

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION**

ENSERION, LLC,

§

v.

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Civil Action No. 4:20-cv-108

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(Judge Mazzant)

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ORTHOFIX, INC.

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CLAIM CONSTRUCTION MEMORANDUM OPINION AND ORDER

Before the Court is Enserion, LLC’s (“Plaintiff’s” or “Enserion’s”) Opening Claim Construction Brief (Dkt. #47), Defendant Orthofix, Inc.’s (“Defendant’s” or “Orthofix’s”) Responsive Claim Construction Brief (Dkt. #48), and Plaintiff’s Reply Claim Construction Brief (Dkt. #50). Also before the Court are the parties’ December 30, 2020 P.R. 4-3 Joint Claim Construction and Prehearing Statement (Dkt. #45) and the parties’ February 19, 2021 Joint Claim Construction Chart (Dkt. #51).

The Court held a claim construction hearing on February 25, 2021, to determine the proper construction of the disputed claim terms in United States Patent No. 10,216,904 (“the ’904 Patent”).

The Court issues this Claim Construction Memorandum Opinion and Order and hereby incorporates-by-reference the claim construction hearing and transcript as well as the parties’ demonstrative slides (Dkt. #52; Dkt. #53) presented during the hearing. For the following reasons, the Court provides the constructions set forth below.

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BACKGROUND

Plaintiff alleges infringement of United States Patent No. 10,206,904 (Dkt. #48, Ex. 1). Plaintiff submits that the '904 Patent relates to “cloud-assisted rehabilitation” technology, particularly “the use of wearable intelligent rehabilitation members within rehabilitation apparatuses that gather rehabilitation information from patients and link to a cloud-assisted rehabilitation portal to aggregate and de-identify musculoskeletal rehabilitation information.” (Dkt. #47, at p. 1). Defendant submits that the patent “generally relates to collecting, manipulating, and sharing ‘musculoskeletal rehabilitation information’ for use in medical rehabilitation.” (Dkt. #48, at p. 1). “Specifically,” Defendant submits, “the '904 Patent describes a ‘cloud-assisted rehabilitation system’ that consists primarily of (1) intelligent musculoskeletal rehabilitation apparatuses attached to a plurality of patients that generate musculoskeletal rehabilitation information using conventional sensors (e.g., accelerometers), and (2) a ‘rehabilitation portal’ that

receives, de-identifies, processes, aggregates, and reports the musculoskeletal rehabilitation information collected from the sensors.” (*Id.*)

The ’904 Patent, titled “Cloud-Assisted Rehabilitation Methods and Systems for Musculoskeletal Conditions,” issued on February 26, 2019, and bears an earliest priority date of April 16, 2014. The Abstract of the ’904 Patent states:

Embodiments of the invention include a cloud-assisted rehabilitation system for assisting in the rehabilitation of musculoskeletal conditions, and a method for rehabilitating patients having musculoskeletal conditions. A rehabilitation portal can aggregate and de-identified [*sic*] musculoskeletal rehabilitation information that is gathered from various intelligent musculoskeletal rehabilitation apparatuses attached to a group of patients. The rehabilitation portal can facilitate crowd communication among the group of patients. A particular rehabilitation experience can be compared with other rehabilitation experiences and data from other patients. The rehabilitation portal can also facilitate crowd communication among a group of healthcare professionals so that the plurality of healthcare professionals can communicate with each other and compare information regarding different rehabilitation experiences based at least on the aggregated de-identified musculoskeletal rehabilitation information.

Plaintiff also submits that “[f]undamental to both [the] ’904 Patent[] and this case is the Health Insurance and Portability Act [*sic*, Health Insurance Portability and Accountability Act] of 1996 (‘HIPAA’),” and “HIPAA privacy protections provide a framework to technologists as to how to protect ‘individually identifiable information’ (or ‘personally identifiable information,’ ‘PII’).” (Dkt. #47, at pp. 1 & 2).

LEGAL STANDARDS

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). The purpose of claim construction is to resolve the meanings and technical scope of claim terms. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). When the parties dispute the scope of a claim term, “it is the court’s duty to resolve it.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

“It is a ‘bedrock principle’ of patent law 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) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The Court examines a patent’s intrinsic evidence to define the patented invention’s scope. *Id.* at 1313–14; *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). Intrinsic evidence includes the claims, the rest of the specification, and the prosecution history. *Phillips*, 415 F.3d at 1312–13; *Bell Atl. Network Servs.*, 262 F.3d at 1267. The Court gives claim terms their ordinary and customary meaning as understood by one of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

Claim language guides the Court’s construction of claim terms. *Phillips*, 415 F.3d at 1314. “[T]he context in which a term is used in the asserted claim can be highly instructive.” *Id.* Other claims, asserted and unasserted, can provide additional instruction because “terms are normally used consistently throughout the patent.” *Id.* Differences among claims, such as additional limitations in dependent claims, can provide further guidance. *Id.*

“[C]laims ‘must be read in view of the specification, of which they are a part.’” *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). In the specification, a patentee may define his own terms, give a claim term a different meaning than it would otherwise possess, or disclaim or disavow some claim scope. *Phillips*, 415 F.3d at 1316. Although the Court generally presumes terms possess their ordinary meaning, this presumption

can be overcome by statements of clear disclaimer. See *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343–44 (Fed. Cir. 2001). This presumption does not arise when the patentee acts as his own lexicographer. See *Irdeto Access, Inc. v. EchoStar Satellite Corp.*, 383 F.3d 1295, 1301 (Fed. Cir. 2004).

The specification may also resolve ambiguous claim terms “where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.” *Teleflex*, 299 F.3d at 1325. For example, “[a] claim interpretation that excludes a preferred embodiment from the scope of the claim ‘is rarely, if ever, correct.’” *Globetrotter Software, Inc. v. Elan Computer Group Inc.*, 362 F.3d 1367, 1381 (Fed. Cir. 2004) (quoting *Vitronics*, 90 F.3d at 1583). But, “[a]lthough the specification may aid the court in interpreting the meaning of disputed language in the claims, particular embodiments and examples appearing in the specification will not generally be read into the claims.” *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988); accord *Phillips*, 415 F.3d at 1323.

The prosecution history is another tool to supply the proper context for claim construction because a patentee may define a term during prosecution of the patent. *Home Diagnostics Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) (“As in the case of the specification, a patent applicant may define a term in prosecuting a patent.”). The well-established doctrine of prosecution disclaimer “preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.” *Omega Eng’g Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). “Indeed, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover.” *Spectrum Int’l v. Sterilite Corp.*, 164 F.3d 1372, 1378–79 (Fed. Cir. 1988) (quotation omitted). “As a basic principle of claim interpretation,

prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Omega Eng'g*, 334 F.3d at 1324. However, the prosecution history must show that the patentee clearly and unambiguously disclaimed or disavowed the proposed interpretation during prosecution to obtain claim allowance. *Middleton Inc. v. 3M Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002). Statements will constitute disclaimer of scope only if they are "clear and unmistakable statements of disavowal." *See Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1358 (Fed. Cir. 2003). An "ambiguous disavowal" will not suffice. *Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1285 (Fed. Cir. 2010) (citation omitted).

Although "less significant than the intrinsic record in determining the legally operative meaning of claim language," the Court may rely on extrinsic evidence to "shed useful light on the relevant art." *Phillips*, 415 F.3d at 1317 (quotation omitted). Technical dictionaries and treatises may help the Court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but such sources may also provide overly broad definitions or may not be indicative of how terms are used in the patent. *Id.* at 1318. Similarly, expert testimony may aid the Court in determining the particular meaning of a term in the pertinent field, but "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful." *Id.* Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.*

The Supreme Court of the United States has "read [35 U.S.C.] § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). "A determination of claim indefiniteness is a

legal conclusion that is drawn from the court’s performance of its duty as the construer of patent claims.” *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005) (citations and internal quotation marks omitted), *abrogated on other grounds by Nautilus*, 134 S. Ct. 2120. “Indefiniteness must be proven by clear and convincing evidence.” *Sonix Tech. Co. v. Publ’ns Int’l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017).

