IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRUINJECT CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-592-LPS-JLH
	)	
GALDERMA, S.A., GALDERMA LABORATORIES, L.P., and NESTLÉ SKIN HEALTH, INC.,	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Presently pending before the Court are the parties' claim construction disputes related to terms in United States Patent Nos. 9,792,836 (the "'836 Patent"), 10,290,231 (the "'231 Patent"), and 10,290,232 (the "'232 Patent"). The Court held a *Markman* hearing on June 8, 2020. I recommend that the Court adopt the constructions as set forth below.

The parties agreed on the constructions of a number of terms in the '836, '231, and '232 Patents. (D.I. 218 at 5-7.) In accordance with the parties' agreement, I RECOMMEND that those terms be construed as follows:

	Term	**Court**
1	"[clear layer of] elastomer coating" "[clear layer of] elastomer" ('836 Patent, Claim 1)	"a clear layer of elastic material that simulates skin or muscle"
2	"a base layer" ('836 Patent, Claim 1)	"a top layer or surface of the base"

3	"a three-dimensional (3D) tracking system positioned inside the base and configured to determine a location of a needle inserted into the clear layer" ('836 Patent, Claim 1)	"a tracking system contained inside the base that tracks the location in three dimensions of the needle inserted into the clear layer"
4	"injection measurement data" ('836 Patent, Claim 16)	"data indicative of the depth, angle, pressure or accuracy of the injection"
5	"a recommended action" ('231 Patent, Claim 1)	"training resources or materials directed at an aspect of the injection technique"
6	"use characteristics of the syringe" ('231 Patent, Claim 1)	"two or more pieces of information about use of the syringe as the syringe delivers the training injection, but excluding information indicative of the position of the syringe"
7	"[a/the] collection of injection training data" ('231 Patent, Claim 6)	"data associated with previous training injections"
8	"A simulated delivery of therapeutic agent to the digital model of the training apparatus" ('232 Patent, Claim 1)	"a simulated flow of therapeutic agent delivered from the digital model of the syringe to the digital model of the training apparatus"
9	Location sensing system ('232 Patent, Claim 1)	A location tracking system
10	"[the three-dimensional graphical depiction comprises] a digital model of the syringe" "the digital model of the syringe" ('232 Patent, Claims 1, 20, 27)	"[the three-dimensional graphical depiction comprises] a/the three-dimensional digital model of the syringe"
11	"first location sensing means" ('232 Patent, Claim 27)	Means-plus-function: Function: sensing location Structure: the syringe sensor [4:40–5:6], defined as a position sensor, accelerometer, 3D position sensor, orientation sensor, inertial measurement unit, pressure sensor, antenna to detect radio waves, or a microphone to detect sound.

12	"second location sensing means" ('232 Patent, Claim 27)	Means-plus-function: Function: sensing location Structure: the apparatus sensor [206], defined as an optical measurement and tracking system (4:25–28), at least two stereoscopic cameras (4:28–31), a three-dimensional tracking system (a camera, two cameras or an array of light sensors) (7:27–31), a camera (17:6–7), or magnetometer (17:14–15)

Further, as announced at the hearing on June 8, 2020, I RECOMMEND that the following disputed claim terms of the '836 and '231 patents be construed as follows:

	Term	**Court**
1	"[partially hollow] base configured to provide structural support" ('836 Patent, Claim 1)	"an apparatus with a cavity or space that is used to provide structural support for the clear layer and opaque layer"
2	"the base, clear layer, and opaque layer form an anatomical shape" ('836 Patent, Claim 1)	"the base, clear layer, and opaque layer together form an anatomical shape"
3	"at least one evaluation criterion" ('231 Patent, Claim 1)	"one or more standards used to assess an injection"
4	"at least one performance requirement" ('231 Patent, Claim 1)	"one or more standards used to measure injection performance"
5	"the information set" ('231 Patent, Claim 6)	"the data collected during the injection training from the syringe or training apparatus, but must include data collected from at least one syringe sensor"
6	"information describing the training injection" ('231 Patent, Claim 6)	Indefinite
7	"information describing the training session" ('231 Patent, Claim 12)	Indefinite for lack of antecedent basis

