

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

KINETIC CONCEPTS, INC., and KCI USA, §
INC., §

Plaintiffs, §

v. §

WAKE FOREST UNIVERSITY HEALTH §
SCIENCES, §

Defendant. §

§ **Consolidated Civil Action Nos.**
§ SA-11-CV-163-XR and SA-11-CV-713-XR

WAKE FOREST UNIVERSITY and WAKE §
FOREST UNIVERSITY HEALTH §
SCIENCES, §

Plaintiffs, §

v. §

KINETIC CONCEPTS, INC., KCI USA, §
INC., KCI LICENSING, INC., KCI §
MEDICAL RESOURCES, MEDICAL §
HOLDINGS LIMITED, and KCI §
MANUFACTURING, §

Defendants. §

ORDER

On this date, the Court considered the motion for summary judgment of no invalidity. Doc. No. 80. After careful consideration, the motion is DENIED. In addition, the Court has construed the six contested terms at issue in this case.

BACKGROUND

In October 1993, Kinetic Concepts, Inc. and Wake Forest University (“WFU”) entered into a partnership to develop and sell Negative Pressure Wound Treatment (“NPWT”) products.¹ This technology had first been developed by WFU researchers Dr. Louis Argenta and Dr. Michael J. Morykwas. NPWT products work by using differentials in air pressure to promote tissue migration to close open wounds. (651 Patent at 4:18-23). Prior to the development of these products, medical professionals sometimes found it difficult to close large wounds with traditional methods such as staples, sutures, and stitches. Due to their success in closing wounds, these NPWT products have become commonplace in hospitals and with the military.

The parties entered into an agreement (the “License Agreement”) that granted Kinetic Concepts, Inc. and its affiliates (collectively “KCI”) the exclusive rights to certain NPWT Patents that were owned by WFU. The patents at issue in this case are United States Patents 5,636,643 (“the ‘643 patent”), 5,645,081 (“the ‘081 patent”), 7,198,046 (“the ‘046 patent”), and 7,216,651 (“the ‘651 patent”) (collectively the “Patents”). In return for these rights, KCI agreed to pay WFU royalties on the NPWT products it sold. WFU subsequently assigned all of its rights under the License Agreement and the underlying patents to Wake Forest University Health Sciences (“WFUHS”). KCI has incorporated the Patents into its Vacuum Assisted Closure Therapy System (“V.A.C. System”) and other wound care products.

¹ The uncontested facts have been taken from the parties’ respective opening briefs on claim construction. (Docs. Nos. 75-76).

KCI first introduced the V.A.C. system in 1996. The NPWT market expanded rapidly during the second half of the 1990s, turning into a billion-dollar industry. KCI's competitors began to develop similar wound closure devices based on the same or similar technology. As a result, KCI filed and/or joined seven lawsuits in the U.S. to defend the validity and scope of WFUHS' patents against would-be infringers seeking to enter the lucrative NPWT market.² KCI also defended its interest in WFUHS' patents abroad. KCI and WFUHS spent years as allied co-parties during these cases, some of which were appealed to the Federal Circuit. The parties dispute what was argued and held in these cases, and two of such cases are of special relevance to the current case.

In 2003, KCI and WFUHS sued Bluesky on the 081 and 643 patents ("*Bluesky I*"). Bluesky alleged numerous defenses. In particular, Bluesky claimed that the patents were obvious and referenced much of the same prior art as KCI now seeks to assert against WFUHS. This prior art was insufficient to convince a jury that the patents were obvious, and the district court entered judgment of no invalidity. *Kinetic Concepts, Inc. v. Bluesky Med. Corp.*, SA-03-CV-832-WRF, 2007 WL 1113085 (W.D. Tex. Apr. 4, 2007). Bluesky appealed, and the Federal Circuit affirmed the non-obviousness findings along with all of the other district court findings. *Kinetic Concepts, Inc. v. Bluesky Med. Grp., Inc.*, 554 F.3d 1010 (Fed. Cir. 2009).

² *Kinetic Concepts, Inc. v. Med. Ctr. of Louisiana*, Civ. No. 1-cv-2950 (E.D. La.) (asserting 081 and 643 Patents); *Kinetic Concepts, Inc. v. Botsford Gen. Hosp.*, Civ. No. 3-cv-70135 (E.D. Mich.) (asserting 081 and 643 Patents); *Kinetic Concepts, Inc. v. Bluesky Med. Corp.*, Civ. No. 3-cv-832 (W.D. Tex.) (asserting 081 and 643 Patents) ("*Bluesky I*"); *Kinetic Concepts, Inc. v. Bluesky Med. Grp., Inc.*, Civ. No. 8-cv-102 (W.D. Tex.) (asserting 081, 643 and 651 Patents) ("*Bluesky II*"); *Kinetic Concepts, Inc. v. Medela AG*, Civ. No. 8-cv-87 (W.D. Tex.) (asserting 651 Patent) ("*Medela*"); *Wake Forest Univ. Health Sci. & Kinetic Concepts, Inc. v. Innovative Therapies, Inc.*, Civ. No. 8-cv-32 (M.D.N.C) (asserting 081, 643 and 651 Patents); and *Kinetic Concepts, Inc. v. ConvaTec, Inc.*, Civ. No. 8-cv-918 (M.D.N.C) (asserting 081, 643 and 651 Patents) ("*ConvaTec*").

