

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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| BIOTRAS, LLC, | § | |
| | § | |
| Plaintiff, | § | |
| v. | § | |
| | § | Civil Action No.: 3:16-CV-00566-K |
| CLEAR BALLISTICS, LLC and | § | |
| JOEL EDWARDS, | § | |
| | § | |
| Defendants. | § | |

MARKMAN MEMORANDUM OPINION AND ORDER

Before the Court are the parties’ briefs on the issue of claim construction of the patents in suit: U.S. Patent Number 9,275,556 (“the ‘556 Patent”); U.S. Patent Number 9,280,915 (“the ‘915 Patent”); U.S. Patent Number 9,378,661 (“the ‘661 Patent”). The Court has reviewed the parties’ briefs and all related filings and evidence, including the patents in suit, the specifications, the patent prosecution histories to the extent it was submitted by the parties, as well as the parties’ proposed claim constructions and arguments. The Court hereby construes the disputed claims according to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 360 (1996).

I. Background

A. Procedural

This dispute stems from a prior business relationship between the Plaintiffs and Defendants regarding the creation, research, and development of certain patented

inventions. The patents in suit regarding these inventions are currently owned by Biotras, LLC. The Defendants assert that they should be included as an inventor or owner of the patents in suit based on their involvement in the creation of the invention.

The parties assert that, in order to resolve this inventorship dispute, it is necessary for the Court to construe disputed claim phrases under the Court's authority under *Markman*, 52 F.3d 967.

B. The Patents in Suit

All three patents in suit address very similar inventions used for medical training. In general, the inventions are models that mimic parts of a body. The form of the body is made from a gel, such as a ballistic gel. Ballistic gels are synthetic gels that were developed to mimic the consistency and density of human tissue. Ballistic gels were originally developed for testing the effect of projectiles fired from firearms on human tissue. Because ballistic gels have properties that mimic the consistency and density of human tissue, they also mimic the tactile feel and response of human tissues. The inventions of the patents take advantage of these properties of ballistic gels to create a model that can be used for medical training that provides a simulated human body with realistic tactile response.

The particular embodiments of the inventions provide examples of these models. These examples have at least part of a human torso shape formed from ballistic gel, with a human spinal column embedded into the gel. The patents also described the addition of other components of the model that may be included, such as simulated vertebral

discs between the sections of the spinal column. The net effect is to create a model that is anatomically correct and has tactile properties similar to human tissue.

Another aspect of ballistic gels is that they are generally clear. This allows teachers and students using the model to observe the inside portion of the model, and in particular to see the bones placed within the model.

One disclosed use of the models is to use the models for injection training for injections that are placed between the vertebrae of the spinal column. Because the model responds like human tissue, it gives the user realistic tactile feedback, and because the gel is clear, both students and teachers can observe the injection path and the final placement of the needle used for injection.

Another aspect of the invention is a feature that allows for old needle tracks to be removed from the models after use of the models. The gel used for the models softens and flows when heated. Old needle tracks can be removed from the models by heating the gel until it becomes flowable. The gel then fills in the void created by the needle. After the gel cools, the old needle tracks are gone and the models are ready for use again without interference from the old needle tracks. The patents describe embedding heaters into the gel near the locations of expected needle tracks for this purpose.

II. Applicable Law

A. Principles of Claim Construction

Claim construction is a matter of law. *See Markman*, 52 F.3d at 979. The Federal Circuit Court has held that “the claims of a patent define the invention to which the

patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quotation marks omitted). The Supreme Court has stated that the claims are “of primary importance, in the effort to ascertain precisely what it is that is patented.” *Phillips*, 415 F.3d at 1312 (quotation marks omitted). A court looks to three primary sources when determining the meaning of claims: (1) the claims, (2) the specification, and (3) the prosecution history. *Markman*, 52 F.3d at 979. The claims of the patent must be read in view of the specification of which they are a part. *Id.* The specification consists of a written description of the invention which allows a person of ordinary skill in the art to make and use the invention. *Id.* This description may act as a dictionary explaining the invention and defining terms used in the claims. *Id.* Although a court should generally give such terms their ordinary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, so long as the special definition of the term is clearly stated in the patent specification or file history. *See Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The court starts with the claim itself, read in light of the specification. *See Vivid Techns., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999). While the claims themselves provide significant guidance as to the meaning of a claim term, the specification is generally dispositive as “it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1314-1315. In addition to the claim language and specification, the prosecution history is often helpful in understanding the intended

meaning, as well as the scope of technical terms in the claims. *See Vivid*, 200 F.3d at 804. In particular, the prosecution history is relevant in determining whether the patentee intends the language of the patent to be understood in its ordinary meaning. Using these tools, the court construes only the claims that are in controversy and only to the extent necessary to resolve the dispute. *Id.* at 803.

The words of a claim are usually given their ordinary and customary meaning. *See Phillips*, 415 F.3d at 1312. Ordinary and customary meaning is the meaning the claim term would have to a person of ordinary skill in the art (e.g., field of the invention). *See id.* at 1313; *Markman*, 52 F.3d at 979. A person of ordinary skill in the art would read the claim term in the context of the entire patent, including the specification, not just the particular claim where the term appears. *Phillips*, 415 F.3d at 1313. There are instances where the ordinary meaning of claim language, as a person of skill in the art would understand it, “may be readily apparent even to lay judges,” thereby requiring “little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. In these situations, general purpose dictionaries are useful. *Id.*

But, in many cases, the court must determine the ordinary and customary meaning of the claim terms which have a certain meaning in a field of art. *Id.* The court can look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* These sources can include “the words of the claims themselves, the remainder of the specification, the

prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of the technical terms, and the state of the art.” *Id.*

Aside from the written description and the prosecution history, the claims themselves also offer assistance as to the meaning of certain claim terms. *Id.*

When the intrinsic evidence, that is the patent specification and prosecution history, unambiguously describes the scope of a patented invention, reliance on extrinsic evidence, which is everything outside the specification and prosecution history, is improper. *See Vitronics*, 90 F.3d at 1583. While the Court may consult extrinsic evidence to educate itself about the invention and relevant technology, it may not rely upon extrinsic evidence to reach a claim construction that is clearly at odds with a construction mandated by the intrinsic evidence. *See Key Pharm. v. Hercon Lab. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998).

III. Construction of the Patent Claims and Terms

A. The Disputed Claim Phrases

The parties dispute the meaning of certain phrases used in the claim language of the patents in suit. The parties disagree to as to the meaning of the following phrases:

- “visibly clear,” which occurs in claims 1 and 12 of the ‘556 patent; claim 1 of the ‘915 patent; and claims 1-4, 6, 7, 11, 14, and 18 of the ‘661 patent.
- “thermally fusible,” which occurs in claims 1 and 12 of the ‘556 patent; claim 1 of the ‘915 patent; and claims 1-4, 6, 7, 11, 14, and 18 of the ‘661 patent.
- “visibly clear, thermally fusible,” which occurs in claims 1 and 12 of the ‘556

patent; and claim 1 of the '915 patent. The Defendants argue that this phrase should also be applied to the claims of the '661 patent.

- “synthetic gel matrix,” which occurs in claims 1, 7, 8, 12, 17, and 18 of the '556 patent; claims 1 and 9 of the '915 patent; and claim 10 of the '661 patent.
- “skeletal structure,” which occurs in claims 1, 2, 11, 12, 13, and 21 of the '556 patent and claims 1, 6, 8, 11, 13, 17, and 18 of the '661 patent.
- “partial human torso,” which occurs in claims 1, 10, 12, and 20 of the '556 patent and claims 1 and 9 of the '915 patent.
- “training and injection practice,” which occurs in claims 1 and 12 of the '556 patent.
- “thermoplastic elastomer matrix,” which occurs in claims 1, 2, 3, 4, 7, 11, 14 and 18 of the '661 patent.

The full language of all of the claims of each patent in suit are in the record before the Court and the Court has fully reviewed all the claims of these patents, including those containing the disputed phrases. The Court finds no need to repeat the full language of those claims in this order.