I. LEGAL STANDARDS

A. Claim Construction

The purpose of the claim construction process is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." *Markman v. Westview Instruments*, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). When the parties have an actual dispute regarding the proper scope of claim terms, their dispute must be resolved by the judge, not the jury. *Id.* at 979. The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

"[T]here is no magic formula or catechism for conducting claim construction." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). But there are guiding principles. *Id.*

"The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* at 1313. In some cases, the ordinary meaning of a claim term, as understood by a person of ordinary skill in the art, is readily apparent even to a lay person and requires "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. Where the meaning is not readily apparent, however, the court may 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." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources 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 technical terms, and the state of the art." *Id.*

"The claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Considering other, unasserted, claims can also be helpful. *Id.* "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition, the "claims must be read in view of the specification, of which they are a part." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification "is always highly relevant to the claim construction analysis." *Id.* (quoting *Vitronics*, 90 F.3d at 1582). The specification may contain a special definition given to a claim term by the patentee, in which case, the patentee's lexicography governs. *Id.* at 1316. The specification may also reveal an intentional disclaimer or disavowal of claim scope. *Id.* However, "even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal marks omitted).

Courts should also consider the patent's prosecution history. *Phillips*, 415 F.3d at 1317. It may inform "the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* Statements made by a patentee or patent owner during *inter partes* review may also be considered. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017).

In appropriate cases, courts may also consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For example, dictionaries, especially technical dictionaries, can be helpful resources during claim construction by providing insight into commonly accepted meanings of a term to those of skill in the art. *Phillips*, 415 F.3d at 1318. Expert testimony can also be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.*; *see also Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331-32 (2015).

B. Indefiniteness

Section 112 of Title 35 imposes a definiteness requirement on patent claims. 35 U.S.C. § 112(b) (requiring that the claims "particularly point[] out and distinctly claim[] the subject matter which the inventor . . . regards as the invention"). "The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.*, competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prod., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002).

"A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Definiteness, like claim construction, should be assessed from the viewpoint of a person of ordinary skill in the art at the time the patent was filed, and it should be considered in view of the patent's specification and prosecution history. *Id.* at 908.

The party asserting indefiniteness has the burden to prove it by clear and convincing evidence. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

II. THE COURT'S RULING

My Report and Recommendation regarding the disputed claim terms of the '836 and '231 Patents was announced from the bench at the conclusion of the hearing as follows:

> At issue in this case are three patents. U.S. Patent No. 9,792,836 is titled "Injection Training Apparatus Using 3D Position Sensor." The '836 patent has two related terms in dispute. U.S. Patent No. 10,290,231 is titled "Automatic Detection of Performance Characteristics in an Injection Training System." The '231 patent has five terms in dispute. And U.S. Patent No. 10,290,232 is titled "Automated Detection of Performance Characteristics in an Injection Training System." The '232 patent, per the parties' agreement last week, no longer has any terms in dispute.
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> I'm prepared to rule on all of the disputed claim terms today. I will not be issuing a separate written Report and Recommendation but I will issue a written Report and Recommendation that incorporates my ruling today.
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> And I want to emphasize before I announce my decisions that while I am not issuing a separate opinion, we have followed a full and thorough process before making the decisions I'm about to state. We've reviewed the patents-in-suit. There was full briefing on each of the disputed terms. The parties submitted their briefing in accordance with my procedures, so each side had the opportunity to submit two briefs and they were combined into one joint claim construction brief incorporating all arguments.
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> The parties' joint claim construction brief also attached several exhibits. Those exhibits included portions of the prosecution history relied on by the parties, a post-grant review document, and expert declarations. An expert declaration from Dr. Blake Hannaford was submitted in support of Truinject's positions and two expert declarations from Dr. Gianluca De Novi were submitted in support of SHDS's positions.
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> Plaintiff also submitted a technology tutorial. Neither party elected to put on live expert testimony, but the Court did permit

lengthy oral argument here today, and all of that has been carefully considered.