By 2007, Bluesky had been acquired by Smith & Nephew, a major KCI competitor. KCI and WFUHS brought suit again to enforce WFUHS's patents ("*Bluesky II*"). Smith and Nephew attacked the validity of the patents on the grounds of obviousness and that the patents lacked a sufficient written description. A jury panel disagreed and found that the patents were not invalid. The district court in *Bluesky II* then granted Smith and Nephew's motion for judgment as a matter of law, thereby declaring the patents invalid. *Kinetic Concepts, Inc. v. Bluesky Med. Grp., Inc.*, Civ. No. 08-cv-102 (W.D. Tex.) After this development, KCI initially joined WFUHS in an appeal, but later dropped out of the lawsuit. WFUHS successfully appealed the trial court's granting of JMOL to the Federal Circuit, which held that the district court had erred by "failing to defer to the jury's factual findings." *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.* 688 F.3d 1342, 1371 (Fed. Cir. 2012).

KCI commenced this lawsuit by filing their Original Complaint in this Court on February 28, 2011. The Original Complaint named WFUHS as the sole defendant and sought the following relief: (1) a declaratory judgment that Kinetic Concepts, Inc. and KCI USA, Inc. owe no royalties under the License Agreement for sales of the V.A.C. System based on the Patents; (2) a declaratory judgment that the Patents that cover the V.A.C. System are invalid; and (3) a declaratory judgment that the V.A.C. System does not infringe any valid or enforceable claim of the Patents.

On March 18, 2011, WFUHS terminated the License Agreement and filed a lawsuit in a North Carolina state court seeking damages for (1) breach of contract; (2) "breach of contract and audit and accounting"; (3) breach of the covenant of good faith and fair dealing; (4) unjust enrichment/restitution; (5) unfair and deceptive trade practices and unfair

competition in violation of North Carolina General Statutes § 75-1.1; and (6) patent infringement. This suit was removed to the U.S. District Court for the Middle District of North Carolina and subsequently transferred to this Court on August 26, 2012. On December 26, 2012, the two cases were combined into this action. On July 29, 2013, WFUHS filed a motion for summary judgment of no invalidity. Doc. No. 80. On September 18, 2013, this Court held a claims construction hearing and also heard oral argument on the motion for summary judgment.

II. LEGAL STANDARD

A. *Summary Judgment Standard*

Summary judgment is proper when the evidence shows “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-252 (1986). Rule 56 “mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails . . . to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Curtis v. Anthony*, 710 F.3d 587, 594 (5th Cir. 2013) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

The court must draw reasonable inferences and construe evidence in favor of the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Although the evidence is viewed in the light most favorable to the nonmoving party, a nonmovant may not rely on “conclusory allegations, unsubstantiated assertions, or only a

scintilla of evidence” to create a genuine issue of material fact sufficient to survive summary judgment. *Freeman v. Tex. Dep’t of Criminal Justice*, 369 F.3d 854, 860 (5th Cir. 2004).

The patent challenger (i.e. the party seeking invalidity) bears the burden of proof by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P’Ship*, 131 S.Ct. 2238, 2242 (2011). Patents may only be found invalid or not invalid. *Durango Assoc., Inc. v. Reflange, Inc.*, 843 F. 2d 1349, 1356 n.4 (Fed. Cir. 1988) (“A patent should not be declared ‘valid’ by a court because other challengers may prove invalidity using different evidence.”). 35 U.S.C. § 282(a) instructs courts to conduct an invalidity analysis claim by claim. The first step of this analysis is to construe the claim in a *Markman* hearing. *Scimed Life Sys. v. Johnson & Johnson*, 87 F. App’x 729, 734 (Fed. Cir. 2004) (“Claim interpretation is the first step of a validity analysis.”). If there are still remaining fact issues, then the second step is for the trier of fact to compare the construed claims against the asserted invalidity criteria as set in 28 U.S.C. § 282 (b).

B. Deference to Prior Cases

In *Markman*, the Supreme Court justified its decision to make claims construction a matter of law for the courts by referencing the “importance of uniformity in the treatment of a given patent.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 390 (1996). Earlier Federal Circuit decisions have *stare decisis* effect upon this court. *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998) (recognizing “the national *stare decisis* effect that [the Federal Circuit’s] decisions on claim construction have”); *Miken Composites, LLC v. Wilson Sporting Goods Co.*, 515 F. 2d 1331 (Fed. Cir. 2008). *Stare decisis* applies only to the

portion of the earlier decision that was necessary to the decision. *Zenith Radio Corp. v. United States*, 783 F.2d 184, 187 (Fed. Cir. 1986).

Stare decisis does not preclude this court from an independent analysis of claims that have been construed in other district courts. *Maurice Mitchell Innovations, L.P. v. Intel Corp.*, 2006 WL 1751779 (E.D. Tex. June 21, 2006) *aff'd*, 249 F. App'x 184 (Fed. Cir. 2007). Instead, this Court gives reasoned deference to the decisions of other district courts that have construed these claims.

The equitable doctrine of judicial estoppel also applies to claims construction. *Biomedical Patent Mgmt. Corp. v. Cal. Dep't of Health Servs.*, 505 F.3d 1328, 1341 (Fed. Cir. 2007). This Court applies the judicial estoppel law of the Fifth Circuit. *Source Search Techs., LLC v. Lending Tree, LLC.*, 558 F.3d 1063, 1071 (Fed. Cir. 2009) (judicial estoppel governed by regional circuit law, not by Federal Circuit). Several factors guide this Court's analysis of whether judicial estoppel is appropriate: (1) whether the party's new position is "clearly inconsistent" with its old position, (2) whether the party had convinced a court based on its old position, and (3) whether it would be unjust to permit a party to change positions. *New Hampshire v. Maine*, 532 U.S. 742 (2001); *Love v. Tyson Foods*, 677 F.3d 258, 261 (5th Cir. 2012).

