UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HOSPIRA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 16 C 651**
	)	
FRESENIUS KABI USA, LLC,	)	**Judge Rebecca R. Pallmeyer**
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Hospira, Inc., a Delaware corporation with its primary place of business in Illinois, manufactures pharmaceuticals and medical supplies. At issue in this case is a chemical compound known as dexmedetomidine, which Hospira sells to health care providers under the brand name Precedex. Between 2012 and 2014, Hospira obtained four patents covering a new product made from dexmedetomidine: U.S. Patent Nos. 8,242,158 (the " '158 Patent"), 8,338,470 (the " '470 Patent"), 8,455,527 (the " '527 Patent"), and 8,648,106 (the " '106 Patent"). (Complaint [1] ("Pl.'s Compl."), 3.)

Defendant Fresenius Kabi USA, LLC, is an American subsidiary of a German pharmaceutical manufacturer which is also registered in Delaware and headquartered in Illinois. On December 4, 2015, Fresenius Kabi notified Hospira that it had filed an abbreviated new drug application ("ANDA") with the FDA, seeking approval to market its own proposed dexmedetomidine products prior to the expiry of Hospira's patents. (Answer to Complaint, Affirmative Defenses, and Counterclaims [10] ("Def.'s Answer"), ¶ 16.) Hospira filed suit a month later, alleging patent infringement. (Pl.'s Compl. 8–9.) Fresenius Kabi has denied the allegations and counterclaimed for a declaration that the four patents at issue are invalid or, alternatively, that Fresenius Kabi's actions will not infringe. (Def.'s Answer 22.)

The parties have presented competing interpretations of two terms common to all four patents-in-suit, and of one term unique to the '527 Patent. The court's construction of those terms follows.

BACKGROUND

A. The Patented Invention

Dexmedetomidine is a chemical compound known as an alpha$_2$-adrenergic agonist. ('158 Patent, JA-2, col. 1 ll. 21–24.) In layman's terms, this means it stimulates certain receptors in the central nervous system to produce a desired effect. U.S. National Library of Medicine, *Adrenergic Agonists*, Medicinal Subject Headings 2018 (last visited Nov. 27, 2017), https://meshb-prev.nlm.nih.gov/record/ui?ui=D000322. Dexmedetomidine is used primarily as a sedative, though it is also used to treat pain, anxiety, and high blood pressure. ('158 Patent, JA-2, col. 1 ll. 21–24.) The compound was originally isolated and patented in 1990 by a Finnish corporation, which later licensed the sales rights to Hospira's predecessor organization, Abbott Laboratories. (Fresenius Kabi USA, LLC's Opening Claim Construction Brief [43] ("Def.'s Opening Br."), 2, 4.) Plaintiff Hospira has sold dexmedetomidine-based medications under the Precedex trade name since 1999. (Hospira's Responsive Claim Construction Brief [47] ("Pl.'s Resp. Br."), 1.)

The original Precedex product, known as Precedex Concentrate, is sold in 2-mL glass vials containing a concentration of 100 micrograms per milliliter (µg/mL) of dexmedetomidine. (*Id*.) This concentration is too strong to administer directly to patients. Accordingly, hospital personnel are required to dilute Precedex Concentrate with a 0.9% sodium chloride solution to a reach a concentration of just 4 µg/mL before injecting patients with the medication. (*Id*. at 2; JA-260 ("Precedex Concentrate Label").) In addition, once diluted, the prepared dexmedetomidine solution must be used within 24 hours for maximum potency. (*Id*.)

As Hospira notes, this extra dilution step has obvious drawbacks, including inconvenience, added cost, and increased safety concerns resulting from possible contamination or overdose. (*Id*.) To address these concerns, Hospira developed a new, pre-diluted dexmedetomidine formulation, which it calls Precedex Premix. (*Id*. at 3.) It is for this invention that Hospira filed for and obtained the patents at issue in this case.