LEVEL OF ORDINARY SKILL IN THE ART

The parties dispute the level of ordinary skill in the art. *See Phillips*, 415 F.3d at 1313 (“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.”); *see also Rambus Inc. v. Hynix Semiconductor Inc.*, 569 F. Supp. 2d 946, 982 n.15 (N.D. Cal. 2008) (Whyte, J.) (resolving dispute about the level or ordinary skill in the art); *but see Med. Research Inst. v. Bio-Engineered Supplements & Nutrition, Inc.*, No. 6:05-CV-417, 2007 WL 128937, at *3 n.2 (E.D. Tex. Jan. 12, 2007) (Davis, J.) (“While the parties dispute—without detailed briefing—the level of ordinary skill in the art for the ’707 patent, the Court’s construction is not affected because the disputed terms are either defined in the patent or are ordinary words not specific to the art to be construed according to their customary meaning.”).

“Factors that may be considered in determining [the] level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citation and quotation omitted).

Plaintiff proposes that “a person of ordinary skill in the art would have a degree in computer science or computer engineering, or equivalent experience, as well as experience with HIPAA-related requirements as they pertain to information technology.” (Dkt #47, at p. 4; Dkt. #50, at p. 1). Plaintiff argues that “[b]ecause the Patent-in-Suit involves both technical and medical components, a POSITA [(person of ordinary skill in the art)] must have experience with both information technology and the protection of personal information.” (Dkt. #50, at p. 1).

Defendant proposes that “a POSITA would possess, at minimum, a 4-year degree in engineering (e.g., mechanical, electrical, biomedical, computer, computer software) or science (e.g., biology, kinesiology) and have at least four years of job-related experience in a related profession. Alternatively, a POSITA could come from one of the relevant health-science fields (e.g., orthopedics, physiatry, rehabilitation medicine, or physical therapy). It is also reasonable that a POSITA may be an individual with at least four years of job-related experience in the field of computer software or systems development.” (Dkt. #48, at p. 3).

As discussed at the February 25, 2021 hearing, because the Court’s analysis herein remains the same under either proposal, the Court need not resolve this disagreement at this time.

ANALYSIS

Agreed Claim Terms

In their December 30, 2020 P.R. 4-3 Joint Claim Construction and Prehearing Statement, the parties submit they have not agreed on constructions for any claim terms. (Dkt. #45, at p. 1).

*Disputed Claim Terms***A. “musculoskeletal”**

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
No construction required. Alternatively: “having to do with the muscles, bones, tendons, and/or ligaments”	pertaining to both the muscles and the bones

(Dkt. #45, Ex. A, at p. 9; Dkt. #47, at p. 9; Dkt. #48, at p. 4; Dkt. #50, at p. 5). The parties submit that this disputed term appears in Claims 1, 3–7, 15, and 18–22. (Dkt. #45, Ex. A, at p. 9; Dkt. #48, at p. 4).

1. The Parties’ Positions

Plaintiff argues that this term requires no construction because the specification gives examples of musculoskeletal systems as well as examples of musculoskeletal conditions. (Dkt. #47, at p. 9). Plaintiff argues that Defendants’ proposal of requiring muscles *and* bones is inconsistent with the plain meaning of the term as well as with the written description of the ’904 Patent, and Plaintiff also submits “the prosecution history shows that the patentee did not limit its teachings to a single anatomical system, or even a combination of only muscles and bones.” (*Id.*, at p. 10).

Defendant responds that its proposal “aligns with the well-known ordinary meaning of ‘musculoskeletal’ and the patentee’s statements during prosecution.” (Dkt. #48, at p. 4). Further, Defendant argues that “[c]onstruing ‘musculoskeletal’ as ‘pertaining to the muscles and bones’ is also consistent with the well-known meaning of the term and the extrinsic evidence.” (*Id.*, at p. 5) (citation omitted).

Plaintiff replies that “[t]he issue is not whether this term *refers* to muscles and bones, but whether a musculoskeletal issue must necessarily *include* both muscles and bones.” (Dkt. #50, at p. 6). Plaintiff argues that “Orthofix is attempting to narrow the meaning of the term by implying that a condition is not ‘musculoskeletal’ if it is either entirely muscle or skeletal in nature.” (*Id.*)

At the February 25, 2021 hearing, Defendant emphasized that the patentee explicitly explained the meaning of “musculoskeletal” in the prosecution history. Plaintiff responded that this term is a broad “umbrella” that encompasses a wide range of structures and conditions.

2. Analysis

Claim 1, for example, recites (emphasis added):

1. A cloud-assisted rehabilitation system for *musculoskeletal* conditions, comprising:

a plurality of intelligent *musculoskeletal* rehabilitation apparatuses each including one or more intelligent rehabilitation members, each of the intelligent rehabilitation members having a logic section, wherein the intelligent *musculoskeletal* rehabilitation apparatuses are configured to be attached to a corresponding plurality of patients to generate, by the corresponding logic section, *musculoskeletal* rehabilitation information; and

a rehabilitation portal configured to receive the *musculoskeletal* rehabilitation information from the plurality of patients, de-identify personal identifying information from the *musculoskeletal* rehabilitation information, process the *musculoskeletal* rehabilitation information, aggregate the de-identified *musculoskeletal* rehabilitation information, and generate one or more reports for one or more healthcare professionals based at least on the aggregated de-identified *musculoskeletal* rehabilitation information.

During prosecution, the patentee argued as follows regarding prior art references identified as “Giuffrida” (United States Patent Application Publication No. 2014/0257141), “Homchowdhury” (United States Patent Application Publication No. 2012/0278095), and “Gao” (United States Patent Application Publication No. 2009/0069642):

Nowhere does Giuffrida include the term “musculoskeletal.” While Giuffrida refers to muscles of the body, there is no mention of *musculoskeletal*, a *specific term which relates to both the muscles and the bones*. There is no mention of bones or skeleton in either Giuffrida or Homchowdhury.

(Dkt. #48, Ex. 4, Amendment and Reply Under 37 C.F.R. § 1.111, at p. 11 (Enserion-000206))

(emphasis added).

Nowhere does Giuffrida, Homchowdhury, or Gao include the term “musculoskeletal.” While Giuffrida refers to muscles of the body, there is no mention of *musculoskeletal*, a specific term which relates to both the muscles and the bones. There is no mention of bones or skeleton in any of Giuffrida, Homchowdhury, and Gao.

(*Id.*, at p. 22 (Enserion-000217)) (emphasis added).

However, as explained above, there is zero mention of *musculoskeletal* rehabilitation information in Giuffrida, a specific term which relates to both the muscles and the bones. There is no mention of either bones or skeleton in Giuffrida.

(*Id.*, at p. 24 (Enserion-000219)) (emphasis added).

Thus, in distinguishing the Giuffrida, Homchowdhury, and Gao references as lacking disclosure of bones or skeleton, the patentee explained that the word “musculoskeletal” refers to “both the muscles and the bones.” (*Id.*)

Plaintiff argues that “[n]othing in the cited references indicates that the patentee was intending to limit the definition to muscle and bone. On the contrary, the cited references indicate that the patentee was intending to broaden the definition to include more than just muscle.” (Dkt. #50, at p. 6).

A fair reading of this prosecution history, however, is that the above-reproduced statements amount to definitive statements by the patentee explaining the meaning of “musculoskeletal.” *Home Diagnostics*, 381 F.3d at 1356 (“As in the case of the specification, a patent applicant may define a term in prosecuting a patent.”); *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). These definitive statements should be given effect in the Court’s construction. *See Omega Eng’g*, 334 F.3d at 1324 (“As a basic principle of claim interpretation,

prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution.”).

The “Background” section of the specification provides examples of (or perhaps examples of *parts* of) “the musculoskeletal system, such as a knee, elbow, wrist, and the like,” and discusses “[f]or example physical therapy for knee conditions”:

Preparation for and recovery from injury or surgery on *the musculoskeletal system, such as a knee, elbow, wrist, and the like*, can be a long and painstaking experience. Likewise, recovery from a host of non-surgical *musculoskeletal conditions* often requires prolonged exercises for recovery of range of motion and strength. * * *

For example physical therapy for knee conditions can be especially intensive and require particular attention by medical professionals. Patellar Chondromalacia—a form of cartilage damage—requires prolonged exercises for strengthening of the extensors to allow return to function. For total knee arthroplasty (i.e., total knee replacement), these patients typically range in age from 55–90 years old. They often need both preoperative and postoperative therapy. Anterior cruciate ligament (ACL) reconstruction patients typically range in age from 15–55 years old. They also require both preoperative and postoperative therapy. Knee arthroscopy patients typically range in age from 18–70 years old. These patients may benefit from postoperative physical therapy.

'904 Patent at 1:22–49 (emphasis added).

Plaintiff emphasizes the example of ACL reconstruction as not involving muscles and bones, but the above-reproduced disclosure regarding ACL reconstruction does not purport to define “musculoskeletal,” and structures such as “a knee, elbow, wrist, and the like” relate to muscles as well as bones. Thus, the specification is consistent with the above-cited prosecution history in which the patentee referred to “musculoskeletal” as relating to muscles *and* bones. Even if the specification were deemed ambiguous in this regard, at a minimum the specification is not *inconsistent* with the *definitive* statements set forth in the above-reproduced prosecution history.

Extrinsic evidence further reinforces this understanding. Both parties cite a medical dictionary that defines “musculoskeletal” as “pertaining to the muscles and the skeleton.” (Dkt.

#48, Ex. 5) (the exhibit shows only the definition, but Defendant cites this exhibit as “Mosby’s Med. Dictionary (10th ed. 2017) at 1176,” and Plaintiff has cited the same definition appearing in a different edition of the same dictionary (Dkt. #45, Ex. A, at p. 11)).

Finally, the opinions of Defendant’s expert are more persuasive on this issue than the opinions of Plaintiff’s expert. (See Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶¶ 3–43; see also *id.*, Ex. B, Dec. 30, 2020 Bergeron Decl., at ¶¶ 46–52). In particular, Plaintiff’s expert’s opinions as to the above-discussed “knee conditions” mentioned in the specification do not undercut the above-discussed definitive statements regarding “musculoskeletal” in the prosecution history that are, moreover, supported by other intrinsic and extrinsic evidence as discussed above. (See *id.*, at ¶ 48).

Although Plaintiff’s expert opines (and Defendant does not appear to challenge) that an individual muscle, bone, cartilage, ligament, or tendon can be “considered to be part of the musculoskeletal system” (*id.*, at ¶ 48(c)), the opinions of Plaintiff’s expert fail to demonstrate that the word “musculoskeletal” itself refers to only muscles, only bones, only cartilage, only ligaments, or only tendons. (See *id.*, at ¶¶ 46–52).

The Court therefore hereby construes “**musculoskeletal**” as “**relating to both the muscles and the bones.**”

B. “intelligent rehabilitation member”

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
<p>No construction required.</p> <p>Alternatively: “device that measures musculoskeletal condition data”</p> <p>Alternatively: “Enserion can agree to the first portion of Orthofix’s construction: ‘device that measures musculoskeletal rehabilitation information.’”</p>	<p>device that measures musculoskeletal rehabilitation information using one or more sensors</p>

(Dkt. #47, at p. 13; *see* Dkt. #45, Ex. A, at p. 15; Dkt. #48, at p. 6; Dkt. #50, at p. 8). The parties submit that this disputed term appears in Claim 1. (Dkt. #45, Ex. A, at p. 15; Dkt. #48, at p. 1).

1. The Parties’ Positions

Plaintiff argues that “Plaintiff does not believe this term requires construction; it is described in throughout the intrinsic record. *See, e.g.*, ’904 Patent at 3:35–45; 3:50–53; 4:16–20; 4:38–40; 11:23–31.” (Dkt. #47, at p. 13). Plaintiff argues that “Orthofix’s construction—‘using one or more sensors’—is misleading and should not be adopted” because of its “implication that information must be gathered by that sensor rather than manually.” (*Id.*) Plaintiff cites disclosure in which range-of-motion information can be sensed or, alternatively, can be manually inputted by the patient or by someone assisting the patient. (Dkt. #47, at pp. 13–14) (discussing ’904 Patent at 4:14–20).

Defendant responds that “[t]he intelligent rehabilitation member cannot perform its intended function without at least one sensor, typically an accelerometer.” (Dkt. #48, at p. 8) (citation omitted). Defendant also argues “[t]his conclusion is also consistent with the patentee’s statements during prosecution” such that “[p]rosecution disclaimer bars Enserion from a

construction of ‘intelligent rehabilitation member’ that excludes a sensor.” (*Id.*) (citation omitted). Further, Defendant argues that its proposed construction does not preclude manual data entry because “[t]he word ‘automatic’ is not in Orthofix’s proposed construction,” and “the ’904 Patent describes that users provide data ‘via manual entry’ on the ‘mobile device,’ not via the intelligent rehabilitation member.” (*Id.* at pp. 8–9).

Plaintiff replies that “[g]iven that Orthofix agrees that data may be collected manually or automatically (Resp. at 8), the dispute over this term centers on whether an ‘intelligent rehabilitation member’ must include one or more sensors,” and “[i]t is clear from the intrinsic record that an ‘intelligent rehabilitation member’ does *not* need to include one or more sensors.” (Dkt. #50, at p. 8).

At the February 25, 2021 hearing, Defendant argued that the types of data contemplated by the specification cannot come from manual input but instead can only be gathered by sensors. Plaintiff argued that the specification discloses manual input and, moreover, data could be gathered by devices other than sensors, such as by timers.

2. Analysis

Defendant cites prosecution history as purportedly demonstrating that an “intelligent rehabilitation member” includes a sensor. In particular, Defendant submits that the patentee argued as follows regarding the “Schrock” reference (United States Patent Application Publication No. 2012/0291563):

The electronic modules mentioned in Schrock . . . can only be referring to the electronic module 22 The electronic module 22 that stores data is separate from the sensors 16A and 16B. In contrast, one rehabilitation member *of the present invention* includes both the sensor, the memory for storing musculoskeletal rehabilitation information, and a transmitter for transmitting the musculoskeletal rehabilitation information. Therefore, Schrock fails to disclose “the logic section of the first intelligent rehabilitation member[”] (*which also includes the sensor*) is configured to store the gathered musculoskeletal rehabilitation information and to

transmit the gathered musculoskeletal rehabilitation information. Schrock also does not teach storing musculoskeletal rehabilitation information gathered by both the first and second intelligent rehabilitation members (*which include the sensors*), in the memory of the first intelligent rehabilitation member.

(Dkt. #48, Ex. 4, Amendment and Reply Under 37 C.F.R. § 1.111 at pp. 30–31 (Enserion-000225–26)) (emphasis modified).

This prosecution history is unpersuasive because the patentee’s argument addressed application claim 10, which depended from claim 9, which expressly recited “a first intelligent rehabilitation member . . . further comprises . . . a first *sensor* . . .; and a second intelligent rehabilitation member . . . further comprises . . . a second *sensor*.” (*See id.*; *see also id.*, at pp. 5–6 (Enserion-000200–01)) (emphasis added). This prosecution history thus does not significantly affect the analysis of whether an “intelligent rehabilitation member” necessarily measures musculoskeletal rehabilitation information using one or more sensors.

Surrounding claim language, however, provides context for understanding the information-gathering role of “intelligent rehabilitation members” in the claimed invention. Claim 1 recites (emphasis added):

1. A cloud-assisted rehabilitation system for musculoskeletal conditions, comprising:

a plurality of intelligent musculoskeletal rehabilitation apparatuses each including one or more *intelligent rehabilitation members*, each of the *intelligent rehabilitation members* having a logic section, wherein the intelligent musculoskeletal rehabilitation apparatuses are configured to be attached to a corresponding plurality of patients to generate, by the corresponding logic section, musculoskeletal rehabilitation information; and

a rehabilitation portal configured to receive the musculoskeletal rehabilitation information from the plurality of patients, de-identify personal identifying information from the musculoskeletal rehabilitation information, process the musculoskeletal rehabilitation information, aggregate the de-identified musculoskeletal rehabilitation information, and generate one or more reports for one or more healthcare professionals based at least on the aggregated de-identified musculoskeletal rehabilitation information.

Also, the specification discloses “intelligent rehabilitation members” gathering types of information that can be readily understood as being gathered by sensors, such as “gait patterns”:

The intelligent musculoskeletal rehabilitation apparatus 108 can include one or more *intelligent rehabilitation members* (e.g., 110, 115, 132, 134, and/or 136) to measure *range-of-motion (ROM) data 142* for an entire extremity and/or for one or more limbs of a human patient 102. Alternatively or in addition, the one or more intelligent rehabilitation members (e.g., 110, 115, 132, 134, and/or 136) can measure *musculoskeletal conditions data 146 including temperature, limb circumference (swelling), gait patterns, step counts, or the like*.

For example, the intelligent musculoskeletal rehabilitation apparatus 108 can include a first intelligent rehabilitation member 110 and/or a second intelligent rehabilitation member 115. Alternatively or in addition, the intelligent musculoskeletal rehabilitation apparatus 108 can include multiple intelligent rehabilitation members (e.g., 110, 115, 132, 134, and/or 136) that can be attached to various parts or locations of the patient 102.

* * *

The ROM data 142 can be automatically gathered by the intelligent musculoskeletal rehabilitation apparatus 108. Alternatively or in addition, the ROM data 142 can be gathered through fillable forms 152 presented on a display 158 of the mobile device 120, which can be manually filled by the patient 102 or another person (not shown) who assists the patient 102.

* * *

[O]ne or more functional scores 156 can be generated and/or collected at specified times postoperatively. The functional scores 156 can include, for example, a “get up and go” test, a walking test, or the like. The functional scores 156 can be automatically generated and/or collected by the intelligent musculoskeletal rehabilitation apparatus 108, and transmitted to the mobile device 120. Alternatively or in addition, the functional scores 156 can be generated based at least on information received manually from the patient 102.

* * *

The intelligent musculoskeletal rehabilitation apparatus 108 can be comprised of individual and separate intelligent rehabilitation members (e.g., 110 and 115) that can be electronically paired to each other, as further described below. The intelligent musculoskeletal rehabilitation apparatus 108 can be configured such that it allows low-friction extension of a limb (e.g., 112) at the joint 105 as shown at 805.

The intelligent musculoskeletal rehabilitation apparatus 108 can include one or more accelerometers 810, one or more transmitters 815, one or more receivers 820, memory 825, a logic section 830, one or more sensors 835, or the like. For example, one or more of the intelligent rehabilitation members (e.g., 110 and 115) can include the one or more accelerometers 810, the one or more transmitters 815, the one or more receivers 820, the memory 825, the logic section 830, the one or more sensors 835, or the like.

* * *

Put differently, the intelligent rehabilitation member 110 can include an actuator 905 for creating a logical pairing between the intelligent rehabilitation member 110 and the intelligent rehabilitation member 115. The intelligent rehabilitation member 110 can include the paired indicator 910 to indicate whether or not the logical pairing between the intelligent rehabilitation member 110 and the intelligent rehabilitation member 115 has occurred. While each of the intelligent rehabilitation members (e.g., 110 and 115) can gather musculoskeletal rehabilitation information (e.g., 148 of FIG. 1), one of the intelligent rehabilitation members (e.g., 110) can be designated the primary member for gathering the musculoskeletal rehabilitation information 142 for a particular intelligent musculoskeletal rehabilitation apparatus 108, and transmitting the musculoskeletal rehabilitation information 142 for the particular intelligent musculoskeletal rehabilitation apparatus 108 to the mobile device (e.g., 120 of FIG. 1).

* * *

Each of the intelligent rehabilitation members (e.g., 110, 115, 132, 134, and/or 136) associated with corresponding intelligent musculoskeletal rehabilitation apparatuses 108 can include a transmitter 815, a first accelerometer 810, a first sensor 835, and a memory 825. In some embodiments, an intelligent rehabilitation member (e.g., 115) associated with a particular intelligent musculoskeletal rehabilitation apparatus 108 can include a second accelerometer (e.g., such as 810) and a second sensor (e.g., such as 835). The logic section 830 of a first intelligent rehabilitation member (e.g., 110) can automatically gather at least some of (e.g., a first portion of) the musculoskeletal rehabilitation information 148 using at least one of the first accelerometer 810 or the first sensor 835. The logic section of a second intelligent rehabilitation member (e.g., 815) can automatically gather at least some of (e.g., a second portion of) the musculoskeletal rehabilitation information 148 using at least one of the second accelerometer or the second sensor.

'904 Patent at 3:35–53, 4:14–20, 4:34–43, 11:15–31, 12:40–57 & 14:65–15:15 (emphasis added); *see id.* at 15:53–55 (“Each of the intelligent rehabilitation members can include one or more sensors and a transmitter.”).

These disclosures refer to embodiments in which “intelligent rehabilitation members” include sensors (and gather types of information that can be readily understood as being gathered by sensors). On one hand, claim terms usually should not be limited to the specific features of particular disclosed embodiments. *See Phillips*, 415 F.3d at 1323 (“although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments”).

On the other hand, Plaintiff does not show that the term “intelligent rehabilitation member” has any well-established meaning outside of the patent-in-suit, so looking to the specification for meaning is appropriate. *See Intervet, Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir. 2010) (“Idiosyncratic language, highly technical terms, or terms coined by the inventor are best understood by reference to the specification.”) (citing *Phillips*, 415 F.3d at 1315); *see also Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1164 (Fed. Cir. 2004) (citation omitted) (“Where a claim term has no ordinary and customary meaning, a court must resort to the remaining intrinsic evidence—the written description and the prosecution history—to obtain the meaning of that term.”).

On balance, the specification provides context for understanding the information-gathering role of the “intelligent rehabilitation members” that is apparent from surrounding claim language. For example, Defendant’s proposal of requiring use of a sensor is consistent with the above-reproduced disclosure regarding measuring “range-of-motion” or “temperature, limb circumference (swelling), gait patterns, step counts, or the like.” ’904 Patent at 3:35–45. Requiring an “intelligent rehabilitation member” to include a sensor gives proper effect to this use of the word “intelligent” when viewed in the context of the claim language and the specification. *See Intervet*, 617 F.3d at 1287 (quoted above); *see also Goldenberg*, 373 F.3d at 1164 (quoted

above); *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1144–45 (Fed. Cir. 2005) (construing “board” to mean “wood cut from a log,” noting that in the intrinsic record the patentee “consistently used the term ‘board’ to refer to wood cut from a log,” and stating that the patentee “is not entitled to a claim construction divorced from the context of the written description and prosecution history”). The opinions of Defendant’s expert are also persuasive as to an “intelligent rehabilitation member” including a sensor. (*See* Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶¶ 47–51).

Although Plaintiff asserts in its reply brief that “[i]t is clear from the intrinsic record that an ‘intelligent rehabilitation member’ does *not* need to include one or more sensors” (Dkt. #50, at p. 8), Plaintiff stated in its opening brief that “[t]he issue with Orthofix’s proposal is not that the ‘intelligent rehabilitation member’ *contains* a sensor, but the implication that information must be gathered by that sensor rather than manually.” (Dkt. #47, at p. 13; *see* Dkt. #45, Ex. B, Dec. 30, 2020 Bergeron Decl., at ¶¶ 64–65).

Defendant has responded: “Enserion erroneously argues that Orthofix’s construction ‘restricts “intelligent rehabilitation member” to *automatically* gathering data via sensors’ and precludes *manual* data entry. (Enserion Br. at 13–14.) It does not. The word ‘automatic’ is not in Orthofix’s proposed construction. And the ’904 Patent describes that users provide data ‘via manual entry’ on the ‘mobile device,’ not via the intelligent rehabilitation member.” (Dkt. #48, at pp. 8–9) (citing ’904 Patent at 4:16–24, 14:25–29 & 16:12–21).

The Court adopts Defendant’s proposed construction with the understanding that although an “intelligent rehabilitation member” includes and uses one or more sensors, this does not necessarily *preclude* manually inputting information.

Finally, at the February 25, 2021 hearing, Plaintiff expressed concern that the parties might dispute the meaning of “sensor.” For example, the specification refers to sensors but also refers to accelerometers, which might be read as implying that a “sensor” is different from an “accelerometer.” *See* ’904 Patent at 11:23–26. This distinction also appears in Claim 9 of the ’904 Patent. Defendant’s expert persuasively opines, however, that an accelerometer is a type of sensor. (*See* Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶¶ 50 & 53). Beyond this, any dispute regarding whether a particular accused instrumentality includes a “sensor” perhaps raises factual issues regarding infringement but does not present any legal question that can be resolved as part of the present claim construction proceedings. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) (“after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact”); *see also Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (“[t]he resolution of some line-drawing problems . . . is properly left to the trier of fact”) (citing *PPG*, 156 F.3d at 1355); *Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1318–19 (Fed. Cir. 2016) (citing *PPG*, 156 F.3d at 1355; citing *Acumed*, 483 F.3d at 806).

With the above-noted understanding that an “intelligent rehabilitation member” includes and uses a sensor but that this does not necessarily preclude manually inputting information, the

Court hereby construes “**intelligent rehabilitation member**” to mean “**device that measures musculoskeletal rehabilitation information using one or more sensors.**”

C. “personal identifying information”

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
No construction required. Alternatively: “information that can be used directly or indirectly to identify a person, either alone or when combined with other information”	Indefinite Alternatively: data that by itself identifies a patient

(Dkt. #45, Ex. A, at p. 5; Dkt. #47, at p. 8; Dkt. #48, at p. 9; Dkt. #50, at p. 4). The parties submit that this disputed term appears in Claims 1 and 15. (Dkt. #45, Ex. A, at p. 5; Dkt. #48, at p. 9).

1. The Parties’ Positions

Plaintiff argues that this claim term requires no construction, particularly in light of explanation in the specification and in HIPAA. (Dkt. #45, at p. 8). Plaintiff also submits: “Orthofix attempts to split hairs over whether ‘personally identifying information’ and ‘personally identifiable information’ are meaningfully different—they are not.” (*Id.*, at p. 9).

Defendant responds that “[t]his term is not a well-known term, and construction would likely aid the trier of fact, particularly considering the parties’ dispute over the meaning.” (Dkt. #48, at p. 9). Defendant argues that “[t]he ’904 Patent describes two categories of information: (1) ‘personal identifying information’; and (2) ‘non-personal identifying information,’” and “[t]he ’904 Patent fails to describe with reasonable certainty what information is ‘personal’ or ‘non-personal’ identifying information.” (*Id.*, at pp. 9–10) (citations omitted). Alternatively, Defendant submits: “The ’904 Patent describes needing to de-identify ‘personal identifying information,’ but never describes needing to de-identify *non-personal* identifying information. Thus, something

‘personal’ like a patient’s name must be ‘de-identified,’ while something ‘non-personal’ like a serial number need not be ‘de-identified’ because it does not, by itself, identify a patient.” (*Id.*, at pp. 10–11). Defendant further notes that “[t]he term ‘personal identifying information’ is not used in any HIPAA regulation” and, moreover, “HIPAA is only an optional aspect of the ’904 Patent, and a POSITA would not understand the single passing reference to the HIPAA Privacy Rule in the ’904 Patent to inform the meaning of ‘personal identifying information.’” (*Id.*, at pp. 11–12) (citations omitted).

Plaintiff replies by reiterating that the specification, as well as extrinsic evidence, demonstrates that this disputed term is readily understandable. (Dkt. #50, at p. 4–5).

At the February 25, 2021 hearing, Plaintiff urged that this term refers to information that *could be used* to identify who a patient is. Defendant responded that this term refers to information that *by itself* identifies who a patient is. Defendant also highlighted that the patentee chose *not* to use a term that is defined in HIPAA, such as “protected health information” or “individually identifiable health information.” Defendant argued that a person of ordinary skill in the art would not know how to determine whether a particular type of information is within the scope of “personal identifying information.” Plaintiff replied that the disputed term is *similar* to terms used in HIPAA, which Plaintiff argued demonstrates that the disputed term would be reasonably clear to persons of ordinary skill in the art.

2. Analysis

Claim 1, for example, recites (emphasis added):

1. A cloud-assisted rehabilitation system for musculoskeletal conditions, comprising:

a plurality of intelligent musculoskeletal rehabilitation apparatuses each including one or more intelligent rehabilitation members, each of the intelligent rehabilitation members having a logic section, wherein the intelligent musculoskeletal rehabilitation apparatuses are configured to be attached to a

corresponding plurality of patients to generate, by the corresponding logic section, musculoskeletal rehabilitation information; and

a rehabilitation portal configured to receive the musculoskeletal rehabilitation information from the plurality of patients, de-identify *personal identifying information* from the musculoskeletal rehabilitation information, process the musculoskeletal rehabilitation information, aggregate the de-identified musculoskeletal rehabilitation information, and generate one or more reports for one or more healthcare professionals based at least on the aggregated de-identified musculoskeletal rehabilitation information.

The specification discloses:

The rehabilitation portal 220 can allow the healthcare provider 210 to generate one or more rehabilitation reports 235 for outcomes studies. Moreover, the rehabilitation portal 220 can uniquely identify the patient 102. In some embodiments, the rehabilitation portal 220 *can uniquely identify the patient 102 using non-personal-identifying information*. The communication between the patient 102 and the healthcare provider 210 *can comply* with Health Insurance Portability and Accountability Act (HIPAA) requirements. The healthcare provider 210 can send feedback 240 back to the patient 102 for adjustment of exercises and/or to provide coaching and encouragement.

. . . The rehabilitation portal 220 can collect and de-identify results on multiple patients 102. In other words, *information that personally identifies the patients 102, for example, by name or other personally or sensitive identifying information, can be removed or otherwise hidden from view*.

'904 Patent at 6:9–30 (emphasis added); *see id.* at 8:3–9 (“information that personally identifies the patients 102, for example, by name or other personally or sensitive identifying information, can be removed or otherwise hidden from view”).

This disclosure contains the patent-in-suit’s only reference to HIPAA, and this disclosure describes compliance with HIPAA as optional (“can comply”) for purposes of the patent-in-suit. *Id.* at 6:15–18. Also, Plaintiff fails to demonstrate that any HIPAA regulation defines the term “personal identifying information.” (*See* Dkt. #48, Ex. 6, 45 C.F.R. § 160.103). Other extrinsic evidence of regulations cited by Plaintiff regarding the meaning of “personal identifiable information” or “personally identifiable information” does not significantly affect this analysis. (*See* Dkt. #47, Ex. 5, U.S. Department of Labor, *Guidance on the Protection of Personal*

Identifiable Information; see also Dkt. #48, Ex. 7, U.S. General Services Administration, *GSA Rules of Behavior for Handling Personally Identifiable Information (PII)* at § 7(a) (Enserion-000432)).

This above-reproduced disclosure in the specification, however, does distinguish between “information that personally identifies the patients” (such as “by name or other personally or sensitive identifying information”) and “non-personal-identifying information,” which “can uniquely identify the patient 102.” ’904 Patent at 6:9–30. That is, “non-personal-identifying information” can uniquely *identify* the patient for purposes of the claimed inventions but can do so without revealing the patient’s *identity*, that is, without revealing *who* the patient is. See *id.*

Defendant argues that “it is unclear what types of information fall into the ‘personal’ and ‘non-personal’ identifying information categories” (Dkt. #48, at p. 10), but the specification provides a useful reference point by referring to “*name or other personally or sensitive identifying information.*” ’904 Patent at 6:22–30 (emphasis added); see *id.* at 8:3–9 (same). That is, this disclosure in the specification identifies a type of personal identifying information, “name,” and explains that this is not the only type of personal identifying information.

On balance, based on the above-discussed disclosure in the specification, the term “personal identifying information” “inform[s] those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. 2129; see *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (regarding a chair leg portion “so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats thereof,” finding that “[t]he patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims”); see also *Nautilus*, 134 S. Ct. at 2128 n.5 (citing *Eibel Process*

Co. v. Minn. & Ontario Paper Co., 261 U.S. 45, 58, 65–66 (1923) (Taft, J.), as “upholding as definite a patent for an improvement to a paper-making machine, which provided that a wire be placed at a ‘high’ or ‘substantial elevation,’ where ‘readers . . . skilled in the art of paper making and versed in the use of the . . . machine’ would have ‘no difficulty . . . in determining . . . the substantial [elevation] needed’ for the machine to operate as specified”) (ellipses and square bracketed text are the Court’s in *Nautilus*); *id.* at 2129 (“The definiteness requirement . . . mandates clarity, while recognizing that absolute precision is unattainable.”). The contrary opinions of Defendant’s expert are unpersuasive. (*See* Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶¶ 73–78).

The Court therefore hereby expressly rejects Defendant’s indefiniteness argument. As to the proper construction, Plaintiff submits the opinions of its expert that “[t]here is no requirement that the information must ‘*directly*’ identify patients,” and “[s]uch a narrowing would eviscerate the mandate under HIPAA and other regulatory strictures to recognize and safeguard personally identifiable information broadly.” (Dkt. #45, Ex. B, Dec. 30, 2020 Bergeron Decl., at ¶ 26).

Plaintiff fails to show any support in the intrinsic evidence for its proposal of “directly or indirectly,” and to whatever extent such a definition appears in HIPAA regulations or other regulations, the specification does not use such regulations to define terms used in the patent-in-suit. Moreover, Defendant’s expert persuasively opines that unlike, for example, terms such as “protected health information” and “individually identifiable health information” (*see* Dkt. #48, Ex. 6, 45 C.F.R. § 160.103), the term “personal identifying information” is not a term of art with any well-established definition. (*See* Dkt. #45, Ex. E, Dec. 30, 2020 Sorley Decl., at ¶ 35 (“does not have a well-understood ordinary and customary meaning”); *see also id.*, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶ 71 (agreeing)).

Instead, the above-discussed disclosures in the specification refer merely to information that identifies who a patient is. '904 Patent at 6:25–30; *see Intervet*, 617 F.3d at 1287 (quoted above); *see also Goldenberg*, 373 F.3d at 1164 (quoted above). Any remaining dispute pertains to factual issues of infringement rather than any legal question for claim construction. *See PPG*, 156 F.3d at 1355 (“after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact”); *see also Acumed*, 483 F.3d at 806 (“[t]he resolution of some line-drawing problems . . . is properly left to the trier of fact”) (citing *PPG*, 156 F.3d at 1355); *Eon*, 815 F.3d at 1318–19 (citing *PPG*, 156 F.3d at 1355; citing *Acumed*, 483 F.3d at 806).

The Court therefore hereby construes **“personal identifying information”** to mean **“information that identifies who a patient is.”**

D. “de-identify,” “de-identifying,” and “de-identified”

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
No construction required. Alternatively: “removing, hiding, or limiting disclosure of personally identifiable information”	Indefinite Alternatively: removal or hiding from view of [data that by itself identifies a patient] ¹

(Dkt. #45, Ex. A, at p. 1; Dkt. #47, at p. 5; Dkt. #48, at p. 13; Dkt. #50, at p. 2). The parties submit that these disputed terms appear in Claims 1, 3, 15, and 18. (Dkt. #45, Ex. A, at p. 1; Dkt. #48, at p. 17).

¹ Defendant previously proposed: “removal of [data that by itself identifies a patient].” (Dkt. #45, Ex. A, at p. 1; *see* Dkt. #48, at p. 13 n.4).

1. The Parties' Positions

Plaintiff argues that the patent-in-suit “explains what it means to ‘deidentify results.’” (Dkt. #47, at p. 5) (citing ’904 Patent at 6:26–31 & 8:6–9). Plaintiff also argues that “HIPAA explicitly defines this term.” (Dkt. #47, at p. 5) (citing 45 CFR § 164.514). “Moreover, HIPAA provides ample guidance to a PHOSITA [(person having ordinary skill in the art)] as to how to implement de-identification.” (Dkt. #47, at pp. 5–6) (citations omitted). Alternatively, Plaintiff argues that its alternative proposed construction “addresses at least three important aspects that should be present in a proper construction”: “First, de-identified data can be removed, hidden, or generally limited from disclosure”; “Second, de-identification can occur even if there remains a chance that a patient may be identified based on disclosed information”; and “finally, de-identification occurs when data that may directly or indirectly identify a person is removed, hidden, or otherwise limited from disclosure.” (*Id.* at pp. 6–7). Plaintiff concludes that “Defendant’s alternative proposal cannot be correct because it limits de-identification to (1) merely removal of data and (2) removal of data that identifies an individual only directly (e.g. by name) rather than indirectly (e.g. by serial number).” (*Id.* at p. 7) (emphasis omitted).

Defendant responds that “[t]he ‘de-identify’ terms are indefinite because the ’904 Patent fails to describe with reasonable certainty what de-identification requires,” and “[s]pecifically, the specification does not describe what information must be removed (or hidden) to be considered ‘de-identified.’” (Dkt. #48 at p. 14) (citations omitted). Defendant argues: “As discussed in Section C, ‘personally [*sic*, personal] identifying information’ is indefinite. Therefore, without being able to ascertain what ‘personal identifying information’ is, a POSITA would not be able to ascertain what information to remove or hide from view.” (*Id.*) (citations omitted). Alternatively, Defendant argues that “the patentee defined the ‘de-identify’ terms as removing or otherwise

hiding from view personal identifying information.” (*Id.*, at pp. 14–15) (citing ’904 Patent at 6:25–30 & 8:3–9). Defendant argues that Plaintiff’s proposal of “or limiting the disclosure of” lacks support in the specification, and “it is unclear how, or to what extent, the disclosure of ‘personal identifying information’ would need to be limited to be ‘de-identified.’” (*Id.*, at p. 15). Defendant also submits that the HIPAA regulations cited by Plaintiff “do not include the phrase ‘de-identification of personal information.’” (*Id.*) (citations omitted). Defendant argues:

Further, the ’904 Patent does not use “de-identify” as a term of art, and a person familiar with HIPAA would not understand the ’904 Patent to be referring to the de-identification procedures outlined in the HIPAA Privacy Rule. (Ex. 3, Sorley Decl. ¶¶ 44–49.) Under the HIPAA Privacy Rule, there are generally only two ways to de-identify information: (1) through a formal determination by a qualified statistician; or (2) through the removal of a set of specified identifiers of the individual. (*See id.* at ¶ 32.) The ’904 Patent does not refer to either of these detailed processes.

(*Id.* at p. 16).²

Plaintiff replies: “. . . Orthofix is attempting to complicate the simple truth that whenever a piece of information has been withheld from disclosure because it may be used to identify a patient, de-identification has occurred. There is no restriction in the Patent-in-Suit regarding how much ‘personal identifying information’ must be ‘de-identified.’ The fact that the Patent-in-Suit does not restrict how much information may be ‘de-identified’ does not render the term indefinite

² Defendant also objects to Plaintiff’s Exhibits 2, 3, and 4 as untimely because Plaintiff did not cite these exhibits in its claim construction disclosures pursuant to P.R. 4-2 and P.R. 4-3. (Dkt. #48, at p. 15 n.5; *see* Dkt. #47, Ex. 2, U.S. Department of Health and Human Services, *Resources for Mobile Health Apps Developers*; *see also id.*, Ex. 3, U.S. Department of Health and Human Services, *Guidance on HIPAA & Cloud Computing*; Ex. 4, U.S. Department of Health and Human Services, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*). These documents, even when considered, do not significantly affect the Court’s analysis. Defendant’s objection as to these exhibits is therefore denied as moot.

any more than does the Patent-in-Suit's silence as to whether de-identification is limited to a certain gender or age group." (Dkt. #50, at 3).

At the February 25, 2021 hearing, the parties reiterated the arguments set forth their briefing as discussed above.

2. Analysis

Claim 1, for example, recites (emphasis added):

1. A cloud-assisted rehabilitation system for musculoskeletal conditions, comprising:

a plurality of intelligent musculoskeletal rehabilitation apparatuses each including one or more intelligent rehabilitation members, each of the intelligent rehabilitation members having a logic section, wherein the intelligent musculoskeletal rehabilitation apparatuses are configured to be attached to a corresponding plurality of patients to generate, by the corresponding logic section, musculoskeletal rehabilitation information; and

a rehabilitation portal configured to receive the musculoskeletal rehabilitation information from the plurality of patients, *de-identify* personal identifying information from the musculoskeletal rehabilitation information, process the musculoskeletal rehabilitation information, aggregate the *de-identified* musculoskeletal rehabilitation information, and generate one or more reports for one or more healthcare professionals based at least on the aggregated *de-identified* musculoskeletal rehabilitation information.

The specification discloses:

The rehabilitation portal 220 can collect and de-identify results on multiple patients 102. In other words, information that personally identifies the patients 102, for example, by name or other personally or sensitive identifying information, can be *removed or otherwise hidden from view*.

* * *

The rehabilitation results 405 can be de-identified. For example, the rehabilitation portal 220 can collect and de-identify the rehabilitation results 405 on multiple patients 102. In other words, information that personally identifies the patients 102, for example, by name or other personally or sensitive identifying information, can be *removed or otherwise hidden from view*.

'904 Patent at 6:25–30 & 8:3–9 (emphasis added).

Further, Plaintiff notes again that the specification refers to HIPAA:

The communication between the patient 102 and the healthcare provider 210 can comply with Health Insurance Portability and Accountability Act (HIPAA) requirements. The healthcare provider 210 can send feedback 240 back to the patient 102 for adjustment of exercises and/or to provide coaching and encouragement.

'904 Patent at 6:15–21. As noted in Section C, above, this use of “can comply” is permissive, not mandatory.

Still, Plaintiff submits persuasive evidence that the term “de-identify” has a well-established meaning in the relevant art. Plaintiff cites a HIPAA regulation that refers to “[d]e-identification of protected health information” in the context of “[h]ealth information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.” 45 C.F.R. § 164.514(a); *see* 45 C.F.R. § 164.502(d)(2) (similar); *see also* 45 CFR § 164.514(b)(2) (examples of types of data that could be relevant).

Defendant argues that “[b]ecause this statement focuses on communications (rather than other uses of patient information), the HIPAA reference in the '904 Patent is to the HIPAA Security Rule—not the HIPAA Privacy Rule or the processes described in § 164.514(a).” (Dkt. #48, at p. 16) (“Under the HIPAA Privacy Rule, there are generally only two ways to de-identify information: (1) through a formal determination by a qualified statistician; or (2) through the removal of a set of specified identifiers of the individual. The '904 Patent does not refer to either of these detailed processes.”) (citing Dkt. #45, Ex. E, Dec. 30, 2020 Sorley Decl., at ¶¶ 32 & 44–49).

Plaintiff replies that “Enserion is not attempting to import rules and procedures from HIPAA,” and “Orthofix’s arguments split hairs and distract from the simple truth that HIPAA

involves protecting patient privacy through de-identification, and HIPAA is referenced in the '904 Patent in that respect.” (Dkt. #50, at p. 3).

Regardless of its applicability as legal authority, this usage of “[d]e-identification” in the context of health information is probative that the “de-identify” terms would be reasonably clear to a person of ordinary skill in the art in the context of the patent-in-suit. 45 C.F.R. § 164.514(a); *see* 45 C.F.R. § 164.502(d)(2) (similar); *see also* 45 CFR § 164.514(b)(2) (examples of types of data that could be relevant).

Thus, particularly in light of the above-discussed disclosures in the specification, the terms “de-identify,” “de-identifying,” and “de-identified” “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. at 2129. The opinions of Defendant’s expert to the contrary are unpersuasive. (*See* Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶¶ 95–99). The Court hereby expressly rejects Defendant’s indefiniteness argument.

As to the proper construction, Defendant argues that the above-reproduced disclosures (*see* '904 Patent at 6:25–30 & 8:3–9) amount to “the patentee defin[ing] the ‘de-identify’ terms as removing or otherwise hiding from view personal identifying information.” (Dkt. #48, at pp. 14–15) (citing *Vitronics*, 90 F.3d at 1582 (Fed. Cir. 1996)). In some cases, a patentee may explicitly define a term, and “[i]n such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness*, 288 F.3d at 1366). In the present case, however, Defendant fails to show that the patentee “*clearly set forth a definition* of the disputed claim term in either the specification or prosecution history.” *CCS Fitness*, 288 F.3d at 1366 (emphasis added).

Plaintiff’s proposal of including merely “limiting disclosure,” however, is vague and lacks support. Plaintiff argues that Defendant’s objection to Plaintiff’s proposal of “limiting” is a “distract[ion]” because “the means of preventing disclosure are not as important as the mere fact

that certain data is not disclosed.” (Dkt. #50, at p. 3). Yet, Plaintiff fails to identify any persuasive support for referring to “limiting” that is somehow different from “hidden from view.” ’904 Patent at 6:25–30 (quoted above). At the February 25, 2021 hearing, Plaintiff argued that “limiting disclosure” is different from “hiding” because information could be hidden but still present. Because this distinction lacks support in the specification, the Court rejects Plaintiff’s proposal of “limiting disclosure.”

The Court therefore adopts the portion of the proposed constructions as to which the parties agree, namely removing personal identifying information or hiding personal identifying information from view.

Finally, as to Plaintiff’s argument that “de-identification can occur even if there remains a chance that a patient may be identified based on disclosed information” (Dkt. #47, at p. 7), this point does not appear to be in dispute. At the February 25, 2020 hearing, Defendant argued that the disputed term is unclear because removing one piece of information, such as a zip code, might be insufficient to prevent identifying who a patient is. Plaintiff urged that there is no support for requiring removal of *all* personal identifying information, and Plaintiff submitted that HIPAA compliance, for example, merely requires certain levels of unlikelihood that information could be used to identify who a patient is. To be clear, the Court hereby expressly rejects any argument that “de-identifying” must necessarily eliminate any possible chance that a particular person could be identified based on the information. Any remaining issue regarding the degree to which information must be removed or hidden relates to factual questions of infringement rather than any legal question for claim construction. *See PPG*, 156 F.3d at 1355 (“after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim

reads on the accused product is for the finder of fact”); *see also Acumed*, 483 F.3d at 806 (citing *PPG*); *Eon*, 815 F.3d at 1318 (citing *PPG* and *Acumed*).

The Court hereby construes “**de-identify**,” “**de-identifying**,” and “**de-identified**”³ to mean “**removing personal identifying information, or hiding personal identifying information from view.**”

E. “rehabilitation experience”

Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
No construction required. Alternatively: “process of preparing for and/or recovering from surgery or an injury”	Indefinite

(Dkt. #45, Ex. A, at p. 30; Dkt. #47, at p. 11; Dkt. #48, at p. 17; Dkt. #50, at p. 7). The parties submit that this disputed term appears in Claims 3 and 18. (Dkt. #45, Ex. A, at p. 30; Dkt. #48, at p. 17).

1. The Parties’ Positions

Plaintiff argues that the meaning of this disputed term is sufficiently clear, particularly in light of the disclosure that “preparation for and recovery from an injury” can be a “painstaking *experience*” that “traditional rehabilitation” did not adequately address. (Dkt. #47, at pp. 11–12) (discussing ’904 Patent at 1:22–35). Further, Plaintiff argues, “the ’904 Patent goes to great length

³ Each party proposes a single construction for all three of these different verb forms, so for the sake of simplicity, and to be consistent with the parties’ proposals, the Court provides a single construction for all three terms. Also, Plaintiff proposes referring to “personally identifiable information,” and Defendant uses its proposed construction for “personal identifying information,” namely “data that by itself identifies a patient.” Although construing these terms with reference to “personal identifying information” gives rise to redundancy when reading the claim phrase “de-identify personal identifying information,” the parties evidently feel that including this context within the construction will assist the finder of fact, and the Court agrees.

to describe the various data points that are gathered by a musculoskeletal apparatus.” (Dkt. #47, at p. 12) (citing ’904 Patent at 3:35–45). Plaintiff urges that “[t]his term is not indefinite simply because it allows for multiple configurations of data gathering,” and Plaintiff submits that “the accused products employ a configuration that is uniform and thus subject to comparison.” (Dkt. #47, at pp. 12–13).

Defendant responds:

The dispute here is whether “rehabilitation experience” is indefinite. If the term is found not to be indefinite, both parties agree it should not be construed. Enserion’s proposed alternative construction should be disregarded.

(Dkt. #48, at p. 17). Defendant argues that “it is unclear as to what activities are included in a ‘rehabilitation experience’ and what information is or is not required to characterize a ‘rehabilitation experience,’” and “it is unclear how healthcare professionals could compare or communicate regarding a particular ‘rehabilitation experience’ or a series of ‘rehabilitation experiences.”” (*Id.*, at pp. 17–18) (citations omitted). Finally, Defendant argues that “[w]hile Enserion’s proposed construction describes what a ‘rehabilitation experience’ might be, it does not inform how healthcare professionals would share or ‘compare a particular rehabilitation experience’ except in the manners expressly excluded and disclaimed by the patentee during prosecution.” (*Id.*, at pp. 19–20).

Plaintiff replies that “[t]he ’904 Patent repeatedly explains that a ‘rehabilitation experience’ is ‘aggregated de-identified musculoskeletal rehabilitation information’ that patients can share with each other,” and “[t]he ’904 Patent mentions several data points that might be collected.” (Dkt. #50, at p. 7) (citing ’904 Patent at 13:59–65). Plaintiff further argues:

Orthofix disputes this position by stating that comparison “occurs at the rehabilitation portal, not the intelligent musculoskeletal rehabilitation apparatus.” Resp. at 19. It is unclear what Orthofix intends with this distinction because it makes no difference where the data is compared. Orthofix also argues that

“Enserion does not describe *how* such information would be shared or compared.” However, a POSITA would have no problem comparing step counts from two patients if step counts were the data points measured. Finally, these data points represent data distinct from what Orthofix believes was disclaimed. *See Resp.* at 19.

(Dkt. #50, at pp. 7–8).

At the February 25, 2021 hearing, Defendant argued that this claim is unclear as to whether merely measuring step count, for example, would be a “rehabilitation experience.” Plaintiff responded that whatever data is gathered and used to represent a particular patient’s experience, and however that data is gathered, the data can be compared with data from other patients so as to compare experiences.

2. Analysis

Claim 3 depends from Claim 1 (which is reproduced above as to other disputed terms), and Claim 3 recites (emphasis added):

3. The cloud-assisted rehabilitation system for musculoskeletal conditions of claim 1, wherein:

the rehabilitation portal is further configured to facilitate crowd communication among a plurality of healthcare professionals so that the plurality of healthcare professionals can communicate with each other and compare a particular *rehabilitation experience* with one or more other patients from among the plurality of patients based at least on the aggregated de-identified musculoskeletal rehabilitation information, and

the rehabilitation portal is further configured to facilitate tracking of individual progress of a particular patient from among the plurality of patients.

Defendant also cites prosecution history in which the patentee distinguished the “Homchowdhury” reference (United States Patent Application Publication No. 2012/0278095). (Dkt. #48, at pp. 19–20) (discussing *id.*, Ex. 4, Amendment and Reply Under 37 C.F.R. § 1.111, at 14–15 (Enserion-000209–10)). The patentee noted “Homchowdhury’s ability to get ‘explicit feedback in a secure fashion’ from pat[i]ents such as [l]evel of pain, mood, etc., along with compliance data such as ‘Did you take all three dosages of the medicine, on time.’” (*Id.*, at p. 15

(Enserion-000210)). The patentee argued that although Homchowdhury “mentions the ability to look for ‘correlation’ among a ‘particular protocol,’ there is no mention of comparing a particular rehabilitation experience, much less based at least on the aggregated de-identified musculoskeletal rehabilitation information” (*Id.*) (emphasis omitted).

No relevant disclaimer is apparent in this prosecution history. *See Omega Eng’g*, 334 F.3d at 1324 (“As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public’s reliance on *definitive* statements made during prosecution.”) (emphasis added). At most, this prosecution history demonstrates that a “rehabilitation experience” involves more than only pain levels, mood, and compliance with instructions.

Defendant’s expert opines that “it is unclear as to what activities are, and are not, included in a ‘rehabilitation experience’ and what information is or isn’t required to characterize a ‘rehabilitation experience,’” and “it is unclear how healthcare professionals could compare one particular ‘rehabilitation experience’ with another or communicate regarding a particular ‘rehabilitation experience’ or a series of ‘rehabilitation experiences’ among themselves.” (Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶ 57; *see id.* at ¶ 59).

The specification provides context for understanding the meaning of “rehabilitation experience” in the context of the claimed invention:

Preparation for and recovery from injury or surgery on the musculoskeletal system, such as a knee, elbow, wrist, and the like, can be a long and painstaking *experience*. Likewise, recovery from a host of non-surgical musculoskeletal conditions often requires prolonged exercises for recovery of range of motion and strength. Traditional rehabilitation requires a multitude of visits to a physician and therapy office. Very little interaction occurs between the patient and the healthcare provider between visits. The healthcare provider has little direct insight into the status of the patient for much of the recovery process. It is difficult to share and compare recovery information and statistics between healthcare professionals using conventional physical therapy techniques.

* * *

The intelligent musculoskeletal rehabilitation apparatus 108 can include one or more intelligent rehabilitation members (e.g., 110, 115, 132, 134, and/or 136) to measure range-of-motion (ROM) data 142 for an entire extremity and/or for one or more limbs of a human patient 102. Alternatively or in addition, the one or more intelligent rehabilitation members (e.g., 110, 115, 132, 134, and/or 136) can measure musculoskeletal conditions data 146 including temperature, limb circumference (swelling), gait patterns, step counts, or the like.

* * *

. . . [C]rowd communication among the plurality of patients can be facilitated, by the rehabilitation portal, so that the plurality of patients can communicate with each other and compare a particular *rehabilitation experience* with those of one or more other patients from among the plurality of patients based at least on the aggregated de-identified musculoskeletal rehabilitation information.

'904 Patent at 1:22–35, 3:35–45 & 10:65–11:5 (emphasis added); *see id.* at 13:59–65 (“the plurality of patients 102 can communicate with each other and compare a particular *rehabilitation experience* with one or more other patients 102”) (emphasis added) & 13:66–14:6 (similar).

Also of note, Defendant’s expert acknowledges that “th[e] separate terms—‘rehabilitation’ and ‘experience’—have common understandings.” (Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶ 62). Admittedly, the Federal Circuit has explained that courts should avoid “focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.” *Phillips*, 415 F.3d at 1321. In light of the above-reproduced disclosures in the specification, however, Defendant fails to persuasively show that a reasonably clear understanding of these words is lost when the words are combined. That is, Defendant has not demonstrated that the context of the claimed invention prevents the “common understandings” of these words from being applicable. (Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶ 62).

Surrounding claim language and the above-cited disclosures provide sufficient context for understanding that the term “rehabilitation experience” does not refer to the subjective feelings of

a patient but rather relates specifically to the data that is collected. The term “rehabilitation experience,” read in the context of surrounding claim language and the specification, thus “inform[s] those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. 2129; *see Orthokinetics*, 806 F.2d at 1576 (regarding a chair leg portion “so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats thereof,” finding that “[t]he patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims”); *see also Nautilus*, 134 S. Ct. at 2128 n.5 (citing *Eibel Process*, 261 U.S. at 58, 65–66 (1923) (Taft, J.)); *id.* at 2129 (“The definiteness requirement . . . mandates clarity, while recognizing that absolute precision is unattainable.”).

In addition, although the Court does not necessarily adopt the interpretation of Plaintiff’s expert, the opinion of Plaintiff’s expert is also persuasive at least on the issue of definiteness. (*See* Dkt. #45, Ex. B, Dec. 30, 2020 Bergeron Decl., at ¶ 56) (“In the context of the ’904 Patent’s claims, ‘rehabilitation experience’ relates to the data (either subjective or objective data) characterizing a patient’s process of preparing for and/or recovering from a medical procedure, and that ‘rehabilitation experience’ data collected from one patient may be analyzed with similar data collected from another patient.”). The contrary opinions of Defendant’s expert, though more extensive on this issue than the opinions of Plaintiff’s expert, are nonetheless unpersuasive in light of the surrounding claim language and the above-cited disclosures. (*See* Dkt. #45, Ex. D, Dec. 30, 2020 Sherman Decl., at ¶¶ 57–63).

As to the proper construction, Plaintiff proposes that this term should be given its plain meaning, and Defendant submits that “[i]f the term is found not to be indefinite, both parties agree it should not be construed.” (Dkt. #48, at p. 17). The Court having rejected Defendant’s

indefiniteness argument, above, no further construction is necessary. *See PPG*, 156 F.3d at 1355; *see also Acumed*, 483 F.3d at 806 (citing *PPG*); *Eon*, 815 F.3d at 1318 (citing *PPG* and *Acumed*).

The Court therefore hereby construes “**rehabilitation experience**” to have its **plain meaning**.

CONCLUSION

The Court adopts the constructions set forth in this opinion for the disputed terms of the patents-in-suit. The parties are ordered that they may not refer, directly or indirectly, to each other’s claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

SIGNED this 4th day of March, 2021.


AMOS L. MAZZANT
UNITED STATES DISTRICT JUDGE