Unlike other estoppel doctrines which are meant to protect parties from repeated litigation, judicial estoppel protects the integrity of the courts by "preventing parties from playing fast and loose with the courts to suit the exigencies of self-interest." *In re Coastal Plains, Inc.*, 179 F.3d 197, 205 (5th Cir. 1999). Courts possess discretion over when to apply

judicial estoppel. *New Hampshire*, 532 U.S. at 750 (differing circumstances “may inform the doctrine's application in specific factual contexts,”).

C. Claims Construction Methodology

It is well settled that claim construction is a matter of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). District courts are not required to construe every term in a patent. *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (“[A] sound claim construction need not always purge every shred of ambiguity”). Accordingly, courts are not required to construe lay terms that would be familiar to the trier of fact. However, this Court is under an obligation to construe every claim for which the parties have a “fundamental dispute.” *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

The Federal Circuit’s decision in *Phillips v. AWH Corp.* guides this Court’s analysis of the claims in this case. 415 F.3d 1303 (Fed. Cir. 2005) (en banc). As an initial matter, “it is a bedrock principle of patent law that ‘the claims of a patent define the invention which the patentee is entitled the right to exclude.’” *Id.* at 1323 (quoting *Inova / Pure Water, Inc. v. Safari Water Filtration Sys.* 381 F.3d 1111, 1115 (Fed. Cir. 2004)). *Phillips* reminded courts that “the words of the claim are generally given their ordinary and customary meaning.” *Id.* at 1343. In turn, the “ordinary and customary” meaning of a term “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of invention.” *Id.* at 1313. Language surrounding the claim in question can provide useful contextual clues as to the term’s meaning. *Id.* at 1314.

When the ordinary meaning of a term is not readily apparent, *Phillips* instructs courts to first look at the intrinsic record: the claim, the remainder of the specification, and the prosecution history. *Id.* at 1314–17. The specification is the “best source” for understanding the meaning of a term because “the person of an ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent.” *Id.* at 1315. The patent specification must also contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. *Markman*, 52 F.3d at 978 (quoting 35 U.S.C. § 112). If the specification indicates that the inventor intended to give a certain meaning to a claim, “the inventor’s lexography governs.” *Phillips*, 415 F.3d at 1316.

The prosecution history may also be used to inform claim construction. *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Phillips*, 415 F.3d at 1317 (citing *Markman*, 52 F.3d at 980). The prosecution history includes the complete record of the proceedings before the PTO and it includes all of the prior art cited during examination of the patent application. *Phillips*, 415 F.3d at 1317 (citations omitted). The prosecution history serves as dialogue between the patentee and the patent office, and therefore can provide useful evidence on the meaning of a given term.

Finally, *Phillips* also permits courts to consider extrinsic evidence, albeit as a secondary method of interpretation. *Id.* at 1317 (citing *Markman*, 52 F.3d at 980). Accordingly, courts are permitted to use expert testimony, dictionaries, and learned treatises to aid with the interpretation of terms. “Such evidence, however, is ‘less reliable than the patent and its prosecution history in determining how to read claim terms.’” *Good Tech. Corp. v.*

Little Red Wagon Technologies, Inc., 2013 WL 4052408 (N.D. Tex. Aug. 11, 2013) (citing *Phillips*, 415 F.3d at 1317).

III. ANALYSIS

1. WFUHS' Motion for Summary Judgment

WFUHS' only argument in its motion for summary judgment is that KCI should be judicially estopped from challenging the validity of the patents. Doc. No. 80. In this case, two main factors guide the appropriateness of judicial estoppel: (1) whether KCI is adopting a "clearly inconsistent" position, and (2) whether a court accepted KCI's prior position. *Love*, 677 F. 3d at 161. In addition, this Court may consider whether KCI would derive an unfair advantage or impose an unfair detriment on WFUHS if not estopped. *New Hampshire*, 532 U.S. at 750.

A. *Is KCI's Position "Clearly Inconsistent" with its Prior Positions?*

WFUHS argues that for each of the twelve asserted claims in this case, KCI has at one point taken the position that those claims are not invalid. Doc No. 80 at 16. In the present case, KCI argues that same claims are invalid. On one level, it is clear that KCI's current position is at least somewhat inconsistent with its earlier position because KCI is advocating for a different conclusion than it did in prior cases.³ However, in the context of a validity challenge, KCI's "positional" inconsistency is not as clear as it may initially appear. Determining invalidity for obviousness requires a court to assess the properly construed claims of the patent against the *combination* of prior art on the record before it. *Scimed Life Sys. v. Johnson & Johnson*, 87 F. App'x 729, 734 (Fed. Cir. 2004).

³ At oral argument, counsel for WFUHS referred to this as "positional estoppel."

It is well established that a finding of no invalidity based on one set of prior art does not preclude a court from later finding invalidity based upon a different combination of prior art. In this case, KCI is asserting that a specific combination of prior art (some of which has never been litigated) renders the claims invalid. Since KCI never argued that this specific combination of prior art was insufficient, it technically has not adopted a “clearly inconsistent” position.⁴ When a party argues for validity, it is necessarily defending against the particular combination of prior art at issue in that case. As a formal matter, that party’s position is that the prior art before it is insufficient. A subsequent position is only “clearly inconsistent” if the same combination of prior art is being asserted.