Hospira summarized its invention as "premixed pharmaceutical compositions of dexmedetomidine, or a pharmaceutically acceptable salt thereof, that are formulated for administration to a patient, without the need to reconstitute or dilute the composition prior to administration." ('158 Patent, JA-2, col. 1 ll. 61–65.) While surmounting the shortcomings of its original, concentrated formulation, Hospira faced several challenges in developing Precedex Premix: namely, the need to ensure that the product remained stable and potent over a much longer shelf-life. (Pl.'s Resp. Br. 2–3.) After conducting trials with modified chemical formulas, Hospira identified the packaging as the solution to its problems. (*Id*.) Specifically, Hospira asserts, it "discovered that glass packaging exhibited superior stability relative to other packaging materials" such as plastic infusion bags or pre-filled syringes. (*Id*.; '158 Patent, JA-8, col. 13 ll. 22–67.) Hospira found further that "developing a sealed system" could ensure shelf-life stability and product sterility. (Pl.'s Resp. Br. 3.) On this front, Hospira "tested several closure systems for integrity without success before finding a stopper that was compatible with the glass container[.]" (*Id*.)

The '158, '470, and '106 Patents all cover the same basic subject matter—the medication itself—and share a title: "Dexmedetomidine Premix Formulation." (*See*, *e.g.,* '158 Patent, JA-1.) The final, '527 Patent addresses "Methods of Treatment using a Dexmedetomidine Premix Formulation." ('527 Patent, JA-29.) All the patents share a common specification. The core of the invention, Hospira states, is "a 'ready to use' dexmedetomidine formulation in a 'sealed glass container.'" (Pl.'s Resp. Br. 3.)

B. The Disputed Claim Terms

The parties contest three claim terms: "ready to use," "sealed glass container," and "intensive care unit." The first two of these terms are present in every asserted claim throughout all four patents, while the third relates to just one claim in the '527 Patent.

The '158 Patent is representative of the manner in which the terms "ready to use" and "sealed glass container" are used in all four patents.[1] It claims:

> 1. A **ready to use** liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL disposed within a **sealed glass container**.
> 2. The **ready to use** liquid pharmaceutical composition of claim 1, further comprising sodium chloride at a concentration of between about 0.01 and about 2.0 weight percent.
> 3. The **ready to use** liquid pharmaceutical composition of claim 2, wherein the sodium chloride is present at a concentration of about 0.9 weight percent.
> 4. The **ready to use** liquid pharmaceutical composition of claim 1, wherein the composition is formulated as a total volume selected from the group consisting of 20 mL, 50 mL and 100 mL.

('158 Patent, JA-14, col. 26 ll. 4–18) (emphasis added).

The '527 Method Patent contains 15 claims covering various concentrations, delivery methods, and settings in which the premixed dexmedetomidine formulation may be administered. ('527 Patent, JA-42, col. 25 l. 24–col. 26 l. 31.) Claim 8 contains the disputed term:

> 1. A method of providing sedation to a patient in need thereof, the method comprising administering to the patient an effective amount of a composition, wherein the composition comprises dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 0.005 to about 50 µg/mL, wherein the composition is a ready to use liquid pharmaceutical composition for parenteral administration to the patient disposed within a sealed glass container.
>
> . . .
>
> 8. The method of claim 1, wherein the composition is administered to the patient in an **intensive care unit**.

[1] The parties agree on this point, and cite to the first-filed '158 Patent in the Joint Appendix when discussing these two terms throughout their briefs. (*See* Def.'s Opening Br. 4 n.3.)

(*Id*. at col. 25 ll. 25–32, col. 26 ll. 16–17) (emphasis added).

C. Prosecution History

The inventors filed the four patent applications between January 4, 2012, and April 22, 2013. ('158 Patent, JA-1; '106 Patent, JA-43.) The Patent Office issued the patents between August 14, 2012, and February 11, 2014, in the order in which they were filed. (*Id*.) The prosecution history of the first-filed '158 Patent reflects the history of the family of patents as a whole.

In the original application, the independent claim of the '158 Patent read:

> 1. A pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL, wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed with a sealed container as a premixture.

(JA-175.) The phrase "ready to use" and word "glass" to describe the sealed container were not yet present. The Patent Office rejected all four claims as anticipated or made obvious by the prior art: in this case, the label that appears on the Precedex Concentrate product. (*Id*. at 286.) The examiner's comments explained that the Precedex Concentrate label "teaches that the dexmedetomidine HCL formulation must be diluted in 0.9% sodium chloride solution prior to administration" and "provides instructions for dilution." (*Id*.) (emphasis in original). Notably, the label disclosed that Precedex Concentrate was sold in "clear glass vials and . . . ampules." (*Id*. at 261.) The examiner further stated in regards to the claimed "sealed container" that, given the choice between diluting the solution in a sealed versus unsealed container, "[t]he artisan would clearly immediately envisage the mixing of the formulation in a sealed container in order to maintain the sterility of the composition for parenteral administration." (*Id*. at 287.)

In response, the inventors amended the claim to read "wherein the composition is disposed within a sealed glass container as a ready to use premixture." (JA-298) (emphasis in original). In support of these amendments, the record states:

> [Hospira] noted that the claims are directed to a composition comprising 4 µg/mL dexmedetomidine that is a premixture, which does not require dilution prior to administration to a subject. The claimed composition differs from the formulation described by the cited reference, which requires dilution to a concentration of 4 µg/mL dexmedetomidine prior to administration to a patient. As such, [Hospira] maintained that unlike the claimed composition, the formulation disclosed by the cited reference is not a ready to use premixture.

(*Id*. at 299.) As for the modification of "sealed container" to "sealed glass container," Hospira successfully argued that the prior art did not meet the legal standard for inherent anticipation because the examiner's conclusion was based on the "mere probability that the skilled artisan would prepare the dilution in a sealed glass container and not in an unsealed container" made of another substance. (*Id*. at 301–02.) Anticipation "may not be established by probabilities or possibilities," (*Id*. at 301 (citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)), and Hospira distinguished Precedex Premix as being "*necessarily* disposed with a sealed glass container." (*Id*. at 302) (emphasis in original).

Hospira further argued that a "sealed glass container" was not obvious in the light of the prior art because a skilled artisan would likely prepare a solution for intravenous delivery to a patient in a plastic infusion bag rather than a sealed glass container. (*Id*. at 303.) While Precedex Concentrate was sold in glass vials, it was not diluted in those same containers. Hospira also presented evidence that distributing Precedex Premix in sealed glass containers exhibited superior potency over a longer shelf life than alternative vessels. (*Id*.) The PTO accepted these arguments as "effective to overcome the previous rejection" for inherent anticipation and obviousness. (JA-421.)

The '158 Patent reached its final form on March 30, 2012, through an amendment requested by the examiner and authorized by the inventors. (*Id*. at 420.) The amendment maintained the inventors' addition of "ready to use" and "glass" to the claims, but rearranged the sentence for grammar and syntax to read:

> 1. A **ready to use** liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL disposed within a **sealed glass container**.

(*Id*.; '158 Patent, JA-14, col. 26 ll. 4–8.) The remaining patents underwent a similar process of rejection and modification before being approved by the PTO. (*See, e.g.*, JA-757–66; JA-843–65) (discussing the term "sealed glass container" in the context of the '470 Patent).

DISCUSSION

A. Legal Standards Governing Claim Construction

The claims of a patent define the scope of the invention to which the patentee may exercise his right of exclusivity. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Where a claim's meaning is disputed, the court must determine its proper construction as a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). Claim construction is an objective exercise, and courts should generally give claim terms the ordinary and customary meaning they would have "to a person of ordinary skill in the art at the time of the invention." *Phillips*, 415 F.3d at 1313. Claim construction often "involves little more than the application of the widely accepted meaning of commonly understood words." *Id*. at 1314 ("In such circumstances, general purpose dictionaries may be helpful."). Importantly, however, judges must always read claims "in the context of the entire patent." *Id*. at 1313.

The Federal Circuit instructed in *Phillips* that if the meaning of a disputed claim term is not readily apparent, the court should first turn to sources of evidence intrinsic to the patent. 415 F.3d at 1314–19. Foremost among these intrinsic sources is the patent's specification, which must include a "full, clear, concise, and exact" description of the claimed invention as the inventor saw it. *Id*. at 1316 (quoting 35 U.S.C. § 112). If the specification defines or gives consistent meaning to certain terms, "the inventor's lexicography governs." *Id*. The same rule applies if an inventor explicitly limits the scope of a term in the specification. *Id*. If the specification merely provides examples or preferred embodiments of an invention, however, *Phillips* warns courts not to confine the patent's claims to those embodiments. *Id*. at 1323; *see also Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136 (Fed. Cir. 2011) (declining to limit a claim "where the references to a certain limitation as being the 'invention' are

not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent.").

In addition to the specification, the court may look to the patent's prosecution history as further evidence of how the inventor and the Patent Office understood the invention. *Id*. at 1317. The court must be mindful, however, that the prosecution history represents an ongoing discussion, and may be less clear than the specification "and thus less useful for claim construction purposes." *Id*. Finally, while consulting the intrinsic evidence will resolve ambiguities in most situations, courts must sometimes go beyond the contents of the patent itself and consider extrinsic evidence—such as technical dictionaries, treatises, or expert testimony—to aid in claim construction. *Id*. Though the Federal Circuit in *Phillips* outlined several reasons why extrinsic evidence is less reliable than intrinsic evidence, it declined to exclude such evidence provided it is not used to contradict claim language made clear by intrinsic evidence. *Id*. at 1318–19, 1324; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

With these standards of construction in mind, the court turns to the disputed claim language.

B. "ready to use" (all asserted claims)

Claim Term	**Plaintiff Hospira's Proposed Construction**	**Defendant Fresenius Kabi's Proposed Construction**
"ready to use"	"formulated to be suitable for administration to a patient upon manufacture without dilution or reconstitution"	"suitable for administration to a patient without requiring dilution"

The '158 Patent defines the term "ready to use" as an embodiment of the invention "formulated as 'ready to use' compositions which refer to premixed compositions that are suitable for administration to a patient without dilution." ('158 Patent, JA-3, col. 3 ll. 57–59.) The specification previously defines a "premix" or "premixture" as "a pharmaceutical formulation that does not require reconstitution or dilution prior to administration to a patient." (*Id*. at ll. 48–

50.) Such compositions, the specification continues, do not require dilution by "a clinician, hospital personnel, caretaker, patient, or any other individual." (*Id*. at ll. 53–55.) Here, the inventor has clearly acted as his own lexicographer. *See Philips*, 415 F.3d at 1316. As such, Hospira's proposed construction more accurately describes the scope of the term "ready to use."

Fresenius Kabi contends that its proposed construction appropriately describes the "distinguishing characteristic" of "ready to use"—namely, "the ability to administer the compositions without further dilution." (Def.'s Opening Br. 13.) That construction, however, relies on an incomplete quotation of the patent's definition and cuts out the phrases "formulated and "premixed compositions." Viewing the term "ready to use" in the light of the patent's complete definition confirms that the term should be read as "ready to use" in its original formula or design, not merely "ready to use" whenever no further dilution step is required. *See also Formula, Formulate*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (10th ed. 1997). Fresenius Kabi contends that relying on the term "premixed" to define "ready to use" is improper; as the terms are not used interchangeably, Fresenius Kabi insists they must mean different things. (Fresenius Kabi USA, LLC's Reply Claim Construction Brief [60] ("Def.'s Reply Br."), 5–6) (citing *Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005)). But "ready to use" compositions can fairly be understood to be a subset of "premixed" compositions—which the specification clearly states are "formulations" that do not require dilution by anyone, at any time. ('158 Patent, JA-3, col. 3 ll. 49–55.) A "ready to use" composition must thus also be "premixed" and incorporate any additional meaning the parent term bears.

The most straightforward reading of the term necessarily implies that the composition is "ready to use" from the moment it leaves Hospira's possession. Fresenius Kabi contends this is an improper "attempt to impute a temporal limitation" onto the term. (Def.'s Reply Br. 3.) Assuming such a temporal limitation is appropriate at all, Fresenius Kabi asserts, the temporal limitation on "ready to use" more appropriately dates to the moment the dexmedetomidine is

removed from the sealed glass container, not to "the specific point of manufacture." (*Id*. at 4.) Thus, "the focus is not on whether the composition had ever been diluted, but whether it requires a dilution step before administration." (Def.'s Opening Br. 13.) The court disagrees. The Defendant's definition is overbroad, and would cover any dexmedetomidine formulation that had been diluted at any point in the past. (Pl.'s Resp. Br. 7.) The specification does not support such a reading.

Fresenius Kabi cites to the prosecution history to bolster its reading, highlighting passages where Hospira distinguished the Precedex Concentrate prior art as "[u]nlike the claimed composition that is formulated at a concentration which is *ready for administration to a patient upon removal from the sealed glass container*." (Def.'s Opening Br. 13) (quoting JA-97–98) (emphasis in original). In this passage again, however, Fresenius Kabi's proposed construction ignores all language stressing that the medication is "formulated" as such. Throughout the patents-in-suit, the inventors stress that the core distinction between Precedex Concentrate and Precedex Premix is that the formulas are different. Any person of ordinary skill in the art ("POSITA") would have to incorporate that distinction in understanding the patents' scope.

Fresenius Kabi also asserts that Hospira is impermissibly trying to "convert its composition claims into product-by-process or method claims." (Def.'s Reply Br. 2) (citing *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2001)). As Fresenius Kabi reads Hospira's proposed claim construction, Hospira is attempting to redefine its claims to cover "how a composition is made" rather than "what the composition is." (*Id*.) Again, the court disagrees: recognizing the necessary temporal limitations that define the claimed product is not the same as imposing process restrictions on the claims. Fresenius Kabi's position suggests that any "do-it-yourself" product can be transformed into a "ready to use" product after the customer has put it together on his own. This is an untenable conclusion. If a consumer buys a flat-pack bookcase at IKEA, it will never be a "pre-built" bookcase. Some

assembly—even if not done by the consumer himself—will always be required. A bookcase, like a premixed dexmedetomidine formulation, is either "ready to use" from the outset, or not at all. Any POSITA handling a product described as "ready to use" would recognize that it requires no further manipulation by anyone. Fresenius Kabi itself recognized as much when it stated "[t]he appropriate question for infringement is whether the accused infringer sells a product that does not require further dilution." (Def.'s Reply Br. 4.)

Hospira is correct that "ready to use" includes a temporal component, but this court nevertheless declines to adopt Hospira's construction wholesale. The record bears no support for Hospira's attempt to insert the term "upon manufacture." The specification's summary section states that "[t]he present invention relates to premixed pharmaceutical compositions of dexmedetomidine, or a pharmaceutically acceptable salt thereof, that are formulated for administration to a patient, without the need to reconstitute or dilute." ('158 Patent, JA-2, col. 1 ll. 61–64.) As stated above, the definitions section describes "ready to use" compositions in the same manner: calling them "formulations" and "premixed compositions" may imply that the compositions are ready for use "upon manufacture," but such a phrase is not part of the claim. (*Id*. at col. 3 ll. 57–59.)

Indeed, the parties' efforts to draw a line between the moment of manufacture and the moment of dispensing may well be academic: if the glass container is "sealed," the contents of that container are likely "ready to use" when the seal is placed during manufacturing. The patents-in-suit do not anticipate any additional intermediate steps between making and bottling the premixed dexmedetomidine. In most cases, therefore, the parties' constructions overlap. To the extent Defendant suggests that the dexmedetomidine composition may be diluted by anyone else at some point before administration, the court rejects that construction. Likewise, pinpointing the precise moment of readiness to be "upon manufacturing" is unnecessary and overly specific. That is simply not what the claims refer to.

Accordingly, this court adopts the following construction: "formulated to be suitable for administration to a patient without dilution or reconstitution."

C. "sealed glass container" (all asserted claims)

Claim Term	Plaintiff Hospira's Proposed Construction	Defendant Fresenius Kabi's Proposed Construction
"sealed glass container"	"glass container closed to maintain the sterility by having a seal or another closure that passes closure integrity testing"	"closed tightly to prevent unwanted materials entering or exiting the glass container"

The parties do not dispute the meanings of "glass" or "container." Instead, they propose different interpretations of what it means for a glass container to be "sealed." Notably, the specification does not define the term "sealed glass container." The only detailed reference to the subject matter states:

> In certain non-limiting embodiments, the premixed dexmedetomidine composition of the present invention is disposed in a container or vessel that can maintain the sterility of, or prevent the contamination of, a premixed dexmedetomidine composition that is purified or substantially free of any contaminants. In certain non-limiting embodiments, the container or vessel is a sealed container or vessel.

('158 Patent, JA-6, col. 9 ll. 1–7.) In addition, the specification details at length the process by which Hospira developed the "sealed glass container" by experimenting with different container types and closures.

Hospira seeks to supplant the common-place meaning of "sealed" with a lengthy set of standards referencing the need to maintain sterility and pass FDA-recommended closure-integrity tests. (Pl.'s Resp. Br. 8–9.) This level of detail is unnecessary. For one, whether a container is "sterile" is a separate question from whether it is "sealed." It is just as possible for a sealed container to be keeping contaminants in rather than out. The specification clarifies that a sterile container and a sealed container are not used interchangeably. (*See* '158 Patent, JA-6, col. 9 ll. 1–7) (describing a sterile container and a sealed container as separate non-limiting embodiments of the invention). Furthermore, maintaining sterility is not the only purpose of

sealing the container—Example 6 describes additional aims of potency and stability. ('158 Patent, JA-12, col. 21 ll. 18–44.) The specification does not suggest that one of these goals must be elevated to define the term "sealed" while the others should not. Finally, inserting the phrase "to maintain the sterility"—or any other language suggesting the purpose of the seal—would be redundant. The act of sealing a container already implies that the contents will remain untouched until the seal is broken. The additional language Hospira proposes adds nothing to a POSITA's ability to understand the commonplace word "sealed."

The latter half of Hospira's proposed construction, "by having a seal or another closure that passes closure integrity testing," is similarly unsupported by the specification. Hospira criticizes Fresenius Kabi's construction as "raising more questions than it answers," but in advocating for this court to incorporate the entire body of FDA closure integrity standards by reference, Hospira is guilty of the same transgression. (Pl.'s Resp. Br. 9.) As noted by Fresenius Kabi: "[a]dding all the extra terminology that Hospira asks to add would mean not only collecting material wholesale from third party extrinsic sources, but then would require another round of claim construction briefing to understand what that new terminology would actually require." (Def.'s Reply Br. 7.) While Hospira may prefer the incorporation of its preferred embodiment—a glass container sealed using a "Helvoet FM 259/0 OmniflexPlus fluoropolymer coated stopper"—the specification cannot be read to mean that such a stopper is the only means of sealing the glass container. (*See* '158 Patent, JA-12, col. 21 ll. 1–2.) Nor was that the view of the named inventor or of Hospira's own corporate witness, both of whom confirmed that "a sealed glass container refers to a container that is closed sufficiently [ ] to maintain the integrity of the . . . solution inside the glass bottle." (Dep. of Robert Cedergren, Ex. 1 to Def.'s Reply Br., 194:3–7; Dep. of Rao Tata-Venkata, Ex. 2 to Def.'s Reply Br., 41:9–12.) Hospira's corporate witness, Dr. Rao Tata-Venkata, went further; he pointed out that "'sealed' is a very general term," and observed that, in his experience, "sealed" means "closed with a closure."

(Dep. of Rao Tata-Venkata 41:2–8.) This intrinsic evidence, and the use of the general term "sealed," signals that the patents' claims were intended to sweep broadly.

Fresenius Kabi's proposed construction is closer to the mark, but is arguably too imprecise. This court agrees with Plaintiff Hospira that "sealed" means something beyond "covered" or "closed," and even beyond the Defendant's proposed meaning "closed *tightly*." (Pl.'s Resp. Br. 9) (emphasis added). In common usage, the Defendant's proposal is not incorrect, but in the context of a prescription drug patent a POSITA would read the word "sealed" to suggest something more secure and permanent than just "tightly closed." Thus, in a patent infringement case from the District of Delaware regarding an anti-tumor medication, the court addressed the term "sealed container" and concluded that "[t]he ordinary meaning of the term 'sealed' is different from, and encompasses something more than, the ordinary meaning of the term 'closed.'" *Pharmacia & Upjohn Co. v. Sicor & Sicor Pharm., Inc.*, 447 F. Supp. 2d 363, 373 (D. Del. 2006)

A standard dictionary definition of a "seal" is "a tight and perfect closure (as against the passage of gas or water)." *Seal*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (10th ed. 1997). The verb "to seal" means either "to fasten with or as if with a seal to prevent tampering," or "to close or make secure against access, leakage, or passage by a fastening or coating." *Id*. Despite Hospira's assertions that a "sealed" container requires rigorous closure testing, the concept is not a complicated one. The court concludes no construction of this term is required. That said, the court does not understand the term "sealed" as broad enough to include containers that are merely "closed" as a person might close a desk drawer or a book. If the court were to adopt a construction of the term, it would adopt Fresenius Kabi's proposal, as it more accurately reflects the broad scope of the chosen claim language.

D. "intensive care unit" ('527 Patent, claim 8)

Claim Term	Plaintiff Hospira's Proposed Construction	Defendant Fresenius Kabi's Proposed Construction
"intensive care unit"	"any setting that provides care to critically ill patients, typically characterized by high nurse-to-patient ratios, continuous supervision, and intensive monitoring"	"any setting that provides care to critically ill patients" OR "any setting that provides intensive care"

Defendant Fresenius Kabi's proposed construction relies of this term relies on the recent findings of Delaware District Court Judge Andrews in a parallel case, *Hospira Inc. v. Amneal Pharm. LLC*, No. 15-cv-697-RGA, 2016 WL 3021719 (D. Del. May 25, 2016). That case featured the same plaintiff seeking to enforce the same four patents at issue in this case. *Id*. at *1. Hospira pushed for the same construction of "intensive care unit" there as here: "any setting that provides care to critically ill patients, typically characterized by high nurse-to-patient ratios, continuous supervision, and intensive monitoring." Judge Andrews declined to adopt Hospira's construction, stating:

> The latter part of Plaintiff's proposed construction—"typically characterized by high nurse-to-patient ratios, continuous medical supervision, and intensive monitoring"—is rejected. This language finds no support in the intrinsic record. I cannot discern any material distinction between "any setting that provides care to critically ill patients" and "any setting that provides intensive care." I therefore decline to construe the term further at this time.

Id. at *3.

Fresenius Kabi urges this court to defer to Judge Andrews' findings. (Def.'s Opening Br. 18–19.) The doctrine of issue preclusion likely does not apply in this situation as the parallel litigation has not reached a final judgment on the merits. *Kollmorgen Corp. v. Yaskawa Elec. Corp.*, 147 F. Supp. 2d 464, 469 (W.D. Vir. 2001) ("[J]udicial statements regarding the scope of patent claims are entitled to collateral estoppel effect in a subsequent infringement suit only to the extent that determination of scope was essential to a final judgment on the question of validity or infringement.") (quoting *A.B. Dick v. Burroughs Corp.*, 713 F.2d 700, 704 (Fed. Cir. 1983)); *but see TM Patents, L.P. v. IBM Corp.*, 72 F. Supp. 2d 370, 379 (S.D.N.Y. 1999)

(holding that a prior construction opinion was a sufficiently final judgment to warrant issue preclusion even where the proceedings never reached a final judgment on the merits). Nevertheless, courts "would be remiss to overlook another district court's construction of the same claim terms in the same patent" given the importance of uniform treatment of patents. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1329 (Fed. Cir. 2008) (citing *Markman*, 517 U.S. at 390).

This court finds Judge Andrews' reasoning persuasive and would reach the same conclusion even without his guidance, as there appears to be no support in the intrinsic record for the additional elements Hospira requests. In fact, the specification of the '527 Patent militates against Hospira's proposal. The only reference to "intensive care unit" in the '527 Patent states that the term "as used herein refers to any setting that provides intensive care, as described, for example, in U.S. Pat. No. 6,716,867." ('527 Patent, JA-34, col. 10 ll. 33–35.) The patent referenced, No. 6,716,867, is the method of administration patent for the original concentrated dexmedetomidine formulation and analogous to the present '527 Patent. ('867 Patent, Ex. G to Def.'s Opening Br. [43-2].) The text of the '867 Patent, though cross-referenced in the '527 Patent, adds nothing to that definition—the '867 Patent simply repeating that "an intensive care unit includes any setting that provides intensive care." (*Id*. at col. 1 ll. 18–19.) The specification is clear. Intensive care units, in the context of the patents-in-suit, refer to *any setting* where such care is provided, not merely those additionally "characterized by high nurse-to-patient ratios, continuous supervision, and intensive monitoring."

Hospira's proposed construction generates additional confusion. Hospira has not explained what nurse-to-patient ratios qualify as "high" or what "intensive" monitoring entails. These sorts of threshold judgments are not necessary as no POSITA would think the term requires that level of detailed inquiry. True, most intensive care units are likely to reflect the criteria Hospira recites, but even the medical dictionaries cited by Hospira identify these as typical *features* of intensive care units, not limitations. (*See* Pl.'s Resp. Br. 12.) There is no

evidence in the intrinsic record to suggest that nurse-to-patient ratios, continuous supervision, and intensive monitoring should be considered.

The term "intensive care unit" is largely self-explanatory. At the most basic level, it is merely whatever location a given hospital designates as the "intensive care unit." The specification asserts, and the parties agree in their proposed construction, however, that the term as used in the patent goes further: to any setting, regardless of title, where intensive care is provided. As the parties also recognize, "intensive care" involves patients who are seriously or "critically" ill. *See also Intensive Care*, MERRIAM-WEBSTER COLLEGIATE DICTIONARY (10th ed. 1997). Accordingly, the court adopts the Defendant's construction of "intensive care unit" as meaning either "any setting that provides care to critically ill patients" or "any setting that provides intensive care."

CONCLUSION

The claim terms in the '158 Patent, '470 Patent, '527 Patent, and '106 Patent are construed as follows:

Claim Term	**Construction**
"ready to use"	formulated to be suitable for administration to a patient without dilution or reconstitution
"sealed glass container"	no construction required
"intensive care unit"	any setting that provides care to critically ill patients OR any setting that provides intensive care

ENTER:

Dated: November 27, 2017

REBECCA R. PALLMEYER
United States District Judge