def. Opening 13–14)

Only the term "[c]onverted to liothyronine" is truly at issue here. The other three disputed terms just insert defendants' proposed constructions (most of which I have already rejected) into the existing patent language.

The specification lays out certain test results that allegedly demonstrate the increased stability of Fresenius's levothyroxine formulation with the reduced amount of mannitol. For example:

> The stability of levothyroxine was analyzed for solid compositions that contained 100 μg levothyroxine sodium and from 2 mg to 10 mg mannitol.... The liquid mixtures were lyophilized to provide solid compositions, which were then stored in amber tinted vials at temperatures of 40° C. or 55° C. The stability of the levothyroxine in the solid compositions at different temperatures was determined by measuring the amount of liothyronine (T3) in each composition over time, as T3 is a degradation product of levothyroxine (T4)....
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> ...
>
> As shown in Table 1, during storage at 40° C. the amount of T3 in the composition containing 10 mg mannitol varied from 0.30% to 0.57% over a period of from 1 to 3 months, a range of approximately 90% [90.0%=100%x(0.57-0.30)/0.30]. In contrast, the amount of T3 in the compositions containing from 2 mg to 4 mg mannitol remained relatively stable under the same conditions, varying only by approximately 6% [5.6%=100%x(0.19-0.18)/0.18)]. In the compositions containing 2 to 4 mg mannitol, at most 0.19% of the levothyroxine sodium was converted to liothyronine when stored at 40° C. over a period of 3 months.

('289 Patent 5:31–6:17) Table 1 shows snapshots of the level of liothyronine at one-month intervals. ('289 Patent 5:47–63)

Defendants argue, in essence, that to prove increased stability, Fresenius should have isolated the rate at which levothyroxine is converted into liothyronine through a "cumulative measure of degradation" and not just measured the liothyronine levels at monthly intervals. (Def Opening 14) This follows, they say, from the fact that liothyronine also degrades on its own at some unspecified rate. (*Id.* at 15–17) The argument, in one of its permutations, seems to be that, while a stable proportion of liothyronine might demonstrate stability in the conversion of levothyroxine to liothyronine, it might alternatively

demonstrate that both levothyroxine and liothyronine are degrading in parallel. (*Id.* at 17–19)

This appears to be at best an invalidity argument, rather than one bearing on claim construction.

> While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction. Instead, we have limited the maxim to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.

Phillips, 415 F.3d at 1327 (internal quotation marks and citations omitted). It may be, as defendants say, that the observed effect is attributable to something else. But the claim is clear enough; defendants' real argument is that the patent does not validly claim an invention that functions as advertised.[10]

"[A]bsent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis." *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008). Defendants ask that this Court alter the plain meaning of the patent to conform to their theory regarding the proper method of measuring the stability of levothyroxine. But "courts cannot alter what the patentee has chosen to claim as his invention," *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989), and I will not do so here.

The meaning of "converted" in the patent is plainly and unambiguously "turned into." (Indeed, "turned into" does not really add any clarity to "converted," the meaning of which is already apparent.) There is nothing in the record before me that would support an alternative definition.

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[10] Consider a claim for "an automobile that travels at 800 mph." In a *Markman* hearing, a challenger might urge that the radar gun must have been improperly calibrated, a contention which, if correct, would suggest that this is not really a miracle car. That contention, however, would seem to present a patentability issue, rather than a claim construction issue. There is no definitional dispute as to what "800 mph" means.

5. "Predetermined time period"

Term	Fresenius	InnoPharma & Fera
"Predetermined time period" ('238 Patent: 2, 3, 12, 13, 22, 23; '239 Patent: 2, 3, 4)	Plain and ordinary meaning "A set period of time for storing."	Indefinite under 35 U.S.C. § 112.

(Pl. Opening 16; Def. Opening 22)

Courts in this Circuit routinely decline to address indefiniteness arguments in claim construction because they are potentially dispositive, require a high burden of proof, and may more profitably be considered in connection with patent validity. *See Waddington N. Am., Inc. v. Sabert Corp.*, Civ No. 09–4883, 2010 WL 4363137, at *2 (D.N.J. Oct. 27, 2010); *see also, e.g., Purdue Pharm. Products, L.P. v. Actavis Elizabeth, LLC*, Civ No. 12–5311, 2014 WL 2624787, at *6 (D.N.J. June 11, 2014), *aff'd*, 627 F. App'x 931 (Fed. Cir. 2016); *Alcon Research, Ltd. v. Barr Labs. Inc.*, Civ No. 09–0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011); *CSB-Sys. Int'l Inc. v. SAP Am., Inc.*, Civ No. 10–2156, 2011 WL 3240838, at *18 (E.D. Pa. July 28, 2011). I, too, find it prudent to defer this indefiniteness argument.

II. CONCLUSION

I construct the disputed terms as follows:

1. "Buffer" means a system that resists changes in pH when acid or base is added.

2. "Phosphate buffer" requires no further construction in light of #1.

3. "Dibasic sodium phosphate" refers to anhydrous Na_2HPO_4 and the hydrate forms associated with Na_2HPO_4.

4. The numerical terms "at most 0.15%", "at most 0.20%", and "less than .20%" do not require further construction.

5. "Converted to liothyronine" means turned into liothyronine, and the rest of the disputed conversion terms require no further construction in light of ## 1-4, above.

6. I decline to address indefiniteness arguments during claim construction; they may be raised at a later stage.

An appropriate order accompanies this Opinion.

Dated: September 20, 2016

Hon. Kevin McNulty
United States District Judge