WFHUS argues nonetheless that KCI’s “new evidence” should not excuse its change of position based upon *Bd. of Trustees of Plumbers & Pipefitters Natl. Pension Fund v. Fralick*, 2013 WL 1743869 (N.D. Tex. Apr. 23, 2013) (“*Fralick II*”). In *Fralick II*, the court applied judicial estoppel to prevent a party from changing positions on the basis of new deposition testimony in an employment case. WFUHS argues that *Fralick II* stands for the proposition that new evidence does not excuse a change of position. The Court finds that *Fralick II* is distinguishable because of the inherent differences between employment law and patent law. Substantive patent law recognizes a strong federal policy of encouraging new (and sometimes repeated) challenges to patents. *Lear v. Adkins*, 395 U.S. 653 (1969). There is simply no analogous policy rationale for favoring repeated challenges in the employment law context. Accordingly, it may be appropriate for a court to apply judicial estoppel in an employment case and decline to do so in a patent case. This is especially true in a case such as

⁴ The Court takes note of the fact that KCI knew of the existence of this prior art during its previous litigation. However, this does not ultimately change the analysis. KCI’s “position” in those cases is defined in reference to the prior art asserted by its opponents, not by the entire universe of existing prior art.

this one because it is not entirely clear that KCI is actually asserting a “clearly inconsistent” position. While KCI now advocates for a different outcome, in the unique legal context of validity challenges, KCI may not be asserting a clearly inconsistent position inasmuch as their prior stance on no invalidity was based on the prior art before it at that time.

WFUHS also advances an alternative argument that KCI should be judicially estopped from using any piece of prior art which it once argued did not render one of the patents in suit invalid. This argument mischaracterizes the nature of the obviousness inquiry because a party’s position is defined in reference to the sum of the prior art it asserts (or is defending against). In other words, each individual prior art reference is not by itself significant. WFUHS relies heavily on *Livesay Industries v. Livesay Window Co.*, to support its proposition that these claims should be barred by judicial estoppel. 202 F. 2d 378 (5th Cir. 1953).

In *Livesay*, a patent holder and licensee initially litigated together against would-be infringers, arguing as co-plaintiffs that the patent was valid. After the relationship fell apart, the Fifth Circuit held that the former licensee was estopped from later challenging the validity of the patent at issue. *Id.* at 383 (“Defendant ought to be, we think it is, completely estopped from doing an about face in this case in the same court and forum and repudiating what it had before as solemnly affirmed there”).

Livesay is distinguishable on the grounds that in this case KCI, unlike the former licensee in *Livesay*, is asserting new defenses that were not fully litigated in prior cases.⁵ KCI argues that the *Lear* decision “killed” *Livesay*. (Doc. No. 95 at 42). The Court need not take a position on this issue, because even if *Livesay* is still good law, this Court still retains discretion over whether to apply judicial estoppel. The Court does find that the fact that

⁵ In this case, KCI is asserting new combinations of prior art, along with new § 112 defenses.

Livesay predates *Lear* calls into question *Livesay*'s precedential value, and magnifies the factual distinctions between the two cases. Moreover, the post-*Lear* trend in the case law casts doubt on the appropriateness of judicial estoppel here. *See, e.g., Clark. Equipment v. Keller*, 197 U.S.P.Q. 83 (D. N.D. Sept. 23, 1976) (declining to apply judicial estoppel to bar former licensee from challenging validity of patents, even though there was no difference in the prior art asserted by the licensee and past challengers).

The Court recognizes that this is a strict/formal reading of the “clearly inconsistent” requirement for judicial estoppel. KCI correctly notes that judicial estoppel is context specific, and that when considering its applicability, courts are to consider the public policy surrounding the specific area of the law in question. *Reed v. City of Arlington*, 650, F.3d 571 (5th Cir. 2011). The parties disagree over what the post-*Lear* case law indicates about the appropriateness of estoppel in patent challenges. Although *Lear* does not expressly preclude a court from judicially estopping a former licensee from challenging a patent, the case stands for the proposition that patent challenges are favored. *Lear*, 395 U.S. at 670 (recognizing the “important public interest in permitting full and free competition in the use of ideas which are in reality are a part of the public domain”). Here, KCI has advanced an argument that their position is not, as a matter of law, “clearly inconsistent” with the positions it adopted in earlier cases. Accordingly, the strong federal policy favoring patent challenges suggests that this Court should decline to exercise its discretion to apply judicial estoppel.

B. Were KCI's Earlier Positions “Accepted” by a Court?

The parties disagree over what constitutes “judicial acceptance” of a party’s earlier position such that judicial estoppel is appropriate. Since the Court has narrowly found that

KCI is not advancing a “clearly inconsistent” position, this particular dispute is of less importance. The Fifth Circuit case law on this area of judicial estoppel is unsettled. In *Hall v. GE Plastic*, the Fifth Circuit stated that judicial estoppel could apply when a party makes an argument “with the explicit intent to induce the district court’s reliance... regardless of whether that party prevailed.” 327 F.3d 391, 399 (5th Cir. 2003). Accordingly, WFUHS initially argued that the success of KCI’s prior attempts to enforce these patents was immaterial. However, in *Hopkins v. Cornerstone America*, the Fifth Circuit declined to overturn *Hall*, but noted “its potential inconsistency with our general approach and with the Supreme Court’s analysis in *New Hampshire*.” 545 F.3d 338, 348 *n.2 (5th Cir. 2008). The general approach has been to require actual acceptance by a court. Actual acceptance can be either preliminary acceptance or final acceptance. *In re Superior Crewboats, Inc.*, 374 F.3d 330, 335 (5th Cir. 2004).