B. Construction of Disputed Claim Phrases

1. “Visibly clear”

The Parties dispute the meaning of “visibly clear,” which is used in claims 1 and 12 of the '556 patent; claim 1 of the '915 patent; and claims 1-4, 6, 7, 11, 14, and 18 of the '661 patent. The Plaintiffs assert that the phrase does not need construction and

should be given its plain and ordinary meaning. In the alternative, Plaintiffs propose the phrase be construed to mean “transparent.” The Defendants assert that the phrase should be construed to mean “transparent and colorless.”

The real dispute between the Parties for the construction of this disputed phrase involves whether or not the gel or elastomer should be colorless. The Plaintiffs propose that, if construction is necessary, the phrase simply be construed to mean “transparent” and that this is essentially the plain meaning of the phrase. The Defendants also acknowledge that the gel or elastomer is transparent. The Defendants include this as part of their proposed construction of the phrase. But, the Defendants also add the requirement that the gel or elastomer also be colorless. Since there is no real dispute over the “transparent” limitation of this construction, the Court will only address the “colorless” limitation proposed by the Defendants.

The Plaintiffs argue that applying a colorless limitation to the disputed phrase would be improper because doing so would add a limitation to the claims that is not supported by the specifications of the patents. The Plaintiffs point out that nothing in any of the claim language requires the gel or elastomer to be colorless and that the specifications only once refer to ballistic gels being colorless.

The Defendants argue that the gel or elastomer must be colorless. In support of this argument the Defendants direct the Court’s attention to the file wrapper of the ‘556 patent and the ‘915 patent. In the file wrapper, the prosecuting attorney made certain remarks regarding the differences between the claimed invention and the prior

art, and the examiner, in a notice of allowance, noted the information contained in this response as part of the reasoning for allowing the claims. The Defendants argue that the inventors silence as to the examiner remarks should be taken to mean the inventor agreed and adopted the remarks and reasoning of the examiner. According to the Defendants, this supports the colorless limitation.

While an inventor, in certain circumstances, may be held to adopt an examiner's comments and reasoning or may be limited by assertions made during prosecution, the Court does not need to determine if that is the situation here because the attorney arguments and examiner comments do not support the Defendants "colorless" limitation, even if these should be imposed upon the claim language. The Court has reviewed these attorney remarks and examiner comments, all of which are in the record before the Court. The Court sees no need to reproduce these within this order. The attorney remarks and examiner comments are directed toward prior art that used an opaque matrix and distinguished the difference between the opaque prior art, which one cannot see through, and the claimed inventions, which use a gel that one can see through. The remarks and comments also address other prior art that uses a visibly clear gel, but in that case, the gel was a fluid gel that did leave needle tracks in the gel.

More importantly, for the purposes here, the remarks and comments in no way discuss that the gel or elastomer must be colorless. The remarks and comments do not address the color or absence of color of the claimed inventions or the prior art. The extent of the subject of discussion in the remarks and comments is limited to the

unique feature of the claimed invention, the ability of the gel or elastomer to leave needle track marks that can be seen by users and others. This does not involve the color of the material at all. Stating that an object is opaque or clear does not refer to the object's color. This only refers to being able or not able to see through the object. So the attorney arguments and examiner's comments only concern the ability to see through the gel and the gel's ability to hold needle tracks marks, which does not provide any support for the Defendants' "colorless" limitation. So, even if the inventor adopted the examiner's comments, these would not support the construction that the Defendants now propose.

The Defendants also appear to argue that the patent specifications support the "colorless" limitation. In support of this, the Defendants point toward specification language that refers to the invention using a "matrix of crystal clear ballistic gel" and other similar comments about the clarity of the gel. '556 patent 1:18-20, 2:34-37, 2:47, 2:54-55, 2:66-67; '915 patent 1:14-17, 2:29-32, 2:41, 2:48-49, 2:60-62. The Defendants also note that the specifications state that "synthetic ballistic gels have been formulated to mimic the properties of natural gelatin, but are odorless and colorless." '556 patent 1:53-55; '915 patent 1:53-55.

The Court finds that these do not provide any more support for the "colorless" limitation than the file wrappers. Like the examiner comments in the file wrapper, the statements regarding the "crystal clear ballistic gel" and other statements about the gel properties all relate to the ability to see through the gel or elastomer, not to the color of

the gel or elastomer. The only mention of ballistic gel being colorless is in a general statement regarding common properties of currently commercially available ballistic gels. This reference does not tie the claimed and described invention to a colorless gel. It is merely a general statement about the properties of commercially available ballistic gels. And, the specific descriptions of the inventions provided in the specifications also do not refer to the color of the gel. So, this does very little to support the inclusion of “colorless” in the construction of this disputed phrase.

So, neither the claim language, the specification language, nor the file wrapper support the Defendants’ proposed colorless limitation. For these reasons, the Court finds that construing the disputed phrase to require the gel or elastomer to be colorless would improperly limit the claims of the patents in suit.

The Plaintiffs propose that this phrase does not need any construction. In support of this contention that “visibly clear” does not need construction, the Plaintiffs direct the Court’s attention to claim language that requires needle tracks formed by inserting a needle into the gel or elastomer should be visible to an external viewer, like what is required in claim 1 of the ‘556 patent. Other claims of the patents in suit have the same requirement. And the patent specifications also repeatedly describe the claimed inventions as being made from a gel or elastomer that one can see through.

The Court agrees with the Plaintiffs that the claims and specifications provide ample support for requiring that the gel be one that a person can see through, but the Court finds that there is no significant difference between the claim language “visibly

clear” and the proposed construction “transparent.” Transparent means that a material is clear enough that one can see through the material. This is the same meaning that a person having ordinary skill in the art would understand “visibly clear” to mean, as it is used in the claim language. Both the language of the claims and the specifications of the patents support this by repeatedly referring to the ability of a user or observer to see through the gel or elastomer so that needle tracks can be seen. Transparent is the plain and ordinary meaning of “visibly clear” as it is used in the patents and what would be understood by a person of ordinary skill in the art to be the meaning of this phrase as it is used in these patents. For this reason, the Court finds that there is no need to construe the disputed phrase because the proposed construction does not add any clarity to the disputed phrase beyond its plain and ordinary meaning.

In summary, the patents and the patent histories do not support inclusion of a colorless limitation into the disputed phrase and the phrase “visibly clear” does not need any construction because, in these patents, it is used so that it has its plain and ordinary meaning. For these reasons, the Court declines to construe “visibly clear” and directs that the phrase shall be given its plain and ordinary meaning.

2. “Thermally fusible”

The Parties dispute the meaning of “thermally fusible” as it is used in Claims 1 and 12 of the ‘556 patent; claim 1 of the ‘915 patent, and claims 1-4, 6, 7, 11, 14, and 18 of the ‘661 patent. The Plaintiffs argue the phrase does not need construction and should be given its plain and ordinary meaning and in the alternative, if construction is

necessary, then the phrase should be construed to mean “a flowable state upon the application of heat.” The Defendants propose that the phrase be construed to mean “application of heat to a material that causes the material to become flowable, when the heat is removed, the material solidifies and adheres to itself, other materials, or joins other materials.”

In support of Plaintiffs’ contention that “thermally flowable” should be construed as “a flowable state upon the application of heat,” the Plaintiffs argue the patent specifications support this construction. They point toward specification language that describes the feature of the invention that allows “needle tracks to be erased.” This language describes the ability of a person to reset the gel or elastomer to its original state after being used by heating the gel or elastomer. The Plaintiff argues that feature of the gel to be heated so that it flows and fills the voids by the needle relates to the phrase “thermally fusible.” The Plaintiffs also argue that the Defendants’ proposed construction improperly adds limitations that the material must adhere to other material or joins other materials because these limitations are not supported by the patents or the patent histories.

The Defendants propose that the phrase should be construed to mean “application of heat to a material that causes the material to become flowable, when the heat is removed, the material solidifies and adheres to itself, other materials, or joins other materials.” In support of their proposed construction, the Defendants cite to the same prosecution history that they used to support their construction of visibly clear.

They argue that the attorney arguments, the examiners comments, and the inventor's silence as to the examiner's comments supports such a construction.

The Court is of the opinion that neither of the proposed constructions fully captures the meaning of "thermally fusible," as it is used in the patents in suit and as it would be understood by a person having ordinary skill in the art. While the Court agrees with both parties that the gel or elastomer becomes flowable when heated, the Court finds that the Plaintiffs' proposed construction falls short by not including the requirement that the gel or elastomer fuses to itself, but the Court also finds that the Defendants' proposed construction improperly adds limitations requiring the gel or elastomer to adhere to other materials or join other materials. The claims themselves, the specifications of the patents, and the prosecution history all support these findings.