To be clear, while my oral ruling will cite to the intrinsic and extrinsic evidence that I conclude best support my recommended constructions, my failure to cite to other evidence provided by the parties does not mean that I ignored or failed to consider it. As I stated, I have considered all of the arguments and evidence cited by the parties.

Now as to my rulings.

As an initial matter, I'm not going to read into the record my understanding of the general legal principles of claim construction and indefiniteness. I set forth those standards in my opinion in *3Shape* [*A/S v. Align Technology, Inc.*, C.A. No. 18-886, 2020 WL 2188857, at *1-2 (D. Del. May 6, 2020)], and I incorporate that articulation by reference.

A claim term is supposed to be given the meaning that the term would have to a person of ordinary skill in the art at the time of the invention. And I note here that neither side has argued that any differences the parties may have in defining one of ordinary skill in the art for any of the three patents is material to resolving the disputes before me today. In other words, neither side is saying not to credit the other side's expert because they're not a person of skill in the art.

Defendant has also argued that a number of the disputed terms are indefinite, and, again, I incorporate by reference my understanding of the law of indefiniteness as set forth in *3Shape*, [2020 WL 2188857, at *2].

I understand that the parties agree on constructions for a number of terms and I will recommend to Chief Judge Stark that he adopt the agreed-upon constructions.

As to the disputed terms, I will start with the '836 patent. As I mentioned, it has two related terms in dispute. Claim 1 recites, in pertinent part:

> [1.] An anatomically shaped injection training apparatus comprising:
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> an at least partially hollow base configured to provide structural support;

> a clear layer of elastomer coating at least partially covering a base layer; [and]
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> an opaque layer at least partially covering the clear layer, wherein the base, clear layer, and opaque layer form an anatomical shape. . . .

The primary dispute for these terms is about which portion or portions of the training apparatus need to be anatomically shaped. I will start with the phrase "[partially hollow] base configured to provide structural support."

Truinject argues that the term should be construed as "an apparatus with a cavity or space that is used to provide support for the training device." According to Truinject, the base is required to provide support and be partially hollow, but it doesn't have to be anatomically shaped. Truinject points to the use of the word "may" in the specification to support its argument, for example, at column 3, lines 55 to 57. ['836 Patent at 3:55–57 ("In some embodiments, the base layer of the apparatus may be a clear plastic shell simulating a human or animal body part, such as, for example, a human or animal head.").]

SHDS argues that the base must be anatomically shaped. It argues that the specification only teaches one way in which the base is configured to provide structural support and that is because it is anatomically shaped. SHDS also argues that the PTAB's recent denial of IPR institution further supports its construction.

Starting with the claims, there is nothing in the claims suggesting that the base is required to be anatomically shaped. Nor does the specification suggest that the base must be anatomically shaped, and the specification does not criticize prior art on the basis that it's not.

As for SHDS's argument that all of the examples in the patent show anatomically shaped bases, the Federal Circuit has made clear that it is improper to import limitations into claims from examples or embodiments appearing only in a patent's written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that the patentee intends for the claims and the embodiments in the specification to be strictly coextensive. [*See Phillips,* 415 F.3d at 1323.]

I don't think the *ICU* case cited by SHDS during argument today is particularly informative. [*ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374-76 (Fed. Cir. 2009).] In that case, the Federal Circuit held that the term "spike" had to be pointed. The specification examples were consistent with the common understanding that a spike has to be pointy.

That case falls on the side of construing the claims in light of the specification. SHDS's argument here falls on the side of improperly importing limitations from the specification into the claims.

Turning to the prosecution history, I do not find SHDS's argument regarding the PTAB's decision persuasive. To the extent that particular PTAB decision denying IPR is even relevant to claim construction, I don't think it is informative on the issue here. I read that decision. The PTAB was assessing a piece of prior art that looked like a breast sitting on top of a giant hinged base that was in the shape of the letter Z. The PTAB stated that the prior art "does not describe explicitly a base that forms part of the anatomical shape" as was claimed in the '836 Patent. [D.I. 211, Ex. A at JA 14, 17-18.]