One of KCI’s primary arguments is that its positions were not “accepted” by the courts in *Bluesky II* because KCI withdrew as a party before the Federal Circuit reinstated the jury verdict. (Doc. No. 95 at 40). Although not central to its decision on judicial estoppel, this Court expressly rejects this argument. First, the jury verdict constituted a sufficient preliminary acceptance of KCI’s position. Second, the logical effect of the Federal Circuit’s decision to overturn the district courts’ JMOL order was to reinstate the jury’s decision. Accordingly, KCI’s positions in that case were accepted by the court, both as a preliminary and final matter.

C. Does Fairness Compel Judicial Estoppel in this Case?

Another factor to consider is whether judicial estoppel is necessary to prevent KCI from obtaining an unfair advantage or to prevent WFUHS from suffering an unfair detriment. The parties disagree vehemently over this point. As an initial matter, the Court agrees with KCI that it is not “unfair” to require WFUHS to defend its patents. At the same time, however, KCI’s claim that WFUHS is trying to hold them in an “unfair” bind is unpersuasive. The “bind” that KCI finds itself in is the result of the Licensing Agreement to which it freely agreed. Although this Court declines to apply judicial estoppel today, it reiterates that its decision is grounded in the strong federal policy favoring patent challenges, and accordingly the Court takes no position on which party has the better of the fairness arguments.

Ultimately, WFUHS’ motion for summary judgment requires this Court to balance two competing interests. On the one hand, there is the interest in judicial integrity protected by judicial estoppel, and on the other is the strong public interest in promoting patent challenges. Based upon: 1) the argument that KCI is not, as a matter of law, advancing a “clearly inconsistent” position; and (2) the strong federal policy favoring patent challenges, this Court declines to grant summary judgment based on judicial estoppel. Accordingly, the Court must therefore construe the claims at issue in this case.

2. Claim Construction

a. “Healing”

This term appears in the ‘081 and ‘651 patents. KCI proposes construing this term as “improving the condition.” WFUHS argues for ordinary meaning. In the alternative, WFUHS argues that this term must be construed consistently with the Federal Circuit’s treatment of “healing” as used in the phrase “selected stage of healing” to require “facilitat[ing] wound

closure.” *Bluesky I*, 554 F.3d 1010, 1015 (Fed. Cir. 2009); *Bluesky II*, 688 F.3d 1342, 1361 (Fed. Cir. 2012)).

KCI argues that “healing” should not be defined solely in reference to wound closure. In support, KCI points out examples of dependent claims where the “selected stage of healing” contains additional limitations such as “substantially filling the wound with granulation tissue” or “migration of epithelial and subcutaneous tissue toward the wound.” *Id.* at col. 30, rows 26-29. KCI states that “[b]ecause the degree of closure is just one type of wound condition that may be improved . . . the term ‘healing’ must encompass more conditions than the narrower term ‘wound closure.’” Doc. No. 75 at 12-13. KCI argues that other dependent claims confirm that “wound closure” is narrower than the term “healing.”

The Federal Circuit has found a presumption that where a particular limitation is added in a dependent claim, that limitation it is not necessarily present in the independent claim. *Phillips*, 415 F.3d at 1314-1315. Here, the examples cited by KCI are additional limitations on the phrase “selected *stage* of healing.” Under *Phillips*, the examples cited by KCI constrain the specific stage language and not the express term “healing.” Therefore, KCI’s use of these examples to imply that the construction of “healing” must include more than wound closure does not persuade the Court.

In response, WFUHS argues that the intrinsic evidence supports construing the term “healing” with some reference to wound closure. WFUHS calls the Court's attention to the background of the disclosure where it refers to the purpose of the invention – to address open wounds that are too large to spontaneously close. ‘651 Patent col 1, lines 29-33. WFUHS then notes that the specification plainly states that the patented techniques are directed at closing

such wounds *Id.* at col. 4, lines 18-23. The Court agrees that the invention itself is intended to close wounds and that wound closure is not merely one intended use. For example, the specification describes the invention as:

[A] method of treating tissue damage is provided which comprises applying a negative or reduced pressure to a wound over an area sufficient to promote the migration of epithelial and subcutaneous tissue toward the wound and for a time period sufficient *to facilitate closure of the wound.*

‘651 Patent at 4:18-23 (emphasis added). Thus, the specification itself provides support for WFUHS’ proposed limitation on “healing” to require some reference to wound closure. *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1317 (Fed. Cir. 2006) (Limitations should come from the specification and not preferred embodiments of claims). One of ordinary skill in the art would understand the examples provided in the patents as various stages of the overall healing process. In other words, in the context of these patents, the healing process refers to the closure of wounds too large to spontaneously close on their own. Accordingly, the Court construes “healing” to be facilitating wounds towards closure.

b. “Selected Stage of Healing”

This term appears in both the ‘651 and the ‘643 patents. KCI argues that this term should be construed as “improved condition of a wound.” WFUHS argues for ordinary meaning. In the alternative, WFUHS contends that the term must be construed consistently with the Federal Circuit’s treatment of the phrase “selected stage of healing” as requiring “facilitat[ing]” wound closure.” *Bluesky II*, 688 F.3d at 1364.