The specifications of the patents fully disclose what is meant by "thermally fusible." The specifications describe that when the inventions are used, a person inserts a needle into the device for practice or training purposes. The gel or elastomer is pierced by the needle and does not reform or fuse together to close the needle track. This leaves the needle track visible, so the user or observer can determine if the correct approach and path of the needle was used. Since the tracks do not automatically close, after repeated use it may become difficult to distinguish between a new track and older tracks from previous use. In order to solve this problem, the invention has a feature by which the old needle tracks can be removed.

This is accomplished by heating the gel or elastomer. Heating the gel or

elastomer near its melting point causes the gel or elastomer to become soft, so that it flows. The flowing gel then fills in the voids created by the needle. Once cool again, the gel or elastomer reattaches to itself, thereby removing the needle tracks. This all supports the argument that a person of ordinary skill in the art would understand that “thermally fusible” includes both the ideas that the gel or elastomer is flowable when heated and that it adheres to itself when cooled.

Other claim language also supports this meaning of “thermally fusible.” For example, claim 1 of the ‘556 patent requires that the invention function as just described. One element of this claim is:

wherein visible needle tracks are formed in the synthetic gel matrix, resulting from the needle penetration and extraction of a needle along the path of the needle after inserting at a point on the contoured surface to a target below the contoured surface, at least a portion of the needle tracks extending along the path remaining visible until the needle tracks are fused closed with a heat source, whereby the needle tracks are fused closed upon heating the synthetic gel matrix such that the needle tracks are no longer visible in the synthetic gel matrix. ‘556 patent 6:14-23.

This element of the claim requires that the needle tracks be fused closed so they are no longer visible. This is done by heating the gel until it becomes flowable and then cooling the gel. During this process, the gel must flow into the needle void and then adhere to itself upon cooling to erase these tracks. Which, supports a construction requiring the gel to have the ability to adhere to itself.

The prosecution history cited by the Defendants does little to assist in the construction of “thermally fusible.” The prosecution history cited by the Defendants

involves attorney remarks distinguishing the claimed invention from prior art by pointing out differences in the claimed inventions and the prior art. In particular the remarks are directed toward opaque gels and gels that are flowable. The remarks regarding opaque gels have nothing to do with “thermally fusible.” The remarks regarding the prior art that uses a flowable gel do not relate to erasing or removing the needle marks. Instead, these remarks relate to prior art that uses a gel which is flowable without heating. This prior art does not leave needle tracks because it is flowable in its normal state. This provides little guidance as to the meaning of “thermally fusible” as used in the patents in suit because there is no need to use heat to close needle tracks in the prior art because there are no needle tracks. The examiner’s comments suffer from the same problem because they are directed to the same prior art and the distinguishing features of the claimed inventions. So, even if, the inventors could be held to have adopted the examiner’s remarks, the remarks and comments do not support the Defendants’ contention that a “thermally flowable” material must adhere to itself, adhere to other materials, or join other materials. The remarks and comments do not address these proposed limitations.

Likewise, the patents’ claims and specifications do not support adding the limitations requiring that the gel adhere to other materials or to join other materials. The discussion in the specifications of the patents in suit regarding the thermal fusibility of the gel used are all directed toward the feature of the invention that allows the marks to be erased or removed from the gel or elastomer, which only has to do with

the gel being able to fuse to itself. They do not relate to any ability of the gel or elastomer to adhere to or to join other materials. The closest that the patents in suit come to describing something of this nature is to describe that certain other components, such as structural components and heaters, are embedded in the gel or elastomer. But, the patents do not describe these materials as adhering or joining the gel or elastomer. They are simply surrounded by the gel or elastomer, which, to a person of ordinary skill in the art, is different than joining or adhering to something. For these reasons, the Court declines to adopt the portion of Defendants' proposed constructions that includes the limitations that the "thermally fusible" material must adhere to or join to other material.

In summary, since the patents' claims and specifications support the notion that a "thermally fusible" material is a material that becomes flowable upon the application of heat and that adheres to itself upon cooling, but does not necessarily adhere or join other material the Court construes the phrase "thermally fusible" to mean "a flowable state upon the application of heat, when the heat is removed the material solidifies and adheres to itself."

3. "Visibly clear, thermally fusible"

The Parties also dispute the meaning of the phrase "visibly clear, thermally fusible," which occurs in claims 1 and 12 of the '556 patent and claim 1 of the '915 patent. From the parties briefing, it appears to the Court that the Defendants assert that this disputed claim phrase also occurs in the claims of the '661 patent or that the

claims of the '661 patent should be read as to include this language that is not present in the claims of this patent. In their briefing the Defendants provide argument as to the construction of this phrase as it relates to the '661 patent. But, Defendants provide no argument as to why this phrase, which does not occur in the claims of the '661 patent, needs to be added into this claim language, if that is what Defendants are asserting.

In the Plaintiffs' briefing the Plaintiffs point out that this phrase does not occur in the claims of the '661 patent and adding this language into these claims would be an improper redrafting of the claims. The Court agrees with the Plaintiff. The phrase does not appear in any of the claims of the '661 patent and the Defendants provide no reason or argument as to why this disputed phrase and the Defendants' proposed construction of this phrase should be inserted or applied to the claims of the '661 patent. For this reason, the Court construes this disputed phrase only to the extent that the disputed phrase is actually present in the claims at issue, which would be claims 1 and 12 of the '556 patent and claim 1 of the '915 patent.

The Plaintiffs argue that "visibly clear, thermally fusible" does not need any construction and should be given its plain and ordinary meaning. In the alternative, the Plaintiffs propose the phrase be construed to mean "transparent, a flowable state upon the application of heat." The Plaintiffs also point out that this disputed phrase is simply a combination of the previous two disputed phrases, "visibly clear" and "thermally fusible," with a comma separating the two phrases. So, the Plaintiffs' proposed alternative construction of this phrase is the same proposed alternative constructions of

the other disputed phrases with a comma separating the two.

Plaintiffs provide the same arguments and support for construction of the combined version of the disputed phrase that they provided for the individual phrases. That “visibly clear” should only be construed to mean transparent because there is no support in the patents or the patent histories for imposing a colorless limitation. And, that “thermally fusible” should be construed to mean that the material becomes flowable when heated because this is what the patent specifications describe.

The Defendants propose that “visibly clear, thermally fusible” be construed to mean “The material is both visibly clear and thermally fusible, such that the material is transparent (not translucent) and colorless, remains transparent and colorless when reused repeatedly, and is sufficiently solid that the material has the capability to provide visible needle tracks, and that upon the application of heat, the material starts to transition to a flowable state and the material adheres to itself, other materials, or joins other materials to seal the needle tracks closed.”

In support of this lengthy proposed construction, the Defendants, in their opening brief cite to the same attorney arguments and examiner’s comments contained within the file wrappers of the patents in suit that they cited in support of their proposed constructions of the individual phrases. In particular, the Defendants argue that these arguments, remarks, and the inventors’ subsequent silence amount to prosecution estoppel, which supports their proposed construction of “visibly clear, thermally fusible.”

As an initial note, the Court notes that it agrees with the Plaintiffs that the disputed phrase “visibly clear, thermally fusible” is just a combination of the previous two disputed phrases, “visibly clear” and “thermally fusible” with a comma between the two phrases. Because of this, the Court is of the opinion that, if the phrase needs any further construction at all, then this construction should align with the constructions given to the individual phrases.

In the construction of the individual disputed phrases, the Court considered the Defendants’ prosecution history estoppel argument and concluded that even if estoppel had occurred, which appears unlikely, the file wrapper cited by the Defendants does not support their proposed constructions because the attorney arguments and examiner comments do not address the limitations that the Defendant now wants to impose upon these claims.

The Court also notes that, even though this disputed phrase is merely a combination of the other two disputed phrases, the Defendants’ proposed construction of the combined disputed phrase is not simply a combination of the Defendants’ individually proposed constructions for these phrases. Instead the Defendants have added in a number of new limitations into their proposed construction of the combined phrase. These include: that the material is not translucent; that the material remains transparent and colorless when reused repeatedly, and that the material is sufficiently solid that the material has the capability to provide visible needle tracks. But, the Defendants have not provided any arguments as to why these additional limitations

should apply to the combined phrase and not the appropriate individual phrases.

Because this disputed phrase is simply a combination of two other disputed phrases and the Defendants have given no compelling reason why the combination of these phrases should be construed differently than the individual phrases, the Court finds that it is unnecessary to construe the phrase “visibly clear, thermally fusible.” Instead, the Court orders that each portion of this disputed phrase shall be given the construction held by the Court above. Specifically, “visibly clear” shall be given its plain and ordinary meaning and “thermally fusible” shall mean “a flowable state upon the application of heat, when the heat is removed the material solidifies and adheres to itself.”

4. “Synthetic gel matrix”

The parties dispute the meanings of “synthetic gel matrix,” as it is used in claims 1, 7, and 8 of the ‘556 patent; claims 1 and 9 of the ‘915 patent; and claim 10 of the ‘661 patent.

The Plaintiffs proposed that this phrase does not need construction and that it be given its plain and ordinary meaning and in the alternative that it be construed to mean “a non-naturally occurring gel-substance.” In support of their proposed construction, the Plaintiffs argue that specification language supports their proposed construction.

Defendants propose the phrase be construed to mean “The matrix is a synthetic ballistic gel material manufactured by Clear Ballistics having characteristics similar to

human muscle tissue with density and feel substantially similar to that of human tissue. The matrix of synthetic gel is sufficiently solid such that the material has the capability to provide visible needle tracks, and that upon application of heat the material starts to transition to a flowable state and the synthetic gel adheres to itself to seal the needle tracks closed.”

In support of their construction of the disputed phrase, the Defendants, argue that specification language supports their proposed construction and also, once again, argue that the construction is supported by attorney arguments and examiner’s comments in the file wrapper; that the inventor’s silence shows the inventor’s acceptance of the examiner’s comments; and that this prosecution history prevents Plaintiffs from taking a different position on the meaning of the terms now.

The Plaintiffs respond that the Defendants’ proposed construction improperly imports specification limitations and a limitation based on a commercial embodiment of the invention.

The Court begins with the Defendants’ proposed construction. The Court first notes that the Defendants’ proposed construction does not appear to even attempt to define or explain the meaning of the words of the disputed phrase “synthetic gel matrix.” Instead these particular words are simply repeated in the Defendants’ proposed construction, which appears to indicate that there is really no dispute as to the meaning of these words.

The additional language in the Defendants’ proposed construction is directed

toward particular properties of the synthetic gel matrix. These include: that the gel is manufactured by Clear Ballistics; that the gel has characteristics similar to human muscle tissue with density and feel substantially similar to that of human tissue; that the gel be solid enough to provide visible needle tracks; that the gel transitions to a flowable state when heated; and that the gel adheres to itself to seal needle tracks closed. The Defendants argue the specifications of the patents sufficiently describe the gel of the inventions as having these properties so the gel of the claims should be limited to these properties.

The Court finds that it is unnecessary to consider if the specifications support inclusion of most of these limitations into the claims because the claims already contain these limitations. The claims already contain limitations requiring the gel to be similar to human muscle or tissue; to be able to retain needle tracks that can be seen; to become flowable upon heating; and to fuse to itself to remove the needle tracks. For example, regarding the human tissue limitation, claim 1 of the '566 patent requires the "synthetic gel matrix providing tactile feedback substantially similar to human tissue" '556 patent 6:3-5. Regarding the ability to retain visible needle tracks, claim 1 of the '566 patent requires the gel to have the properties "wherein visible needle tracks are formed in the synthetic gel matrix, resulting from needle penetration and extraction" with "at least a portion of the needle tracks . . . remain visible." '566 Patent 6: 14-20. Regarding the ability to remove the needle tracks by heating, the same claim requires that the "needle tracks remain visible until the needle tracks are fused closed with a

heat source, whereby the needle tracks are fused closed upon heating.” ‘566 Patent 6:19-24. The same claim has the “thermally fusible” limitation already construed by the Court that already addresses the gels properties regarding its ability to flow when heated and to fuse to itself when cooled. In short all of these limitations that the Defendants’ propose that the Court address in the construction of “synthetic gel matrix” are already included in the language of the claim itself. The other claims that use the disputed phrase have the same or similar limitations.

For the Court to construe “synthetic gel matrix” to have these properties would be at best redundant and unnecessary. To do so could also make the meaning of the claims less clear, which is contrary to the purpose of claim construction. Under either outcome, adopting these limitations does nothing to clarify the meaning of the claims because these properties are already included in the claim language, the Court declines to adopt these portions of the Defendants’ proposed construction. Because of this, the Court need not consider the Defendants’ arguments regarding the support in the patents’ specifications for inclusion of these limitations.

The remaining limitation in the Defendants’ proposed construction is the requirement that the “synthetic gel matrix” be manufactured by Clear Ballistics. The Court finds absolutely no support in the specifications for including this limitation in the claims. The specifications mention that Clear Ballistics manufactures a ballistic gel. This is the only specific mention of the ballistic gel manufactured by Clear Ballistics and the statement only addresses possible suppliers of ballistic gel. ‘556 Patent

1:55-60. In this very same sentence, another manufacturer of ballistic gel, Ballistek Gel, LLC, is also described as a potential supplier of ballistic gel that could be used in the claimed inventions.

More importantly, the remainder of the specifications, including the summaries and the detailed descriptions, are silent as to the specific manufacturer of the gel. The references to the gel are in general to its properties and characteristics, not to who made the gel. Absent any support at all that the specification requires that the gel being used was manufactured by Clear Ballistics, the Court declines to adopt this proposed limitation into its construction of “synthetic gel matrix.”

The Court is also not persuaded by the Defendants’ file wrapper argument regarding the construction of this phrase. As already discussed, with the exception of the requirement that the gel be manufactured by Clear Ballistics, the other proposed limitations of the Defendants are already addressed in the claim language. For this reason, it appears unnecessary to further address the file wrapper argument. But, even so, the Court is of the opinion that the portions of the file wrapper cited by Defendants in support of their proposed construction does not support their proposed construction.

The sections of the file wrapper the Defendants direct the Court’s attention to are attorney arguments and examiner comments discussing the differences between the claimed inventions and the prior art. The Defendants assert that the inventors are now limited to these assertions regarding the inventions. In their briefing, the Defendants

fail to show the Court how those arguments and remarks have a bearing on the now proposed limitations of “synthetic gel matrix.” The Court has reviewed these arguments and remarks and finds that, even if the inventors are limited to these assertions, these arguments and remarks do not support the Defendants’ proposed construction.

Having decided not to adopt any of the limitations proposed by the Defendants in the construction of “synthetic gel matrix,” the only issue remaining is to determine if this phrase should be given its plain and ordinary meaning or if it needs to be construed. The Plaintiffs propose that the phrase be given its plain and ordinary meaning and in the alternative be construed as “a non-naturally occurring gel substance.”

The Court is of the opinion that there is little difference between the meaning of the words of the disputed phrase, “synthetic gel matrix,” and the Plaintiffs’ proposed alternative construction, “a non-naturally occurring gel substance.” The proposed construction changes the word “synthetic” to the phrase “non-naturally occurring.” As it is used in the patents in suit, there is no difference between synthetic and non naturally occurring, so applying this construction does nothing to clarify the meaning of “synthetic.” The remainder of the Plaintiffs’ proposed construction adds the word “substance” after the word “gel.” The Court is of the opinion that this change does nothing to further clarify the meaning of the disputed phrase. For these reasons, the Court declines to adopt the proposed alternative construction of the Plaintiffs.

In summary, the Court finds that there is no support in the patents or file

wrapper to require that the gel be manufactured by Clear Ballistics; that all other limitations proposed by Defendants are already addressed in other claim language; and that the plain and ordinary meaning of the disputed phrase is the meaning that a person having ordinary skill in the art would apply to the phrase. For these reasons, the Court holds that “synthetic gel matrix” shall be given its plain and ordinary meaning and that no construction beyond this plain and ordinary meaning is necessary.

5. “Skeletal structure”

The Parties dispute the meaning of the phrase “skeletal structure,” which is used in claims 1, 2, 11, 12, 13, and 21 of the ‘556 patent and in claims 1, 6, 8, 11, 13, 17, and 18 of the ‘661 patent. The Plaintiffs propose that the phrase does not need construction and should be given its plain and ordinary meaning and in the alternative should be construed to mean “A portion of simulated or natural skeleton.” The Defendants propose the phrase should be construed to mean “Spinal column made from human bone.”

Based upon the Parties’ proposed constructions, there are two disputed issues in the construction of this phrase. The first issue is whether the skeletal structure must be made from human bone, as proposed by the Defendants, or if the structure can be a synthetic structure or one made from a natural skeleton, as proposed by the Plaintiffs. The second issue is whether the skeletal structure can be any portion of a skeleton, as proposed by the Plaintiffs, or if the structure must be a spinal column, as proposed by the Defendants.

Regarding the issue of using a synthetic structure versus using human bone, the Plaintiffs direct the Court's attention to both claim language and specification language. In particular, the Plaintiffs point out that certain dependent claims limit the skeletal structure of the independent claims, which provides guidance as to an understanding of what a person of ordinary skill in the art would understand "skeletal structure" to mean. Dependent claim 11 of the '556 patent requires the skeletal structure of the independent claim to be comprised of human bone, and dependent claim 13 of the '661 patent requires the skeletal structure of the independent claim to be comprised of natural bone.

In support of their contention that the skeletal structure must be made from human bone, the Defendants cite to multiple portions of the specifications of the patents that describe the skeletal structure as preferably being natural bone and human bone and to specification language describing the significant draw backs of using synthetic bone structures, including the inability of synthetic bone structures to fully mimic real bone when using fluoroscopic imaging and monitoring. Defendants also cite the file wrappers of the '915 patent and the '661 patent as further support of the idea that the structure must be human bone.

The Court is of the opinion that the Plaintiffs' claim differentiation argument is informative into the meaning that a person having ordinary skill in the art would apply to "skeletal structure." The independent claims, which contain this disputed phrase, do not have any other language informative of this meaning. The dependent claims that

provide additional limitations to the skeletal structure, however, do have other language that is informative to the “skeletal structure” meaning. There are dependent claims that further limit the skeletal structure to “human bone,” claim 11 of the ‘556 patent, and that limit the skeletal structure to “natural bone,” claim 13 of the ‘661 patent.

Dependent claims must further limit the independent claim on which they depend. In the case of these dependent claims, the claims only add the limitation directed toward the composition of the skeletal structure. They do not limit the independent claims in any other manner. So, if the dependent claims limit the skeletal structure of the independent claims to natural bone and human bone, the skeletal structure of the independent claims should be broader than the limitations of the dependent claims.

If the skeletal structure of the independent claims was already limited to human bone, then the dependent claims would not limit the independent claims at all. In the case of claim 13 of the ‘661 patent, the dependent claim would actually be broader than the independent claim. Because all that dependent claim 13 of the ‘661 patent requires is “natural bone,” which is not necessarily “human bone.” This claim differentiation argument strongly favors not limiting the skeletal structure of the independent claims to “human bone,” as proposed by the Defendants. The Court also acknowledges that claim differentiation arguments are not also absolutely dispositive on the matter of claim construction, if there is other evidence to overcome the claim differentiation.

In certain situations, the specification language and description of the embodiments of an invention can overcome the construction supported by claim differentiation. In support of their proposed construction, the Defendants cite to multiple specification statements that look to support their proposed construction limiting the skeletal structure to human bone.

These include references to the preferred use of natural bone, the drawbacks of using synthetic bone, and the use of natural bone in the embodiments. For example, the abstract of the '556 patent describes the invention as "a spinal model [that] includes a complete natural bone vertebral column" and refers to the assertion that "natural bone offers significantly better image contrast over radiopaque replicas." '556 Patent Abstract. The field of the invention and the summary of the '556 patent also refer to the invention using natural vertebrae and natural bone, respectively. '556 patent 1:17-21; 2:44-66. And, the described embodiment of the '556 patent specifically uses natural bone. 4:54-61.

While these statements indicate that the skeletal structure is at least natural bone, the statements are also coupled with other statements showing that a person having ordinary skill in the art would understand that natural bone is strongly preferred to synthetic bone because the natural bone produces better x-ray and fluoroscopic images. Implied in this is the fact that synthetic bone could be used for the invention, but with decreased x-ray and fluoroscopic imaging qualities.

The '661 patent specification not only specifically declares that this is the case,

but also specifically states that the invention of the '661 patent could use synthetic material for the skeletal structure. For example, in the summary of the '661 patent, the inventors state that "In one embodiment, at least a portion of the skeletal structure is natural bone." 3:3-5. Which leaves open that the other portion of the skeletal structure is not natural bone, i.e. it is synthetic bone. And the detailed description of the invention of the '661 patent states, "In one embodiment, vertebral column 130 is natural bone, in other embodiments vertebral column 130 may be formed from materials that provide contrast during fluoroscopic imaging that simulates or is representative of human bone." '661 patent 5:25-28. This language makes it even clearer that, at least as for the '661 patent, the skeletal structure does not have to be human bone or natural bone. The skeletal structure could be formed from a material that simulates or is representative of human bone. If the skeletal structure had to be human bone, there would be no need for that material to simulate or be representative of human bone because it is human bone. Which strongly supports not construing "skeletal structure" so that it is limited to human or natural bone.

In summary, the doctrine of claim differentiation supports not limiting the skeletal structure to human bone; the specification language of the '556 patent indicates that human bone is strongly preferred over synthetic materials, but is not necessarily required; and that the specification language of the '661 patent specifically states that the skeletal structure need not be human or natural bone. For these reasons, the Court is of the opinion that the "skeletal structure" of the claims should not be

limited to human bone, or even natural bone and should be construed accordingly.

The Court disagrees with the Plaintiff that this portion of the phrase should be given its plain and ordinary meaning because the plain and ordinary meaning of “skeletal structure” does not indicate the difference between a natural structure or a synthetic structure. Construction of this phrase beyond the plain and ordinary meaning is necessary to clarify the meaning of the phrase. The Plaintiffs have proposed an alternative construction that specifies that the skeletal structure may be “simulated or natural.” The Court is of the opinion that this distinction clarifies that, as it is used in these patent claims, the “skeletal structure” may also be synthetic.

The second dispute between the Parties in the construction of “skeletal structure” is whether or not the structure must be a spinal column, as proposed by the Defendants, or if it can be any portion of a skeleton, as proposed by the Plaintiffs. Both Plaintiffs and Defendants point toward specification language to support their respective proposed constructions. Defendants also argue the file wrapper supports their construction.

The Defendants cite specification language from the ‘556 and ‘661 patents that indicates that the skeletal structure is a vertebral column. For example, the technical field section of both the ‘556 and the ‘661 patent refer to embedded vertebrae. ‘556 patent 1:18-21; ‘661 patent 19-22. The background section of each patent refers to the usefulness of a spinal model containing a vertebral column. ‘556 patent 2:44-47; ‘661 patent 2:15-18. And the specific embodiments describe the use of a vertebral column.

'556 patent 4:10-13; '661 patent 4:42-46.

The Plaintiffs cite other specification language indicating that the skeletal structure could be other portions of a skeleton besides a spinal column. For example, the specification of the '661 patent states, "Although the models described and illustrated herein include a human vertebral column, models of different portions of human anatomy with different skeletal structures may be constructed." '661 patent 8:49-53.

The Court is of the opinion that the "skeletal structure" of the claims of the patents in suit are not limited to a spinal column. This interpretation is supported by both claim language and the specifications of the patents in suit.

Other claim language supports the interpretation that the "skeletal structure" is not limited to a spinal column. The disputed phrase initially occurs in independent claim 1 of the '661 patent and independent claim 1 of the '556 patent. For each of these patents, there are dependent claims that further limit the "skeletal structure" of the independent claims. For example, claim 8 of the '661 patent and claim 2 of the '556 patent further limit the skeletal structure so that it "comprises a vertebral column." Under the doctrine of claim differentiation, this dependent claim language supports a construction of "skeletal structure" that is broader in scope than a "vertebral column." The Defendants' proposed construction, which limits the skeletal structure to a "spinal column," is not broader than a "vertebral column." The two phrases essentially have the same meaning. The language of the dependent claims supports a construction of

“skeletal structure” that is broader than the Defendants’ proposed “spinal column.”

The specifications of the patents also support a construction of the disputed phrase that is broader than the Defendants’ proposed construction. The particular embodiments described in the patents use a spinal structure, there is nothing else in the specifications to indicate that the claimed invention must be limited to a spinal column. Absent any further support to limit the claim language, the limitations provided in the preferred embodiments are insufficient to impart those limitations onto the claims.

Instead of providing further support for limiting the claim language, the specification of the ‘661 patent does the opposite. The specification of the ‘661 patent clearly states that “Although the models described and illustrated herein include a human vertebral column, models of different portions of human anatomy with different skeletal structures may be constructed.” ‘661 patent 8:49-53. This leaves no doubt, that the inventors intended for the “skeletal structure” of the claims of the ‘661 patent to be much broader than a spinal or vertebral column and that a person of having ordinary skill in the art would understand that this is what the inventors intended.

Considering that the dependent claim language of the patents support a broad construction of “skeletal structure” based on claim differentiation; that there is no support in the specifications to limit the claims to the described embodiments; and that the ‘661 patent specifically states that other structures besides vertebral columns could

be used in the invention, the Court is of the opinion that adopting the Defendants' proposed construction of this part of the disputed phrase would improperly limit the claims of the patents. Since there is no support to construe the disputed phrase so that it is limited to a spinal column, the only remaining issue is if this portion of the disputed phrase should be given its plain and ordinary meaning or if construction is required beyond the plain and ordinary meaning.

The Court is of the opinion that this portion of the disputed phrase should be given its plain and ordinary meaning. The Plaintiffs' proposed alternative construction, as it pertains to this portion of the disputed phrase, is "a portion of a . . . skeleton." The Court finds that this language does not differ in meaning from the plain and ordinary meaning of "skeletal structure." No additional construction besides the plain and ordinary meaning is needed to further clarify this term.

In summary, the Court holds that: the patent specifications support a construction of "skeletal structure" that includes both synthetic and natural bone; "skeletal structure" does not need additional construction to clarify that this is a portion of a skeleton; claim and specification language do not support limiting the "skeletal structure" to a spinal column; and limiting the "skeletal structure" to a spinal column would improperly limit the claims to the described embodiments. For these reasons, the Court construes "skeletal structure" to mean "simulated or natural skeletal structure."

6. "Partial human torso"

The parties dispute the meaning of the phrase “partial human torso,” which occurs in claims 1, 10, 12, and 20 of the ‘556 patent and in claims 1 and 9 of the ‘915 patent. The Plaintiffs propose that the phrase does not need construction and should be given its plain and ordinary meaning. In the alternative, the Plaintiffs propose that the phrase should be construed as “a portion of a human torso.” The Defendants propose that “partial human torso” be construed to mean “The part of the human body to which the skull and limbs are attached, extending the length of the human spine below the skull to the end of the spine, the width of the shoulders, back, waist and hips, as viewed from behind a human torso, and excluding the front of the torso, skull, shoulders, pelvis, arms, legs, ribs, including only the spinal column.” While the Plaintiffs request no construction of the phrase because the partial human torso can be any particular part of a human torso, the Defendants request that the phrase should be construed so that the partial human torso is limited so that the partial human torso must have a particular shape and form essentially encompassing an entire spinal column and it must not have certain other features such as a front, legs, arms, and certain bone structures.

In support of such a limiting construction, the Defendants cite specification language that they argue is consistent with their proposed construction. The Defendants cite specification language that states that the invention is a spinal model including a natural bone vertebral column that is used for training needle techniques for spinal and lumbar injections and also point to the figures of the patents showing the

“partial human torso.” For example, the ‘556 patent states, “The present invention seeks to address the shortcomings of past spinal training models by providing a spinal model that includes a complete natural bone vertebral column that is embedded in a matrix of crystal clear ballistic gel.” ‘556 patent 2:44-48. The Defendants cite other similar statements from the patents. *See* ‘556 patent Abstract, 1:25-29, 2:29-32,; ‘915 patent Abstract, 1-14-17, 1:19-25, 2:24-27, 2:38-41. Generally, these quotes support an argument that the invention composes a full spinal column, which includes a partial human torso as described by the Defendants’ proposed construction because this is the portion of the torso related to the spinal column.

The Plaintiffs’ respond that the language cited by the Defendants describes the particular embodiments disclosed in the patents and that the limitations of the embodiments should not be used to limit the claim language.

The Court agrees with the Plaintiffs that the described embodiments should not be used to limit the claim language. Upon review of this specification language, the Court first notes that most of the specifications cited by the Defendants do not actually directly relate to the “partial human torso.” Instead this language mostly relates to the spinal or vertebral column of the embodiments. It appears that the Defendants argue that since this invention must have full spinal column, which the Defendants argue in the construction of “skeletal structure,” then the partial human torso must be defined by its relation to the size and placement of a spinal column.

The Court disagrees with this view. First, the Court has already addressed the

issue of Defendants' asserted position that the invention requires a spinal column in the Court's construction of "skeletal structure." In the construction of that disputed phrase, the Court disagreed with the Defendants that the "skeletal structure" must be a spinal column. So, the Defendants' connection between the requirement of a spinal column and the shape and components of the partial human torso is tenuous at best.

Secondly, if the claimed invention was limited to a skeletal structure that was a spinal column, it does not necessarily follow that the shape and components of the partial human torso should be limited to only the size and shape that goes along with a spinal column. As already noted, the language cited by the Defendants refers mostly to the vertebral or spinal column within the partial human torso. It does not directly relate to the shape, components, and extent of the partial human torso. The language provides very little support for defining the partial human torso as the Defendants have done in their proposed construction of the disputed phrase.

In addition, the Court finds that what little support is provided in the patents' specifications for the Defendants' proposed requirements for the size, extent, and components of the partial human torso is limited to the specific embodiments described by the patents and that importing those limitations into the claim language would be improper. The figures cited by Defendants in support of their construction, show a partial human torso that could be somewhat described by the Defendants' proposed construction because the partial human torso shown is generally defined by the size and extent of the full spinal column also shown in the figures. The Court also

notes that these figures are not exactly consistent with the Defendants' proposed construction. For example, the figures show the partial human torso as having "shoulders" and Defendants' proposed construction specifically excludes shoulders. The figures also show the outline of a pelvic bone and a partial human torso that bounds the pelvic area. In contrast, the Defendants' proposed construction excludes the pelvis from the partial human torso. So, these figures do not support all of the limitations of the Defendants' proposed construction.

Even if the figures support all of the limitations included in the Defendants' proposed construction, the Court is of the opinion that these figures still would not support the inclusion of these limitations into the claim language. The figures depict the described embodiments of the inventions. They do not depict all possible embodiments of the inventions, and patent claims may be broader than the described embodiments. Narrowing broad claim language to the specific details described in embodiments is improper without further support showing that an inventor intended the claims to be so limited or that a person having ordinary skill in the art would understand that the claims were so limited. In the present patents, there is no support at all for importing embodiment language into the patent claims to narrow the extent of the claim language, which is exactly what the Defendants' proposed construction attempts to do. For these reasons, the Court declines to adopt the Defendants' proposed construction.

Having declined to adopt the Defendants' proposed construction, the Court now

turns to the Plaintiffs' proposal, which is to adopt the plain and ordinary meaning of the phrase or, in the alternative, to construe the phrase to mean "a portion of a human torso."

The Court agrees with the Plaintiffs that the phrase does not need construction and should be given its plain and ordinary meaning. A "partial human torso," as used in the claims of the patents in suit, is no different than the ordinary meaning that a lay person would apply to this phrase. The Court sees no support in the patents that requires or even contemplates a meaning beyond the plain and ordinary meaning of the phrase. The Court also notes that the Plaintiffs' proposed alternative construction does nothing to clarify the plain and ordinary meaning. The Plaintiffs' proposed alternative construction, "a portion of a human torso," is essentially just a rearrangement of the words of the disputed phrase "partial human torso" with a change of the word "partial" to the phrase "a portion." These have the same meaning, so the Plaintiffs' proposed alternative construction does nothing to clarify the meaning.

In summary, the Defendants' proposed construction includes claim limitations that are not supported by the specifications of the patents in suit; the portions of the Defendants' proposed construction that are supported by the specifications of the patents are related to the description of embodiments for which there is no support for imparting these limitations into the claims of the patent; the Plaintiffs' proposed alternative construction of the disputed phrase does not provide any clarification of the meaning of the phrase, and "partial human torso" as used in the patents in suit is used

with the meaning that a lay person would apply to the phrase. For these reasons, the Court finds that construction of this phrase is not needed and that the phrase shall be given its plain and ordinary meaning.

7. “Training and injection practice”

The parties dispute the meaning of the phrase “training and injection practice,” which occurs in the preamble of claims 1 and 12 of the ‘556 patent. The Plaintiffs assert that this preamble language is not limiting and for this reason it should not be construed. The Defendants assert that the preamble phrase is limiting and should be construed to mean “spinal models used for training practitioners in injection techniques.”

The Plaintiffs argue that the preamble is not limiting because the claims stand by themselves without a need to include any preamble language into the claim language. The Defendants appear to argue that the preamble language is limiting because the file history supports limiting the preamble. The Defendants argue that certain attorney arguments and examiner comments made during prosecution support inclusion of this preamble language into the claim limitations.

As a general rule, preamble language is not limiting. *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). A preamble does not limit a claim if the preamble only states the purposes of the invention and the claim language sets out a complete invention. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). A preamble may limit a claim that does not set out a complete invention without the preamble or

the preamble is necessary to bring life to the claimed inventions. *Schumer v. Lab. Comput. Sys., Inc.*, 308 F.3d 1304, 1310 (Fed. Cir. 2002).

The Court holds the preamble of these claims is not limiting because each of these claims stands on its own and does not require the preamble language to be a complete claim. The Court has reviewed the language and elements of each of these claims and each claim is complete without the preamble language.

The Court disagrees with the Defendants that the file wrappers of these patents support the conclusion that this preamble language is limiting and needs to be construed. The Court has reviewed the prosecution history cited by the Defendants to support their argument. The Court sees no need to repeat these portions of the files history in this order, which are in the record before the Court. The attorney remarks and examiner's comments relate to distinguishing the claimed inventions from other injection training models in the prior art.

The Defendants fail to show in the first place that the limitation language of the claims is insufficient to stand on its own and that the claims need the preamble to bring meaning or life to them. Absent a showing of this requirement, there is no basis to find the preamble limiting. Even if there was another basis to do so, the Defendants fail to show how these portions of the file wrappers support their conclusion that the phrase is limiting or to support their proposed constructions.

The Court also notes that even though the phrase is contained in the preambles of claims 1 and 12 of the '556 patent, the Defendants do not cite to the '556 patent file

wrapper. Instead they cite to the file wrappers of the '661 and '915 patents. In addition, even assuming that the file wrappers of the other patents are relevant to this issue in the '556 patent, the Defendants have failed to show how the attorney remarks and examiner comments support the conclusion that this preamble language is limiting. To the extent that these remarks are relevant to the disputed preamble language, they do nothing more than what the preamble language itself does, which is to simply state the purpose of the claimed invention.

Because the limitations of these claims describes a complete invention and it is not necessary to impart preamble language into the claim language to provide meaning or bring life to the claim language, the Court holds that this preamble language simply states the purpose of the invention and is not limiting. For this reason, the Court will not construe this language.

8. “Thermoplastic elastomeric matrix”

The Parties also dispute the meaning of the phrase “thermoplastic elastomeric matrix,” which is used in claims 1-4, 6, 7, 11, 14, and 18 of the '661 patent. The Plaintiffs argue that the phrase does not need construction and that it should be given its plain and ordinary meaning. In the alternative, the Plaintiffs propose that the phrase should be construed to mean “a synthetic substance that, with the application of heat, will transition to a flowable state.” The Defendants propose the phrase should be construed to mean “Clear colorless, synthetic ballistic gel material manufactured by Clear Ballistics having characteristics similar to human muscle tissue with density and

feel substantially similar to that of human tissue. The matrix of synthetic gel is sufficiently solid such that the material has the capability to provide visible needle tracks, and that upon the application of heat, the material starts to transition to a flowable state and the synthetic gel adheres to itself to seal the needle tracks closed.”

The Court initially notes that this disputed phrase, “thermoplastic elastomer matrix,” is closely related to other disputed terms, including “synthetic gel matrix” and “thermally fusible.” The disputed phrases “synthetic gel matrix” and “thermally fusible” are primarily used in the claims of the ‘556 patent and the ‘915 patent to describe the limitations of the claimed inventions related to the gel and its properties. The disputed phrase “thermoplastic elastomer matrix” is used in the claims of the ‘661 patent to describe limitations of the claims related to an elastomer.

The Court is of the opinion that this disputed phrase should be construed in a manner analogous to the construction of the related disputed phrases because the Parties provide very similar proposed constructions for the respective phrases, the Parties use very similar arguments to support those constructions, and the specifications of the different patents makes little distinction between each of the limitations.

The Parties provide very similar proposed constructions of “thermoplastic elastomer matrix” as compared to their respective proposed constructions of the other two disputed phrases. The Defendants’ proposed construction of “thermoplastic elastomer matrix” is identical to their proposed construction of “synthetic gel matrix,”

except that the Defendants' proposed construction of "thermoplastic elastomer matrix" adds in the additional limitations that the gel is clear and colorless. The Plaintiffs' proposed construction of "thermoplastic elastomer matrix" does not track its proposed constructions of "synthetic gel matrix" and "thermally fusible" as closely word for word as compared to the Defendants' proposed constructions. The Plaintiffs' proposed construction tracks at least all the major ideas of its proposed constructions for the other terms. For example, the Plaintiffs' proposed construction of "thermoplastic elastomer matrix" includes the limitations that the elastomer is "synthetic" and their proposed construction of "synthetic gel matrix" includes the limitation that gel is "non-naturally occurring." In addition, both of Plaintiffs' proposed constructions for "thermoplastic elastomer matrix" and for "thermally fusible" include the limitation that the gel or substance becomes flowable when heated.

Also, the Parties provide the same arguments to support their proposed constructions of "thermoplastic elastomer matrix" that they do to support their proposed constructions of "thermally fusible" and "synthetic gel matrix."

In addition, the '661 patent claims use the disputed phrase "thermoplastic elastomer matrix" to describe properties of the limitation, but the '661 patent specification's discussion regarding the elastomer is mostly the same language used in the '556 and '915 patents to describe the gel.

Because of this, the Court is of the opinion that similar portions of the current disputed phrase should be construed in a manner analogous to the already construed

portions of the other two disputed phrases, which addresses almost all of the issues in the construction of “thermoplastic elastomer matrix.”

A number of these issues have already been addressed in the Court’s construction of “synthetic gel matrix.” In that construction, the Court addressed many of the properties that the Defendants assert that the gel must have. These include the limitations requiring that the gel be manufactured by Clear Ballistics; have characteristics similar to muscle tissue with a density and feel similar to human tissue; that the gel be solid enough to retain needle tracks; that upon being heated the material becomes flowable; and that upon cooling the material adheres to itself to seal the needle tracks closed. The Court declined to adopt most of these limitations into the construction of “synthetic gel matrix” because the limitations improperly imported specification limitations into the claim language; the limitations improperly imported characteristics of the actual product being manufactured; and because the proposed limitations are duplicative and not helpful in clarifying the meaning of the phrase because other claim language already addresses the limitations. Likewise, the Court has already addressed the limitation requiring the material to adhere to itself upon cooling in its construction of “thermally fusible.”

Out of all of these proposed limitations the only limitation adopted by the Court was the requirement that the material be able to adhere to itself upon cooling. This was included in the Court’s construction of “thermally fusible” because this is required by the feature of the invention allowing needle tracks from prior uses to be removed by

heating the material until it becomes flowable and then cooling it to seal the needle tracks closed.

The Court is of the opinion that, because of the similarities between a “thermoplastic” and “thermally fusible” material, as the terms are used in the patents, a thermoplastic should have the same requirement that it adheres to itself upon cooling after being heated to a flowable state.

The Court is also of the opinion that, because of the same similarities between “thermoplastic elastomer matrix” and a “thermally fusible” “synthetic gel matrix,” as these terms are used in the patents, that all of the other limitations proposed by Defendants should not be included in the construction of “thermoplastic elastomer matrix,” for the same reasons that they were not included in the construction of “synthetic gel matrix.”

The Defendants have also added into the construction of “thermoplastic elastomer matrix” the limitation that the material be clear and colorless. The Court has also already addressed this issue in the construction of “visibly clear.” For that disputed term, the Defendants asserted that the material must be “transparent and colorless.” In that construction, the Court agreed that the material was transparent but did not adopt this part of construction because the plain meaning of the “visibly clear” already conveyed this property of the substance. Regarding the Defendants’ proposed limitation that the material be colorless, the Court did not adopt this limitation in the construction of “visibly clear” because the specifications and file wrapper did not

support inclusion of this limitation.

The Court is of the opinion that these issues should be given analogous treatment in the construction of “thermoplastic elastomer matrix.” Regarding the limitation requiring the material to be clear or transparent, including this limitation in this construction is duplicative in this construction because the claims involved here already specify that the material is “clear.” Regarding the requirement that the material be colorless, the Court declines to adopt this limitation in this construction because it is no more supported by the specification or the file wrapper of the patent than it was in the construction of “visibly clear.”

The only remaining issue in the construction of “thermoplastic elastomer matrix” is the nature of the difference between an “elastomer,” a “gel,” and a “substance,” if there is any difference. The claim language states that the material is an elastomer. The Plaintiffs’ proposed construction states that the material is a substance. The Defendants’ proposed construction states that the material is gel.

In support of its proposal that the material is a gel, the Defendants appear to rely on the specification and file wrapper, which often refers to the material as a gel. The Plaintiffs do not provide any particular support for changing the word “elastomer” to the word “substance.” But, in their briefing, the Plaintiffs did bring to the Court’s attention that the ‘661 patent specification provides some guidance on this issue. The specification states that “One material suitable for use as synthetic gel matrix 120 is a visibly clear thermoplastic elastomer comprising . . . rubber block copolymer with . . .

white oil. . . . Upon cooling, the mixture forms a clear, thermoplastic elastomer suitable for use as a synthetic gel matrix.” ‘661 patent 4:32-41. The next paragraph repeats this language about using a thermoplastic elastomer as a synthetic gel matrix, only using different components.

These statements support the idea that, at least as is used in this patent, that a thermoplastic elastomer is a type or subset of a synthetic gel matrix. So that a synthetic gel matrix is broader in meaning than a thermoplastic elastomer. It also indicates that these two are not necessarily interchangeable. Because of this, the Court is of the opinion that describing the material as a gel in the construction of this phrase would improperly expand upon the meaning of elastomer, as it is used in the claims and specification.

Likewise, the Plaintiffs’ proposed language changing “elastomer” to “substance” would improperly expand the meaning of the claim language. Under its plain and ordinary meaning, “substance” could essentially be any type of material and is not required to be an elastomer or a gel. The Court is of the opinion that this is simply far beyond the scope of the claim language and the scope of the specification, which is limited to gels. For this reason, the Court will not adopt the Plaintiffs’ use of the word “substance” in place of the word “elastomer” in the construction of “thermoplastic elastomer matrix.”

In summary, because the similarities of this disputed phrase and other disputed phrases the Court construes this disputed phrase in a manner analogous to the other

disputed phrase. The Court holds that almost all of the limitations proposed in the Defendants' construction should not be adopted because the limitations are not supported by the specification, are duplicative of other claim language, improperly import embodiment or manufactured product properties into the claim language, or are not supported by the Defendants' file wrapper argument. The exception to this, is the Defendants' limitation requiring the elastomer to adhere to itself upon cooling because this is supported by other claim and specification language. The Court also finds that, as the terms are used in the patent, there is a difference between a "gel" and an "elastomer" and because of this construction of the phrase should not change the claimed "elastomer" into a "gel." The Court also finds that the Plaintiffs' proposed change of the claimed "elastomer" to a "substance" would result in a construction that is broader than is meant by the claims or supported by the specification. For these reasons, the Court construes "thermoplastic elastomer matrix" to mean "an elastomer matrix which has a flowable state upon the application of heat, when heat is removed the material solidifies and adheres to itself."

SO ORDERED.

Signed April 27th, 2017.


ED KINKEADE
UNITED STATES DISTRICT JUDGE

**SUMMARY CHART OF CLAIM CONSTRUCTIONS OF DISPUTED TERMS
OF ‘556 PATENT, ‘915 PATENT, and ‘661 PATENT**

| Language of Disputed Phrase of Claims | Plaintiffs’ Proposed Construction | Defendants’ Proposed Construction | Judge’s Construction |
|---------------------------------------|--|---|---|
| “visibly clear” | Plain and ordinary meaning; no construction necessary; in the alternative “transparent” | “transparent and colorless” | Plain and ordinary meaning |
| “thermally fusible” | Plain and ordinary meaning; no construction necessary, in the alternative “a flowable state upon the application of heat” | “application of heat to a material that causes the material to become flowable, when the heat is removed, the material solidifies and adheres to itself, other materials, or joins other materials” | “a flowable state upon the application of heat, when the heat is removed the material solidifies and adheres to itself” |
| “visibly clear, thermally fusible” | Plain and ordinary meaning; no construction necessary, in the alternative “transparent, a flowable state upon the application of | “The material is both visibly clear and thermally fusible, such that the material is transparent (not translucent) and colorless, remains | No construction necessary beyond the construction of the individual disputed phrases already construed. |

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| | heat” | transparent and colorless when reused repeatedly, and is sufficiently solid such that the material has the capability to provide visible needle tracks, and that upon the application of heat, the material starts to transition to a flowable state and the material adheres to itself, other materials, or joins other materials to seal the needle tracks closed” | |
| “synthetic gel matrix” | Plain and ordinary meaning; no construction necessary, in the alternative “a non-naturally occurring gel substance” | “The matrix is a synthetic ballistic gel material manufactured by Clear Ballistics having characteristics similar to human muscle tissue with density and feel substantially similar to that of human tissue. The matrix of synthetic gel is sufficiently solid | Plain and ordinary meaning |

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| | | such that the material has the capability to provide visible needle tracks, and that upon the application of heat, the material starts to transition to a flowable state and the synthetic gel adheres to itself to seal the needle tracks closed” | |
| “skeletal structure” | Plain and ordinary meaning; no construction necessary, in the alternative “a portion of simulated or natural skeleton” | “spinal column made from human bone” | “simulated or natural skeletal structure” |

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| <p>“partial human torso”</p> | <p>Plain and ordinary meaning; no construction necessary, in the alternative “a portion of a human torso”</p> | <p>“The part of the human body to which the skull and limbs are attached, extending the length of the human spine below the skull to the end of the spine, the width of the shoulders, back, waist and hips, as viewed from behind a human torso, and excluding the front of the torso, skull, shoulders, pelvis, arms, legs, ribs, including only the spinal column”</p> | <p>Plain and ordinary meaning</p> |
| <p>“training an injection practice”</p> | <p>This limitation is in the preamble of Claims 1 and 12 of the ‘556 Patent, is not limiting and, as such, should not be construed.</p> | <p>“spinal models used for training practitioners in injection techniques”</p> | <p>Preamble is not limiting and should not be construed.</p> |
| <p>“thermoplastic elastomer matrix”</p> | <p>Plain and ordinary meaning; no construction necessary, in the alternative “A</p> | <p>“Clear colorless, synthetic ballistic gel manufactured by Clear Ballistics having</p> | <p>“an elastomer matrix which has a flowable state upon the application of heat, when heat is</p> |

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| | <p>synthetic substance that, with the application of heat, will transition to a flowable state”</p> | <p>characteristics similar to human muscle tissue with the density and feel substantially similar to that of human tissue. The matrix of synthetic gel is sufficiently solid such that the material has the capability to provide visible needle tracks, and that upon the application of heat, the material starts to transition to a flowable state and the synthetic gel adheres to itself to seal the needle tracks closed.”</p> | <p>removed the material solidifies and adheres to itself.”</p> |
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