I don't take that statement to mean that the PTAB believed that the base claimed in the '836 patent itself had to be in an anatomical shape. At best, it means that the base must form part of the anatomical shape.

There is a secondary dispute about whether the base has to support the layers. I think that dispute was largely resolved during the hearing today in light of Truinject's agreement that it would modify its proposed construction.

Accordingly, I construe the phrase "[partially hollow] base configured to provide structural support" as "an apparatus with a cavity or space that is used to provide structural support for the clear layer and opaque layer."

Moving now to the phrase "the base, clear layer, and opaque layer form an anatomical shape."

For the same reasons, I agree with Truinject that this limitation does not require that each of the base, clear layer, and opaque layer have an anatomical shape.

There is nothing in the claims, specification, or prosecution history that requires that. Moreover, I do not think that construing the claim in accordance with Truinject's proposal makes the preamble redundant. The preamble tells us that the apparatus is anatomically shaped, and this claim phrase lets us know that it is these three components that give the apparatus its anatomical shape.

Accordingly, I construe this phrase as "the base, clear layer, and opaque layer together form an anatomical shape."

Now I'll move on to the '231 Patent. As I stated earlier, the '231 patent has five terms in dispute, the first two of which are related.

The terms "at least one evaluation criterion" and "at least one performance requirement" are found in Claim 1. Claim 1 provides, in pertinent part:

> [1.] A method to improve performance of an injection technique . . . comprising:
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> . . . evaluating electronically . . . the analyzed sensor-based injection information relative to at least one evaluation criterion; and
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> comparing electronically, . . . the analyzed sensor-based injection information with at least one performance requirement to determine whether the training injection met the at least one performance requirement. . . .

Truinject argues that "at least one evaluation criterion" means "one or more injection standards used to assess an injection." Truinject points out that the phrase is used in the specification, and that the specification provides multiple examples of what the evaluation criterion could be, for example, whether the injection hit the target location. I'm looking at column 7, lines 51 through 64. ['231 Patent, 7:51–64.]

Truinject argues that "at least one performance requirement" means "one or more injection standards used to measure injection performance." That phrase is also used in the specification. For example, at column 7, line 64 through column 8, line 2, it states: "Evaluating the injection information relative to at least one evaluation criterion can comprise comparing the obtained injection information with at least one performance requirement to determine

whether the training injection met the at least one performance requirement." ['231 Patent, 7:64–8:2.]

SHDS argues that the terms are indefinite. SHDS offers the declarations of Dr. De Novi in support of its argument that a person of skill in the art would not understand the scope of those terms.

I have carefully studied the relevant portions of Dr. De Novi's declarations, which are at paragraphs 19 through 29 of his first declaration and 3 through 13 of his second declaration. [D.I. 211, Ex. B ¶¶ 19-29, Ex. E ¶¶ 3-13.] Essentially, his opinion is, one, that the disputed phrases are broad because they cover all possible evaluation criteria and performance requirements. Two, that a person of skill in the art would want to know what subset of all evaluation criteria and performance requirements are covered by the claim. And, three, there is no basis in the patent to define a subset.

I make no finding about Dr. De Novi's opinion as a matter of science. But as a matter of patent law, claims are not indefinite just because they are broad. In paragraph 22 of Dr. De Novi's declaration, he opines that if the term "evaluation criteri[a]" were read broadly -- *i.e.*, to cover all evaluation criteria -- that the claim is not enabled. [D.I. 211, Ex. B ¶ 22.] That conflates definiteness with the question of enablement, which is a distinct inquiry.

The definiteness inquiry looks to see whether the claims, read in light of the specification and the prosecution history, inform with reasonable certainty those skilled in the art about the scope of the invention. The disputed phrases are broad -- and Truinject's construction is broad. I believe that a person of skill in the art would understand them to be broad. In other words, they reasonably inform those of skill in the art that the claims cover all standards used to assess an injection and all standards used to measure injection performance.

The declaration from Truinject's expert, Dr. Hannaford, supports that understanding. [D.I. 211, Ex. C ¶¶ 22-31.] Accordingly, I find that SHDS has not met its burden to show by clear and convincing evidence that the disputed phrases are indefinite.

Because SHDS has not proposed alternative constructions for either term, I will recommend that the court adopt most of Truinject's constructions. However, I do agree with SHDS to the extent it argued that introduction of the phrase "injection standards" into the construction is not helpful.

Accordingly, I construe the phrase "at least one evaluation criterion" to mean "one or more standards used to assess an injection." And I construe "at least one performance requirement" to mean "one or more standards used to measure injection performance."

The next term is "the information set." That term can be found in Claim 6. Claim 6 states in relevant part:

> [6.] A method to analyze a collection of injection training data . . . comprising:
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> . . . receiving, by the one or more signal processors of the injection training system, the collection of injection training data, the collection of injection training data comprising information sets, wherein an information set comprises data collected during the injection training from the at least one syringe sensor, the information set comprising:
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> information describing dynamic motion of the syringe relative to the anatomically-shaped apparatus as the syringe delivers the training injection to the anatomically-shaped apparatus;
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> information describing the anatomically-shaped apparatus; and
>
> information describing the training injection.
> . . .

The parties' dispute over this term is about whether the data in the information set can include data from the training apparatus in addition to the data from the syringe sensor. Truinject says it can. SHDS says it can't.

I agree with Truinject that there is no requirement in the claim that requires the data to be obtained solely from the at least one syringe sensor. The claim language says the information set *comprises* data collected from the syringe sensor. As the Federal Circuit has recognized, the term "comprising" is a term of art which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.

[*See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997).]

I reject SHDS's argument that the applicant limited the scope of this term during prosecution. I have carefully reviewed the cited prosecution history and I do not agree with SHDS that the applicant narrowed its claims in such a way to surrender coverage of information sets that contain data from the training apparatus. [D.I. 194-1, Ex. 4.] Therefore, the term "the information set" is properly construed so that it must contain data collected from the syringe sensor, but it can also contain other data.

Accordingly, I construe "the information set" as "the data collected during the injection training from the syringe or training apparatus, but must include data collected from at least one syringe sensor."

The next term is "information describing the training injection," which is found in Claim 6 of the '231 patent. The relevant portion of Claim 6 is, again:

> receiving, by the one or more signal processors of the injection training system, the collection of injection training data, the collection of injection training data comprising information sets, wherein an information set comprises data collected during the injection training from the at least one syringe sensor, the information set comprising:
>
> [1] information describing dynamic motion of the syringe relative to the anatomically-shaped apparatus as the syringe delivers the training injection to the anatomically-shaped apparatus;
>
> [2] information describing the anatomically-shaped apparatus; and
>
> [3] information describing the training injection. . . .

The phrase "information describing the training injection" was amended during prosecution. The term originally read: "information describing the training session." That is a phrase used in the specification, for example, at column 10, lines 47 to 61, and column 12, lines 13 through 17. ['231 Patent, 10:47–61, 12:13–17.] The latter states that information describing the training session

"includes, without limitation, a training date and time; a training location; a trainee identity; a training session duration; a training score; an injection time; and a pass/fail determination."

The phrase "information describing the training injection" appears nowhere in the specification.

Truinject's opening brief suggested that I should construe "information describing the training injection" coextensive with "information describing the training session." In its reply brief, however, it argued that "information describing the training injection is . . . different from information describing the training session, which includes the date, time location, duration, score, or pass/fail determination." [D.I. 210 at 57.] And it argues that "information describing the training injection" means "data describing the training syringe or training apparatus during the training injection."

Truinject offered the opinion of its expert, Dr. Hannaford, in support of its construction of this term. [D.I. 211 ¶¶ 32–37.] I make no conclusions about Dr. Hannaford's opinion as a matter of science. But Dr. Hannaford does not resolve the linguistic and legal conflict pointed out by SHDS. As SHDS points out, the claim requires the information set to contain, in addition to information describing the training injection, information describing dynamic motion of the syringe and information describing the anatomically shaped apparatus.

Truinject's proposed construction of "information describing the training injection" would encompass information describing the dynamic motion of the syringe and information describing the apparatus, which would render those requirements superfluous.

Truinject and its expert, as far as I can understand them, respond that a person of skill in the art would therefore understand "information describing the training injection" to mean all data describing the training syringe or training apparatus during the training session except what the patent considers "information describing the training session" and except information describing the anatomically shaped apparatus and the dynamic motion of the syringe, both of which are already required by the claim.

The problem is that Truinject's proposed construction captures what Truinject itself agrees cannot be included in the scope of the term. Truinject has not proposed a reasoned basis or

construction to resolve this problem, and I agree with SHDS and its expert that it cannot be done. For that reason, I agree with SHDS that the term "information describing the training injection" is indefinite.

And I want to be clear about why I find this term indefinite but I didn't find the disputed terms in the '836 Patent indefinite. As an initial matter, the disputed '836 Patent terms were actually used in the specification and the specification informed their meaning. Here, in contrast, the specification does not use the disputed phrase.

Moreover, standing alone, the "information describing the training injection" term could be broadly construed as all information that describes the training injection, and that is the approach I took with the disputed terms in the '836 Patent. But unlike the disputed terms in the '836 Patent, claim 6 of the '231 Patent contains two other claim terms that inform the scope of the "information describing the training injection" term. An analysis of the claim language and specification reveals no principled basis or guidance as to how to construe it less broadly so that it does not overlap with or encompass information already captured by the two other terms.

Truinject's proposed construction does not resolve the issue. Nor have Truinject or its expert explained what category of information this term would capture in a way that would inform with reasonable certainty those skilled in the art about the scope of the invention. [*Nautilus,* 572 U.S. at 901.] Accordingly, it is indefinite.

Finally, the term "the information describing the training session" appears in claim 12, a dependent claim to claim 6. Claim 12 recites: "The method of claim 6, wherein the information describing the training session comprises" various things.

I find this claim indefinite for lack of an antecedent basis. As I mentioned, the application claim that became claim 6 originally required "information describing the training session." And the dependent application claim added the additional limitation as to what that information describing the training session must be. When the independent claim was amended to change information describing the training session to information describing the training injection, the dependent claim was not amended. And now it refers back to a term that is no longer there.

As the Court found in the *RetailMeNot* case, the amended claim's lack of an antecedent basis renders it invalid. [*RetailMeNot,*

> *Inc. v. Honey Sci. Corp.*, No. 18-937, 2019 WL 6337719, *23 (D. Del. Nov. 27, 2019).]
>
> In a footnote in its reply brief, Truinject says that the Court can correct the patent by replacing "training session" in claim 12 with "training injection" because the substitution is not subject to a "reasonable debate." The problem with that is that the information comprising the training session in dependent claim 12 is information that Truinject itself argues is different information than what is covered by the phrase "information describing the training injection." In light of that, and in view of the circumstances surrounding the patentee's amendment of the term in claim 6 during prosecution, it's clear that the issue is subject to debate.
>
> The *Energizer Holdings* case cited by Truinject is not to the contrary. That case held that the phrase "said zinc anode" was not indefinite for lack of an antecedent basis because another claim phrase contained the limitation "anode gel comprised of zinc." [*Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1369–71 (Fed. Cir. 2006).] Here, there is no phrase that "the information describing the training session" could be referring to, since Truinject itself agrees that the information describing the training session is different than the information describing the training injection.
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> Given the lack of an antecedent basis for the term "the information describing the training session," I find that it is indefinite.
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> That concludes my claim construction rulings today.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B),(C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

Dated: June 18, 2020

The Honorable Jennifer L. Hall
United States Magistrate Judge