WFUHS contends that the Federal Circuit made an implicit construction of the term “selected stage of healing” in *Bluesky II* as requiring facilitating wound closure. In support of

their contention, WFUHS cites language where the Federal Circuit drew a distinction between the prior art references at issue and the patented techniques disclosed in these patents. For example, the Federal Circuit found that:

Zamierowski ... uses a tubing system to medicate and drain wounds, and thereby 'promote[] healing' generally ... it does not disclose the use and maintenance of *negative pressure* on a wound site to *facilitate wound closure* and thereby promote wound healing, as do the patents.

Bluesky II, 688 F.3d at 1362 (emphasis added). In a concurring opinion, the Federal Circuit added that, “it is simply not possible to meaningfully address the question of obviousness without construing these limitations” *Id.* at 1272 (Dyk, J. concurring). WFUHS uses this language to argue that: (1) the term has already been construed by the Federal Circuit and is thus binding on this Court; and (2) that the Federal Circuit’s construction requires reference to the phrase “facilitating wound closure.”

KCI counters with the observation that the dependent claim language in both the ‘643 and ‘651 patents provide examples of different stages of healing. For example, KCI observes that dependent claims 31 and 32 of the ‘643 patent provide “cessation of partial thickness burn progression” ‘643 patent at col. 25, lines 1-6, and “reduction in bacterial density in the wound by at least 50%.” *Id.* at col. 25, lines 7-13, respectively. KCI argues that these additional limitations imply that the phrase "selected stage of healing" must be broader than facilitating wound closure and that therefore WFUHS’ suggested construction is meritless.

The Court agrees with the observation that the Federal Circuit recognized a distinction between the prior art reference and the techniques and apparatuses described in these patents. However, with respect to the Federal Circuit recognizing the use of negative pressure, the Court finds that all of the asserted claims require the use of negative or reduced pressure as an

express limitation contained in the claim language. The express objective of these patents is to facilitate wound closure. '651 Patent col 1, lines 29-33. Consequently, the Court interprets the above-mentioned language from the *Bluesky II* as an observation by the Federal Circuit of subject matter expressly disclosed by the Patents. Accordingly, *stare decisis* does not apply and the Court is not bound to construe “selected stage of healing” as requiring any reference to “facilitating wound closure”

As to its preferred construction, KCI argues that the '643 and '651 patent specifications provide examples of what constitutes a “selected stage of healing.” Both specifications provide that:

A selected state of improved condition may include formation of granulation tissue sufficient for the attachment of a flap or graft, reduction of microbial infection in the wound, arrest or reversal of burn penetration, closure of the wound, integration of a flap or graft with the underlying wounded tissue, complete healing of the wound, or other stages of improvement or healing appropriate for a given type of wound or wound complex.

'643 patent at col 12, lines 46-54; '651 patent at col. 12, lines 59-66. Again, KCI contends that these examples demonstrate that the proper scope for “selected stage of healing” must be sufficiently broad to include all examples of healing. As such, KCI argues that “improved condition of a wound” properly encompasses all examples of “selected stage of healing.”

As with their proposed construction of “healing,” KCI again runs into the presumption that where a particular limitation is added in a dependent claim, that limitation is not necessarily present in the independent claim. *Phillips*, 415 F.3d at 1314-1315. The dependent claim examples cited by KCI are additional limitations on the term “stage” in the phrase “selected stage of healing” and thus are necessarily narrower than the related independent

claims. Looking at the words of the claims themselves, claim 11 of the '643 patent is representative and recites (emphasis added):

11. A method treating a wound comprising the steps of:
 - (a) applying a reduced pressure to the wound, wherein said applying step comprises the steps of:
 - (i) placing a porous screen over the wound;
 - (ii) locating an impermeable cover over the wound, said cover having a suction port;
 - (iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and
 - (iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and
 - (b) maintaining said reduced pressure until the wound has progressed toward a *selected stage of healing*.

Claim 20 of the '651 patent is also representative and recites (emphasis added):

20. A method for treating a wound, comprising:
 - i. locating a flexible adhesive cover over the wound to provide a chamber between the cover and the wound, said cover adapted for maintaining reduced pressure at the wound;
 - ii. adhesively sealing and adhering the periphery of said cover to tissue surrounding the wound;
 - iii. operably connecting a vacuum system with said chamber at said seal for producing said reduced pressure;
 - iv. interposing a fluid trap between said cover and said vacuum system; and
 - v. maintaining reduced pressure to promote the formation of granulation tissue at the wound until the wound has progressed toward a *selected stage of healing*.

Claim 20, '651 Patent. Observing the context of the contested phrase in each of the independent claims of both the '643 and '651 patents, the phrase is consistently recited in the context of the wound having "*progressed* toward a selected stage of healing." Implicit in this language is the notion that healing is a process. At some point in this process, a medical provider may choose to discontinue use of the negative pressure once the wound has achieved a "selected stage of healing." This stage could be substantial wound closure as recited by

claim 118 of the ‘651 patent. It could also be when the wound was substantially filled with granulation tissue as recited by claim 119 of the ‘651 patent. One of ordinary skill in the art would understand the examples provided as various stages in the process of wound closure. A “selected stage of healing” therefore may be a point in the healing process where a decision is made to discontinue or change the use of the patented device and/or technique. Accordingly, the Court construes the phrase “selected stage of healing” to have its ordinary and customary meaning.

c. “Wound”

This term appears in the ‘081, ‘643, and ‘651 patents. KCI proposes construing it as “tissue damage to the surface of the body, including the epithelial and subcutaneous layers, and excluding fistulae and pus pockets not accompanied by tissue damage to the surface of the body.” WFUHS argues for ordinary meaning, or in the alternative, for the construction WFHUS argues was adopted by the Federal Circuit (“Tissue damage to the surface of the body, including the epithelial and subcutaneous layers, and excluding fistulae and pus pockets.”) *Bluesky I*, 554 F.3d at 1016; *Bluesky II*, 688 F.3d at 1352.

The parties agree that the Federal Circuit has held that “wound” does not include fistulae or pus pockets. Doc. No. 75 at 16; Doc. No. 83 at 5. The question, therefore, is whether this Court is at liberty to add “additional clarifying language,” as KCI proposes. Specifically, KCI wants the limitation on wound accepted by the Federal Circuit (no fistulas or pus pockets) not to include those fistulae and pus pockets which are accompanied by “tissue damage to the surface of the body.” Put another way, KCI argues that there are two relevant varieties of fistulae and pus pockets, ones with tissue damage to the surface of the body and

ones without. KCI wants the Court to construe “wound” to include certain pus pockets and fistulae (i.e. those accompanied by tissue damage). The Court agrees with WFUHS that such a reading is foreclosed by the Federal Circuit’s decisions in *Bluesky I* and *Bluesky II*.

Support for this proposition comes from the Federal Circuit’s analysis of the prior art at record in *Bluesky I* and *Bluesky II*. In *Bluesky I*, the Federal Circuit held that “wound” did not include “the fistulae described in the Chariker-Jeter publications and the ‘pus pockets’ described in the Davydov references.” *Bluesky I*, 554 F.3d at 1018. Both the Chariker-Jeter and Davydov references dealt with pus pockets or fistulae that could be accompanied by tissue damage. By holding that these references fell outside of the meaning of “wound” within the asserted claims, the Federal Circuit necessarily held that “wound” did not include fistulae or pus pockets which were accompanied by tissue damage. Similarly, in *Bluesky II*, the Court considered the Baugutinov prior art that referenced tissue damage in conjunction with a pus pocket. *Bluesky II*, 688 F. 3d at 1361. By ruling that pus pockets were not part of its definition of “wound” by referencing this specific prior art, the Federal Circuit has conclusively determined that, in the context of these patents, “wound” does not include those fistulae or pus pockets that are also accompanied by tissue damage. Based upon *stare decisis*, this Court construes “wound” to mean, “tissue damage to the surface of the body, including the epithelial and subcutaneous layers, and excluding fistulae and pus pockets.”

d. “Treating”

This term appears in the ‘643 and ‘651 patents. KCI proposes construing it as “giving medical care to.” WFUHS argues for ordinary meaning. In the alternative, WFUHS argues for construction consistent with the Federal Circuit’s construction of “treating a wound” as

requiring “treating a wound with negative pressure.” *Bluesky I*, 554 F.3d at 1016; *Bluesky II*, 688 F.3d at 1363. As to WFUHS’ *stare decisis* argument, the Federal Circuit determined in *Bluesky II* that:

[t]he district court was incorrect with respect to its determination that the claims of the asserted patents do not require wounds to be healed by negative pressure. First, in the *Blue Sky appeal*, we concluded that all of the claims of the '081 patent asserted in the present litigation require the use of negative pressure to treat a “wound.” . . . Thus, we have already construed the claims to include this limitation and that legal conclusion was binding on the district court and is binding on this panel . . . In light of our prior holding in [*Bluesky I*], the language of the specification, and the patentee's statements made during reexamination, we find that each of the asserted claims requires the use of negative pressure to heal or treat wounds.

Bluesky II, 688 F.3d at 1363. The Federal Circuit has therefore already found that the asserted *claims* require the use of negative pressure. This conclusion is binding on this court under principles of *stare decisis*. Each of the asserted claims in this case has an express limitation requiring the use of negative pressure and the parties agree on this point. Doc No. 75 at 28-29; Doc No. 76 at 18. However, contrary to WFUHS’ argument, the Federal Circuit has not provided a construction of the express term “treating” as has been requested by the parties here. In this case, the parties did not request the Court to construe the phrase “treating a wound.” A construction of an express term need not repeat what is already a requirement of the claim by its elements. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Accordingly, *any* construction by this court of the express term “treating” would be consistent with the Federal Circuit's determination in *Bluesky II* because the claim limitations already incorporate the use of negative pressure in all of the asserted claims. There is no need to duplicate that limitation from the claim language into the Court’s

construction of the term “treating.” Therefore, *stare decisis* does not directly apply with respect to “treating,” even though the overall claims require the use of negative pressure.

Both WFUHS’s proposal of ordinary meaning and KCI’s proposal of “giving medical care to” require the Court to consider to what extent a term in the preamble is limiting. A preamble may be limiting if “it recites essential structure or steps [or] is 'necessary to give life, meaning and vitality' to the claim.” *Id.* at 808 (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). The term “treating” appears in the preamble of each of the asserted claims. Terms that appear in the preamble of a patent claim are usually not regarded as limitations of scope. *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 13146 (Fed. Cir. 2002). A preamble is not limiting if the remainder of the claim recites a structurally complete invention. Likewise, if the preamble was not added to distinguish the invention from prior art, it is usually not found limiting. *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002). A preamble has no separate limiting effect if it “merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention.” *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1359 (Fed. Cir. 2010) (citing, *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434–35 (Fed. Cir. 2000)).

Claim 29 of the '643 patent is representative and recites:

29. A method of *treating* a wound comprising the steps of:
 - (a) applying a reduced pressure to the wound; and
 - (b) maintaining said reduced pressure until the wound has progressed toward a selected stage of healing, wherein said maintaining of said reduced pressure is conducted in alternating periods of application and non-application of the reduced pressure.

There is no suggestion by the parties nor can the Court locate in the prosecution history that the inventors added the term “treating” in order to distinguish their invention from the prior art. The express term “treating” does not embody an essential component of the invention but rather is a descriptive label stating the purpose or intended use of the claimed invention. Accordingly, under well-settled principles, it is not necessary for the Court to construe “treating,” the parties’ dispute over the term notwithstanding. *Altris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed. Cir. 2002) (“It is well settled that the if body of the claim sets out the complete invention, and the preamble is not necessary to give life, meaning, and vitality to the claim, then the preamble is of no significance to claim construction.”). The Court finds that “treating” is a descriptive term that does not add to the definitions already contained in the claims themselves. Accordingly, no construction is required.

e. “Area of skin including and surrounding the wound”

This term appears in the ‘081 patent. KCI proposes construction as “area of outer surface skin including and surrounding the wound.” WFUHS argues for ordinary meaning. KCI seeks to add the phrase "outer surface" to the contested phrase because the specification does not disclose applying negative pressure to any other surface other than the outer surface.

KCI contends that the specifications and claims do not expressly disclose applying negative pressure to any dimension of skin other than the outer surface. In light of that absence of disclosure, KCI asserts that negative pressure is applied only to a two-dimensional area of skin including and surrounding the wound, and not to a three-dimensional volume of skin. Doc. No. 84. KCI argues that the Court must construe the claim to only include that area. Claims are not necessarily limited to the disclosed embodiments. *Phillips*, 415 F.3d at

1323. In addition, claims should not normally be construed to exclude the preferred embodiment. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The preferred embodiment of the '081 Patent discloses:

A preferred embodiment of the invention . . . comprises a substantially flat section of open cell polyester foam . . . sufficiently large to cover the wound and thus prevent wound overgrowth, a flexible hollow tube . . . inserted into the open cell foam section . . . and joined thereto with an adhesive and extending to attach at its opposite end to a Gast Vacuum pump . . . and an Ioban adhesive sheet . . . overlying the foam section . . . and tubing . . . and adhered to the skin surrounding the wound, thus forming a seal that allows creation of a vacuum when the suction pump operates.

'081 Patent, Col. 5, Lines 23-35.

The specification goes on to describe the invention in the numerous examples provided in the description. One example cites the vacuum or negative pressure increasing the vascularity. Another cites the negative pressure as decreasing the depth of the wound dramatically. One of ordinary skill in the art would understand the operation of the preferred embodiment to operate on width, length, as well as depth, of the disclosed wound complex. Construing an additional limitation into the claim language that confines the application of negative pressure to a 2-dimensional surface, would run counter to the preferred embodiment and numerous examples provided in the description.

The Court also finds that KCI's "outer surface" proposed language lacks support in the specification. One of ordinary skill in the art would understand the meaning of the phrase "area of skin including and surrounding the wound" after reading the entire specification. Accordingly, the Court construes the term to have its ordinary and customary meaning, within the context of the Court's construction of the express term "wound."

f. "Tissue surrounding the wound"

This term appears in the ‘651 patent. KCI proposes construing it as “outer surface of tissue surrounding the wound.” WFUHS argues for ordinary meaning. KCI seeks to add the phrase "outer surface of" to the contested phrase because the specification does not disclose adhering to any surface of the skin other than the outer surface.

As an initial matter, KCI’s proposed addition of “outer surface of” lacks affirmative support in the specification. Additionally, construction should not usually be limited to specific disclosed embodiments. *Phillips*, 415 F.3d. at 1323. This is precisely what KCI suggests here. KCI seeks to imply a limitation based upon the absence of an express disclosure of other any other surface of the skin where the cover may be adhered. Doc. No. 84 at 26. This method of construction is not supported by case law. Moreover, the Court has already construed the term “wound.” A layperson on a jury can readily determine how much tissue counts as “tissue surrounding the wound” without further construction. Perhaps more importantly, further defining the term would only add to the jury’s confusion. Accordingly, Court construes the phrase to have its ordinary and customary meaning, within the context of the Court’s construction of the express term “wound.”

CONCLUSION

In light of the foregoing analysis, WFUHS’ motion for summary judgment is DENIED. Doc. No. 80. As described herein, the contested claims are construed as follows:

Term	Construction
Healing	Facilitating wounds towards closure
Selected Stage of Healing	Ordinary Meaning
Wound	Tissue damage to the surface of the body, including the epithelial and subcutaneous layers, excluding fistulae and pus pockets.

Treating	No construction required
Area of Skin Including and Surrounding the Wound	Ordinary Meaning
Tissue Surrounding the Wound	Ordinary Meaning

SIGNED this 25th day of November, 2013.



XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE