

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SHDS, INC. and GALDERMA LABORATORIES, L.P.,
Petitioner,

v.

TRUINJECT CORP.,
Patent Owner.

IPR2020-00935
Patent 10,290,231 B2

Before JOSIAH C. COCKS, MITCHELL G. WEATHERLY, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

COCKS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

SHDS, Inc. and Galderma Laboratories, L.P. (collectively “Petitioner”) filed a Petition (Paper 1, “Pet.”) to institute *inter partes* review of claims 1, 3, 4, 6, 10–12, 15–19, and 21–24 (“the challenged claims”) of U.S. Patent No. 10,290,231 B2 (Ex. 1001, “the ’231 patent”).¹ See 35 U.S.C. § 311 (2018). We instituted trial to determine whether the challenged claims were unpatentable as follows:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 3, 4, 6, 10, 11, 15, 17, 18, 21–24	103	Samosky, ² Mukherjee 2014, ³ Mukherjee 2012 ^{4,5}
12	103	Samosky, Mukherjee 2014, Mukherjee 2012, Toly ⁶

¹ Petitioner relies on the Declaration of Biswarup Mukherjee, Ph.D. (Ex. 1002) in support of the Petition.

² U.S. Patent Application Publication No. 2013/0323700 A1 published Dec. 5, 2013 (Ex. 1004, “Samosky”).

³ B. Mukherjee; B. George; M. Sivapraksam, *An Opthamalic Anesthesia Training System Using Integrated Capacitive and Hall Effect Sensors*, IEEE TRANS. INSTRUMENT AND MEASUREMENT (2014) (Ex. 1005, “Mukherjee 2014”).

⁴ B. Mukherjee; B. George; M. Sivapraksam, *A Hall Effect Sensor Based Syringe Injection Rate Detector*, IEEE 2012 SIXTH INT’L CONF. ON SENSING TECHNOL. (ICST) (2012) (Ex. 1006, “Mukherjee 2012”).

⁵ In this Decision, we also reference Mukherjee 2014 and Mukherjee 2012 together as “the Mukherjee articles.”

⁶ U.S. Patent Application Publication No. 2005/0181342 A1 published Aug. 18, 2005 (Ex. 1007, “Toly”).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
16, 19	103	Samosky, Mukherjee 2014, Mukherjee 2012, Lampotang, ⁷ Sinclair ⁸

Paper 12 (“Dec. on Inst.”).

Truinject Corp. (“Patent Owner” or “Truinject”) timely filed a Patent Owner Response. Paper 15 (“PO Resp.”).⁹ Petitioner filed a Reply (Paper 20, “Pet. Reply”), to which Patent Owner filed a Sur-reply (Paper 22, “PO Sur-reply”).

Oral argument was conducted on August 18, 2021.¹⁰ A transcript of the oral argument appears in the record. Paper 29.

For the reasons set forth below, we determine that Petitioner has shown, by a preponderance of the evidence, that all of the challenged claims are unpatentable. *See* 35 U.S.C. § 316(e).

B. Related Matters

The parties contend that the ’231 patent is the subject of *Truinject Corp. v. Nestlé Skin Health, S.A., et al.*, No. 1:19-cv-00592 (D. Del.) (filed March 28, 2019) (“the Delaware Action”), which is a related matter under 37 C.F.R. § 42.8(b)(2). Pet. 2; Paper 6, 1. The parties also reference

⁷ US Patent Application Publication No. 2012/0280988 A1 published Nov. 8, 2012 (Ex. 1008, “Lampotang”).

⁸ US Patent No. 5,766,016 issued Jun. 16, 1998 (Ex. 1016, “Sinclair”).

⁹ Patent Owner relies on the Declaration of Dr. Carla M. Pugh (Ex. 2005) in support of its Patent Owner Response.

¹⁰ Oral argument in this proceeding was consolidated with the oral argument in IPR2020-00937.

IPR2020-00042 involving U.S. Patent No. 9,792,836 (“the ’836 patent”) and IPR2020-000937 involving U.S. Patent No. 10,290,232 (“the ’232 patent”).¹¹ Pet. 2; Paper 6, 1. Petitioner states that the ’836 patent and the ’232 patent have been asserted in the Delaware Action. Pet. 2.

C. The ’231 Patent

The ’231 patent is titled “Automated Detection of Performance Characteristics in an Injection Training System.” Ex. 1001, code (54). The ’231 patent characterizes its disclosure as relating “generally to cosmetic and therapeutic training, and more specifically to systems, devices, and methods for cosmetic and therapeutic training.” *Id.* at 1:34–36. Generally, cosmetic and therapeutic treatments can involve injections in various locations on the body to treat medical conditions, address aesthetic imperfections, or perform restorative cosmetic procedures. *Id.* at 1:37–56. The ’231 patent sets forth that problems in the relevant field include a lack of official certification or training processes directed to administering injections, and that current training options are generally limited to hands-on training performed on live models. *Id.* at 2:4–26. The ’231 patent postulates that there is a need for “effective, efficient, and extensible training injection systems, methods, and devices.” *Id.* at 2:58–61. The Abstract of the ’231 patent is reproduced below:

Various systems and methods are provided for injection training by collecting, processing, analyzing and displaying measured information associated with the delivery of an injection. Sensor-based measurements of a syringe’s position and orientation in

¹¹ Institution of *inter partes* review was denied in IPR2020-00042 on April 14, 2020. *See* IPR2020-00042, Paper 7. A Final Written Decision in IPR2020-00937 is issued concurrently with the present Decision.

three-dimensional space are obtained and processed to provide metrics of a trainee's injection performance. The measurements can be combined with a digital model of a training apparatus to deliver a computer generated, graphical depiction of the training injection, enabling visualization of the injection from perspectives unavailable in the physical world. The training injection execution, as reflected in the measured sensor-based data, can be reviewed and analyzed at times after, and in locations different than, the time and location of the training injection. Additionally, injection training data associated with multiple training injections can be aggregated and analyzed for, among other things, trends in performance.

Id. at code (57).

Figure 1 of the '231 patent is reproduced below.

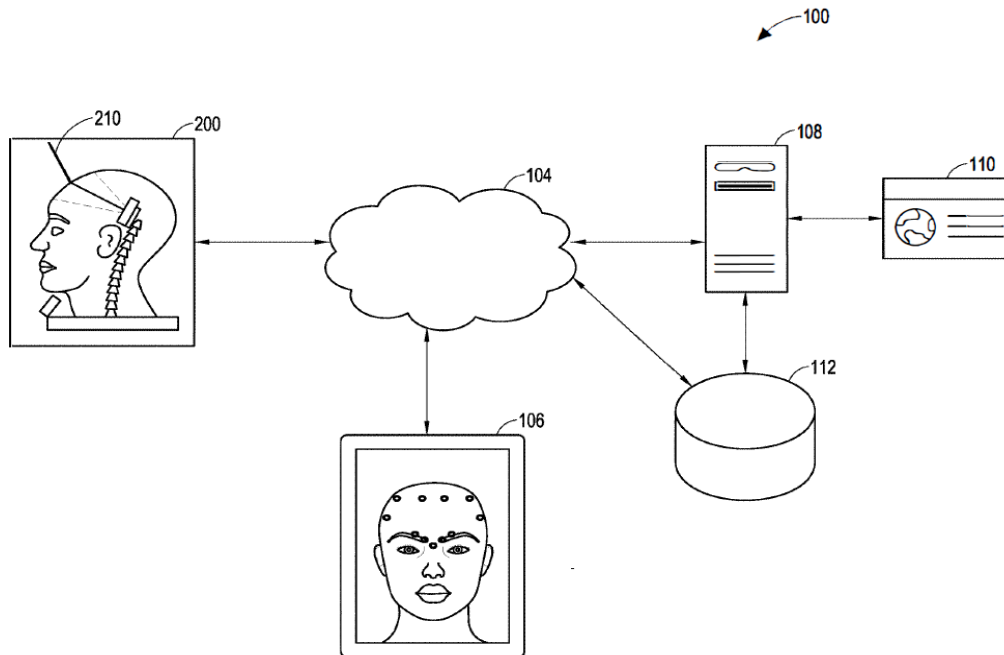


FIG. 1

Figure 1 above shows “an example of an injection training system in which aspects of the present disclosure may be employed.” *Id.* at 12:53–55.

Training system 100 includes training apparatus 200 that is configured to receive a training injection delivered by syringe 210. *Id.* at 14:59–63.

Training apparatus 200 is configured to communicate with local display device 106 via network 104. *Id.* at 15:6–8.

D. Illustrative Claims

Of the challenged claims, claims 1 and 6 are independent. Claim 1 is illustrative and is reproduced below:

1. [i] A method to improve performance of an injection technique using one or more signal processors of an injection training system having an anatomically-shaped apparatus and a syringe, the method comprising:

[ii] providing the anatomically-shaped apparatus, the anatomically-shaped apparatus configured to receive a training injection of the injection technique performed by a user;

[iii] providing the syringe having a needle, a barrel, and a plunger and configured to deliver the training injection to the anatomically-shaped apparatus, [iv] the syringe further comprising at least one syringe sensor on the syringe;

[v] receiving, by the one or more signal processors of the injection training system, sensor-based injection information associated with the training injection of the injection technique, the sensor-based injection information comprising information indicative of the position and use characteristics of the syringe detected by the at least one syringe sensor;

[vi] analyzing electronically, using the one or more signal processors, the sensor-based injection information;

[vii] evaluating electronically, using the one or more signal processors, the analyzed sensor-based injection information relative to at least one evaluation criterion; and

[viii] comparing electronically, using the one or more signal processors, 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;

[ix] outputting by the one or more signal processors, for displaying on a display device during and/or after the training injection, a graphical depiction of the training injection, [x] wherein the graphic depiction includes a digital three-

dimensional model of the anatomically-shaped apparatus [xi] a location of the needle relative to the digital three-dimensional model of the anatomically-shaped apparatus, and [xii] a dynamic position of the plunger in real time, [xiii] the digital three-dimensional model of the anatomically-shaped apparatus comprising facial anatomical features, [xiv] wherein the one or more signal processors are configured to alter a view of the graphical depiction to better visualize the training injection; and [xv] outputting electronically, using the one or more signal processors, based on the analyzed sensor-based injection information, a recommended action to improve injection technique.

Id. at 33:41–34:22 (with the Roman numerals i–xv added for ease of discussion (*see* Pet. 29–30)).

II. ANALYSIS

A. Claim Construction

In the Petition, Petitioner did not expressly construe any claim term of the '231 patent and contended that we need not either. *See* Pet. 13 (“Petitioners submit that the Board need not specially construe any terms of the challenged claims in this proceeding.”). In our Decision on Institution, we expressed the following:

At this time, we give all terms their “ordinary and customary meaning” and determine that it is unnecessary to make explicit that meaning for any term. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that “we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Dec. on Inst. 16.

Patent Owner does not disagree that all the claim terms should be given their ordinary meaning. In its Patent Owner Response, Patent Owner discusses that ordinary meaning for two claim phrases (1) “a graphical depiction of the training injection” (claims 1 and 6), and (2) “a simulated delivery of therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus.” PO Resp. 22–28. In its Reply, Petitioner offers its own views on the meaning of the above-noted claim phrases. Pet. Reply 1–5.

It is clear that there is some disagreement between the parties as to the meaning of those claim phrases. Accordingly, we discuss them below.

1. “graphical depiction of the training injection” (claims 1 and 6)

According to Patent Owner, the ordinary meaning of the above-noted phrase is “a computer-generated portrayal or likeness of the training injection.” PO Resp. 22. In offering that meaning, Patent Owner also contends that, in the context of the ’231 patent, the term “graphical” means “of or relating to visual art of computer graphics,” and points to portions of the ’231 patent that are said to support Patent Owner’s contention. *See id.* at 23 (citing Ex. 1001, 3:6–18). Patent Owner also relies on dictionary definitions of the term “depiction” as allegedly meaning “a portrayal or likeness.” *Id.* (citing Ex. 2008, 4; Ex. 2007, 4). In Patent Owner’s view, “[a]ll the descriptions of graphical depictions of the training injection in the ’231 Patent are computer-generated portrayals or likenesses of the training injection and are not mathematical graphs showing data on a coordinate system.” *Id.* at 24. Patent Owner further attempts to support that view on the basis that, during prosecution of the application that became the

'231 patent, Patent Owner represented to the Examiner examining the application that the claims of the '231 patent exclude such mathematical graphs from being graphical depictions. *Id.* at 25–26.¹²

Petitioner disagrees with Patent Owner. At the outset, Petitioner expresses that “[n]o construction of this term was found to be necessary in the Delaware Action and none is required here.” Pet. Reply 2. Petitioner is of the view that none of the evidence of record, including the '231 patent, the cited dictionary definitions, and the prosecution history, supports the meaning of “graphical depiction of the training injection” offered by Patent Owner, specifically that such phrase excludes “‘mathematical graphs’ showing the position of a needle tip relative to the model of the apparatus.” *Id.* at 2–4. Petitioner also indicates that “the Examiner never accepted [Patent Owner’s] arguments” that “graphical depiction” excludes mathematical graphs, such as those shown in Figures 14A and 14B of Samosky. *Id.* at 4 (citing Ex. 1010, 388–391, 404–405). Rather, Petitioner represents that “the Examiner found that ‘a graphical depiction of the training injection encompasses the 4D graph shown in Figures 14A-B of Samosky.’ *Id.* (citing Ex. 1010, 386–408).

Petitioner makes the better case. We do not discern from the '231 patent any express indication that “graphical depiction” should be read to exclude a type of display recognized as a “graph,” mathematical or

¹² Patent Owner made those representations in the context of discussing Figures 14A and 14B of Samosky, which was a reference applied by the Examiner during examination, and is also a reference on which Petitioner relies in this proceeding.

otherwise.¹³ We share Petitioner’s view that Patent Owner does not make a colorable case that “depiction” must be something limited to a “portrayal or likeness.” We do not discern that the ’231 patent limits “depiction” to such a restricted meaning. The dictionary definitions on which Patent Owner relies (Exs. 2007, 2008) do not limit “depiction” to a portrayal, or, as Petitioner notes, even use the term “likeness.” *See* Pet. Reply 3; Ex. 2007, 4; Ex. 2008, 4. We also do not discern that the ’231 patent presents a basis for concluding that a “depiction” is restricted to a “portrayal or likeness.”

Additionally, it is difficult to reconcile Patent Owner’s view that, simply because it represented to the Examiner during prosecution that “graphical depiction” excludes mathematical graphs, like those shown in Samosky’s 14A and 14B, such exclusion must be true. Patent Owner does not direct our attention to any portion of the record indicating that the Examiner agreed with Patent Owner’s representations. Instead, the record reflects that the Examiner held an opposing view in maintaining that “a graphical depiction of the training injection” is accounted for by Figures

¹³ As noted above, Patent Owner seeks to connect the requirement of “computer-generated” with the claim term “graphical depiction.” We discern that the portions of the ’231 patent that Patent Owner cites for that premise, qualify, in every instance, the term “graphical depiction” with the leading descriptor “computer-generated.” *See, e.g.*, Ex. 1001, 3:6–18. That the ’231 patent specifically sees its necessary to add the term “computer-generated” to describe a “graphical depiction” does not lend itself favorably to a conclusion that the term “graphical depiction” unaccompanied by the term “computer-generated,” nevertheless still requires a graphical depiction that is “computer-generated.” The issue, however, is immaterial with respect to Petitioner’s unpatentability challenges, as there is no dispute before us that the prior art on which Petitioner relies presents images that are understood to be computer-generated.

14A and 14B of Samosky. *See, e.g.*, Ex. 1010, 390 (“a graphical depiction of the training injection (**see figures 14A and 14B** [of Samosky], **showing a graph of the training injection and its location**).”).

We are cognizant that the Examiner ultimately allowed the claims of the '231 patent over the teachings of Samosky. That, however, only occurred after Patent Owner accepted amendments proposed to the claims by the Examiner that are not directed to the particular aspects of a “graphical depiction” that are the focus here. *See* Ex. 1010, 21–25.¹⁴ That such amendments were proposed by the Examiner and accepted by Patent Owner does not indicate that the Examiner retreated from a position that a “graphical depiction of the training injection” encompasses the mathematical graphs of Samosky’s Figures 14A and 14B.

We have considered the parties’ positions as to what is encompassed by the claim phrase “graphical depiction of the training injection.” On the record at hand, we do not find Patent Owner’s position availing that it has offered a suitable basis to regard that phrase as categorically excluding displays of mathematical graphs. Instead, we agree with Petitioner that the record does not establish that mathematical graphs, such as those shown in Figures 14A and 14B of Samosky, are outside of consideration as a “graphical depiction.”

¹⁴ Patent Owner indicates that it “agreed” to the amendments proposed by the Examiner “in the interest of obtaining allowance.” PO Resp. 10.

2. “*a simulated delivery of the therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus*” (claims 23 and 24)

Claim 23 depends from independent claim 1, and claim 24 depends from independent claim 6. Each of claims 23 and 24 adds to their respective independent claim the above-noted claim phrase. Here, Patent Owner contends that the above-noted claim phrase means “a simulated flow of therapeutic agent delivered from a digital model of the syringe to a digital model of the anatomically-shaped apparatus.” Thus, what Patent Owner attempts to emphasize is the premise that the claim phrase requires that the simulated flow of therapeutic agent is delivered from “a digital model of the syringe.” According to Patent Owner, in the Delaware Action, the parties agreed to the above-noted meaning in the context of claims of the related ’232 patent.¹⁵ PO Resp. 27–28.

Petitioner contends the following:

With respect to claim 23, Truinject’s construction (Resp. 26–28) is improper. No digital model of the syringe is recited in claim 23 or claim 1 from which it depends. In contrast, the claims of the ’232 patent that recite “simulated delivery” also recite a “digital model of the syringe.”

As with the ’232 patent claims, claim 24 does require a digital three-dimensional model of the syringe by virtue of its incorporation of claim 6.

Accordingly, as used in claim 24, this term would be understood to mean “a simulated flow of therapeutic agent delivered from *the digital three-dimensional* model of the

¹⁵ The ’232 patent is the subject patent of related proceeding IPR2020-00937.

syringe to the digital *three-dimensional* model of the anatomically shaped apparatus.”

Pet. Reply 4–5.

Thus, with respect to claim 24, the parties are in apparent agreement that the claim requires a three-dimensional digital model of the syringe because of the recitation in independent claim 6 of “a digital three-dimensional model of the syringe.” *See* Ex. 1001, 35:35–36. As Petitioner notes, however, and as we also discern, claim 1 includes no such corresponding limitation directed to a digital model of a syringe. It is apparent from the record that the agreement between the parties in the Delaware Action as to the requirement of a three-dimensional digital model of a syringe is premised on the explicit recitation in the claims of the ’232 patent of a three-dimensional digital model of a syringe.

Patent Owner appears to suggest that a separate limitation of claim 1 gives rise to the requirement of a digital model of the syringe. Specifically, Patent Owner advances the following:

Although Claim 1, from which Claim 23 depends, does not explicitly recite a digital model of the syringe, Claim 1 requires that the graphical depiction include “a location of the needle relative to the digital three-dimensional model of the anatomically-shaped apparatus, and a dynamic position of the plunger in real time,” which amounts to a digital model of the syringe.

PO Resp. 28 (citing Ex. 1001, 34:9–12; Ex. 2005 ¶ 55).

Patent Owner, however, does not articulate meaningfully why the above-quoted feature pertaining to the “location of the needle” and a “dynamic position of the plunger” necessarily “amounts” to a digital model of the syringe. In its Sur-reply, Patent Owner again references the above-noted feature of claim 1, but simply expresses that “[n]o special construction

of this term is required” and provides no further elaboration as to why the feature gives rise to a “digital model of the syringe” where no such recitation appears in either claim 1 or claim 23. Patent Owner simply does not explain adequately why, despite the absence of an express limitation directed to a three-dimensional model of a syringe in either claim 1 or claim 23 of the ’231 patent, those claims should, nevertheless, be regarded as including such a requirement.

On the record before us, we note that the parties are in agreement that claim 24 explicitly requires a three-dimensional model of a syringe that provides the simulated flow of therapeutic agent because claim 24 incorporates the recitation of “a digital three-dimensional model of the syringe” from its independent claim 6. In light of the parties’ mutually acknowledged agreement, and given that we do not see reason to deviate from it on the record before us, we apply the same agreed-to meaning and conclude that claim 24 has such a requirement. By contrast, neither claim 23 nor its independent claim 1 explicitly recites any type of digital model of the syringe. Thus, we conclude that claim 23 does not require a three-dimensional digital model of a syringe.

3. Remaining Claim Terms

We discern that no other term needs an express construction to resolve the parties’ dispute. *See Nidec*, 868 F.3d at 1017.

B. Grounds of Unpatentability

Petitioner proposes three grounds of unpatentability to claims of the ’231 patent: (1) claims 1, 3, 4, 6, 10, 11, 15, 17, 18, 21–24 as unpatentable over Samosky, Mukherjee 2014, and Mukherjee 2012; (2) claim 12 as

unpatentable over Samosky, Mukherjee 2014, Mukherjee 2012, and Toly; and (3) claims 16 and 19 as unpatentable over Samosky, Mukherjee 2014, Mukherjee 2012, Lampotang, and Sinclair.

1. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are “such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which such subject matter pertains.” 35 U.S.C. § 103 (2018). The question of obviousness under 35 U.S.C. § 103 is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).¹⁶

2. Level of Ordinary Skill in the Art

Petitioner offers the following assessment in conjunction with the level of ordinary skill in the art:

The prior art discussed below and Dr. Mukherjee’s Declaration (EX1002) demonstrate that a person of ordinary skill in the art (“POSITA”) as of the effective filing date of the ‘231 patent would have had at least a master’s degree in electrical engineering, robotics engineering, mechatronics, or a similar field. EX1002, ¶22. Alternatively, a POSITA may have had a lesser degree in one of those fields, but accompanied by

¹⁶ Neither party presents any objective indicia of non-obviousness as a part of this proceeding.

practical experience in designing medical training or similar systems. *Id.* The POSITA would have an in-depth working knowledge of machine vision, three-dimensional tracking systems, microprocessors, signal processing, sensors, computer programming, or a combination thereof. *Id.*

In addition to the aforementioned technical skills, the POSITA would have experience in designing and producing realistic anatomical models or life-like mannequins and would have a strong working knowledge of mannequin design, computer-aided design and manufacturing (CAD/CAM), materials selection, human anatomy, related special effects, and known software for collecting, analyzing, and displaying three-dimensional models of training procedures using such models. *Id.*, ¶23. To the extent necessary, the POSITA may have collaborated with other skilled artisans, such that the individual and/or team collectively would have had experience and/or knowledge of particular injection metrics and procedures to be practiced and/or evaluated. *Id.*

Pet. 12–13.

Patent Owner offers the following assessment of the level of ordinary skill in the art:

A person of ordinary skill in the art at the time of the effective filing date of the application that led to the '231 Patent would have had a B.S. in Electrical Engineering, Biomedical Engineering, or any similar type of engineering or biomedical degree and at least one year experience in designing sensor-based motion tracking and simulators for evaluating clinical performances. Ex. 2005 ¶ 30. For individuals with different educational backgrounds, a person could still be of ordinary skill in the art provided that person's additional experience compensates for any differences in that person's education as stated above. *Id.*

PO Resp. 20–21.

Although noting that its assessment of the level of skill in the art “differs from that proposed by Petitioner, Patent Owner believes the

difference is immaterial to deciding the issues raised by the Petition.” *Id.* at 21. Petitioner does not dispute Patent Owner’s contention in that regard, and we also agree that the outcome of this proceeding would be the same under either of the Petitioner’s and Patent Owner’s proposed level of ordinary skill in the art. Nevertheless, for completeness, we adopt Patent Owner’s assessment of the level of ordinary skill. We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

3. Scope and Content of the Prior Art

a) Samosky

Samosky is titled “Hybrid Physical-Virtual Reality Simulation for Clinical Training Capable of Providing Feedback to a Physical Anatomic Model.” Ex. 1004, code (54). Samosky characterizes its disclosure as follows:

The subject innovation relates generally to simulation based training (SBT), and in aspects, the innovation can simulate a clinical procedure utilizing a mixed-reality approach that can incorporate one or more of a physical model, a virtual model (e.g., which can be a 3D model derived from a medical imaging scan (e.g., magnetic resonance imaging (MRI), computed tomography (CT) data, or 3D ultrasound data, etc.) isomorphic to the physical model, etc.), mechatronics and spatial tracking.

Id. ¶ 31.

Samosky further describes the following:

The innovation disclosed and claimed therein, in one aspect thereof, comprises a system that facilitates training in clinical procedures via mixed reality simulations are disclosed. Such a system can comprise a physical model of an anatomic

region that can be associated with the clinical procedure and a virtual model of the anatomic region, wherein the virtual model that can associate a tissue type with each location in the physical model. The system can also include a tracking component that can track at least one location of at least one clinical instrument relative to the physical model and the virtual model, and a feedback component that can provide feedback based at least in part on at least one location in the physical model associated with the at least one location of the at least one clinical instrument.

Id. ¶ 7.

Samosky's Figure 1 is reproduced below:

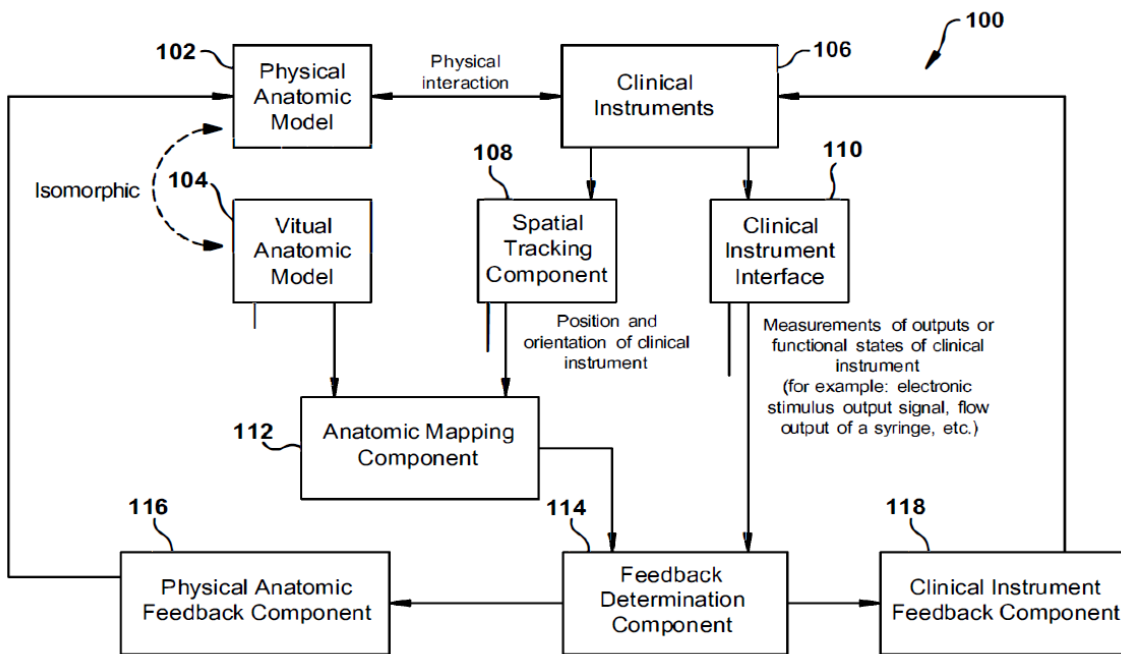


Fig.1

Figure 1 above illustrates “system 100 that can simulate a clinical procedure via a hybrid physical-virtual model.” *Id.* ¶ 39. “Physical anatomic model 102 and virtual anatomic model 104 can model an anatomic region associated with the clinical procedure (e.g., limb, neck, back, or substantially any other anatomic region).” *Id.* Samosky further discloses the following:

The two anatomic models can be co-registered such that the virtual anatomic model 104 can associate tissue types with corresponding locations of the physical anatomic model 102. In various aspects, as described further herein, virtual anatomic model 104 can correspond to real anatomy (e.g., as derived from segmented medical imaging data, from any of a plurality of person, or can corresponding to modifications or simplifications thereof (e.g., for training purposes, etc.).

Id.

Samosky further incorporates a “tracking component that tracks locations of at least one clinical instrument relative to the models.” *Id.* at code (57). Samosky’s Figures 5–8 show example displays of a “hybrid physical-virtual model” according to Samosky’s invention. *Id.* ¶¶ 14–17.

Samosky’s Figure 5 is reproduced below:

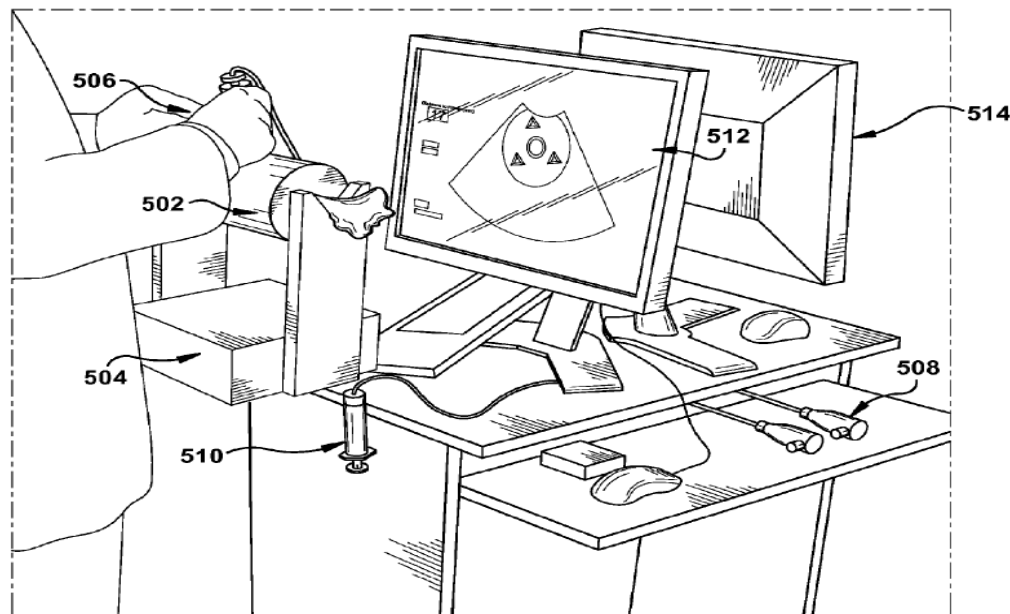


Fig.5

Figure 5 above shows an “example prototype of a hybrid physical-virtual model.” *Id.* ¶ 14. The model includes “cylindrical phantom ‘limb’” 502 and a corresponding virtual model that a trainer can perform a simulated

procedure on. *Id.* ¶ 65. The model further includes instruments 506 for interacting with the model, syringe simulation subsystem 508, anesthetic syringe 510, display 512 for a trainee, and display 514 for an instructor. *Id.*

Samosky's Figure 8 is reproduced below:

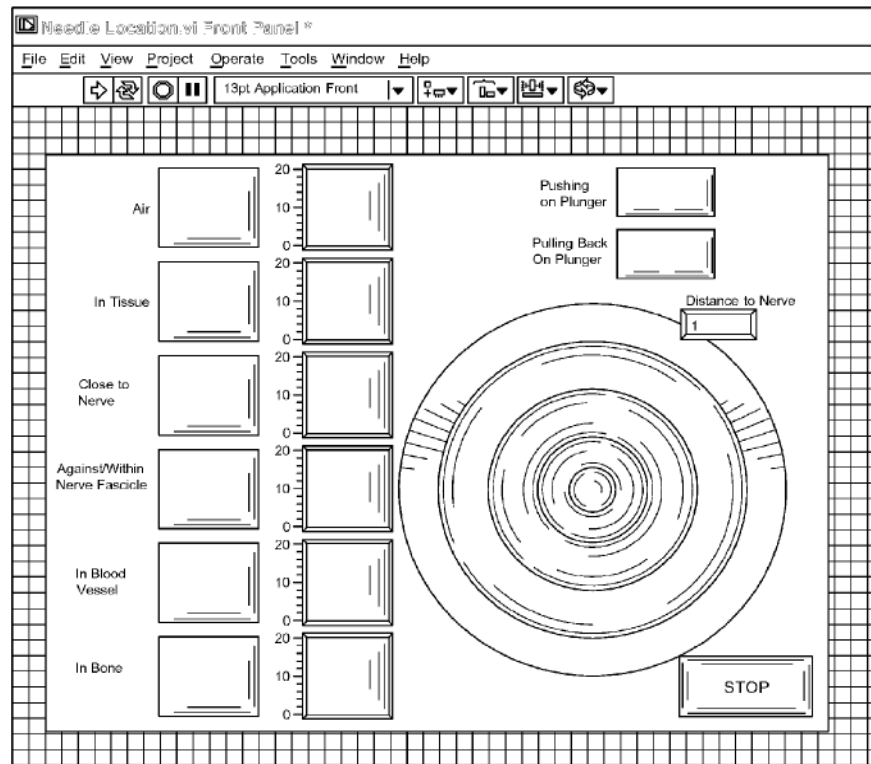


Fig.8

Figure 8 above “illustrates an example display of a prototype instructor interface in accordance with the system shown in” Figure 5. *Id.* at ¶ 17. The instructor interface “can provide indicators identifying the anatomical feature (e.g., tissue type or structure, etc.) at the needle tip location,” “needle to nerve distance, current tissue type the needle tip is located in (air, tissue, vessel, nerve, bone),” and presents “a ‘bull’s-eye’ visualization of the needle tip approaching the nerve.” *Id.* ¶¶ 66–67.

Samosky's Figures 14A and 14B are reproduced below:

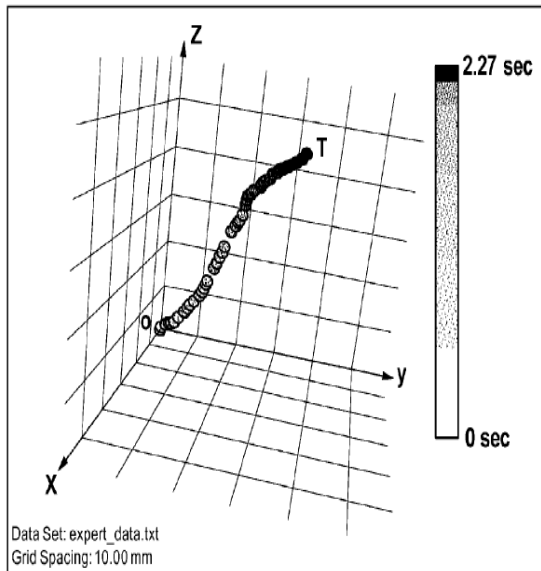


Fig.14A

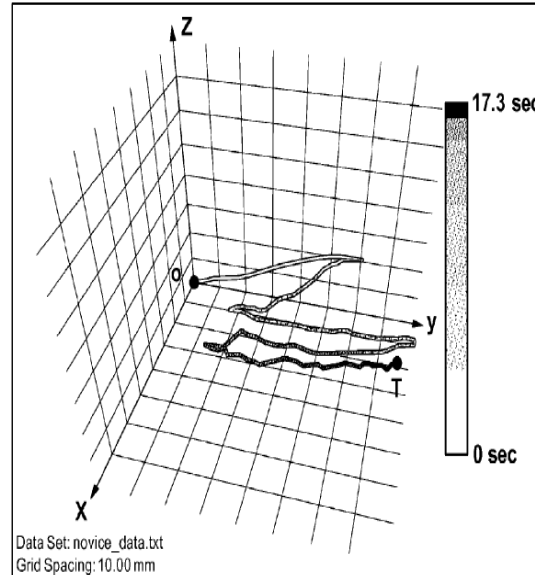


Fig.14B

Figures 14A and 14B above show “a pair of 4D graphs of needle tip trajectories 1402 [on left] and 1404 [on right] recorded with a prototype system in accordance with the subject innovation, as measured with an electromagnetic tracking system.” *Id.* ¶ 74.

b) Mukherjee 2014

Mukherjee 2014 is an article titled “An Ophthalmic Anesthesia Training System Using Integrated Capacitive and Hall Effect Sensors.” Ex. 1005, Title. The training system incorporates a training manikin and training is accomplished through use of a “virtual instrument” (VI) that measures the output from capacitive sensing electrodes and Hall-effect sensors and displays the output to the trainee through a graphical user interface (GUI). *Id.* at Abstract.

Mukherjee 2014's Figure 2 is reproduced below:

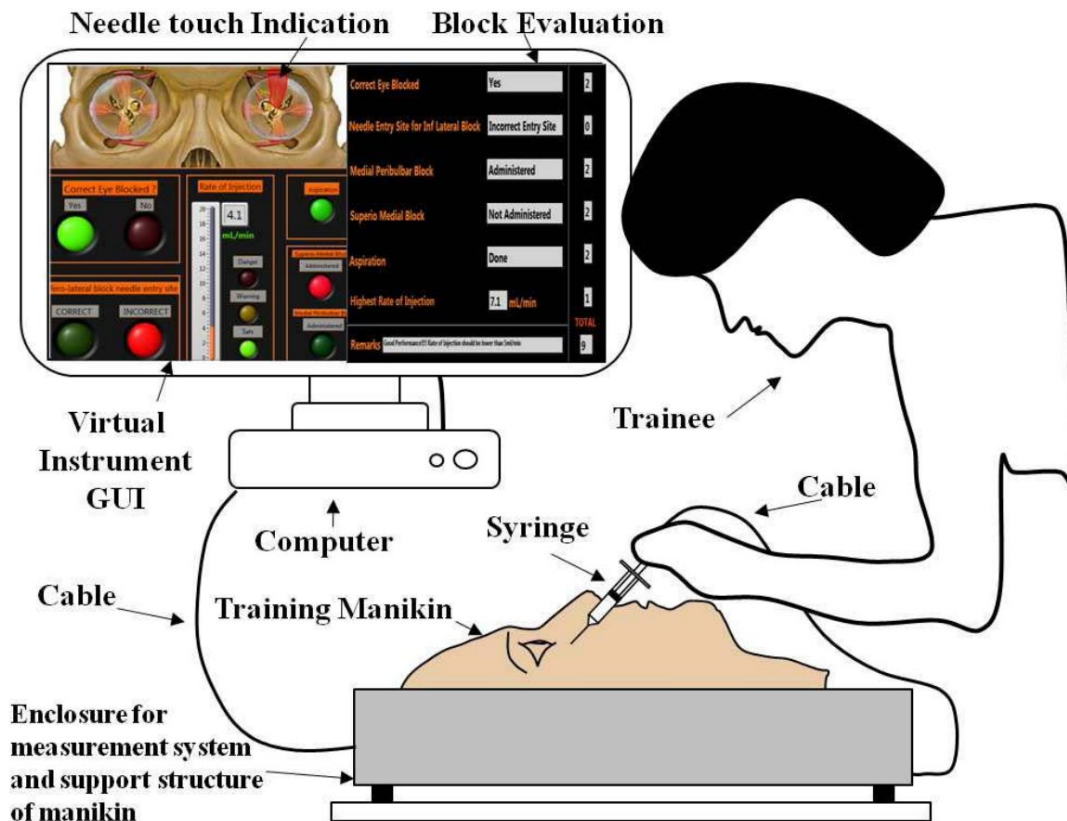


Figure 2 above is a “[c]onceptual diagram of the ophthalmic regional anesthesia training system showing the trainee with a modified syringe administering a block on the manikin.” *Id.* at 1. “A VI shows real-time feedback of the needle proximity and touch of muscles, rate of injection along with a qualitative score based on the trainee’s performance.” *Id.*

c) Mukherjee 2012

Mukherjee 2012 is an article titled “A Hall Effect Sensor based Syringe Injection Rate Detector.” Ex. 1006, Title. Mukherjee 2012 describes a “training system based on a suitably modified syringe equipped with a simple measurement system where a trainee can observe the rate of injection, prior to practicing on live patients.” *Id.* at Abstract.

Mukherjee 2012 also explains that a “Hall Effect sensor along with a permanent magnet senses the position of the syringe piston relative to the syringe body.” *Id.*

Mukherjee 2012’s Figure 5 is reproduced below:

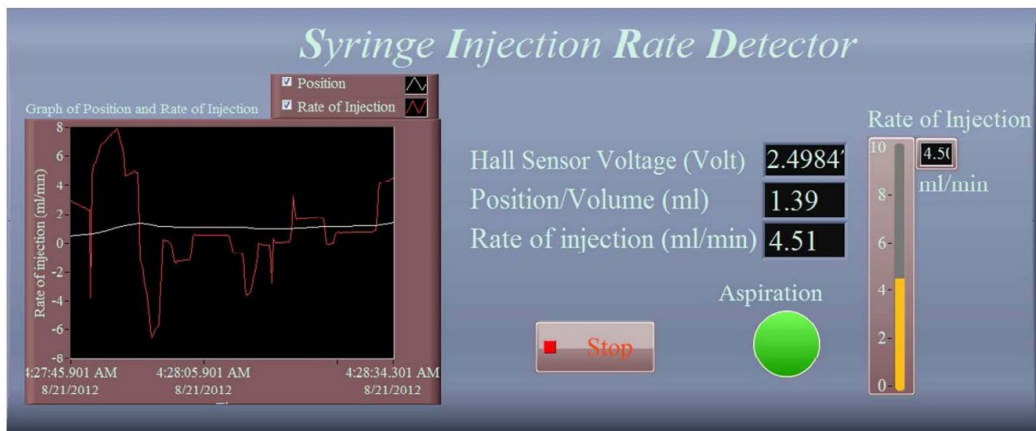


Figure 5 above is described as showing a “LabVIEW based Virtual Instrument front panel showing the rate of injection, piston position and Aspiration indicators in real-time.” *Id.* at 452.

d) Toly

Toly is titled “Medical Training Simulator Including Contact-Less Sensors.” Ex. 1007, code (54). Toly’s Abstract is reproduced below:

A medical training simulator includes contact-less sensors and corresponding detection objects, configured to enable sensor data collected during a training exercise to be used to evaluate the performance of the training exercise. The simulator includes a simulated anatomical structure, at least one contact-less sensor, and at least one detection object. During a training exercise, a spatial relationship between the contact-less sensor and the detection object produces data for evaluating performance of the training exercise. Either the contact-less sensor or the detection object is embedded in the simulated physiological structure, while the other is included in either a support for the simulated physiological structure, or as part of a tool used during the

training exercise. Many types of contact-less sensors can be employed, including capacitance sensors, impedance sensors, inductive sensors, and magnetic sensors.

Id. at code (57).

e) Lampotang

Lampotang is titled “Interactive Mixed Reality System and Uses Thereof.” Ex. 1008, code (54). Lampotang’s Abstract is reproduced below:

An interactive mixed reality simulator is provided that includes a virtual 3D model of internal or hidden features of an object; a physical model or object being interacted with; and a tracked instrument used to interact with the physical object. The tracked instrument can be used to simulate or visualize interactions with internal features of the physical object represented by the physical model. In certain embodiments, one or more of the internal features can be present in the physical model. In another embodiment, some internal features do not have a physical presence within the physical model.

Id. at code (57).

f) Sinclair

Sinclair is titled “Surgical Simulator and Method for Simulating Surgical Procedure.” Ex. 1016, code [54]. Sinclair’s Abstract is reproduced below:

A surgical simulator provides both visual and tactile feedback in order to realistically portray an actual surgical procedure. The visual feedback is provided through an SGI graphics computer which drives a monitor to display two images of an eye at slightly different perspectives. A set of optics, which preferably mimics an actual surgical microscope, combines the two images to form a stereo image of the eye. An instrument for simulating a surgical tool is connected through three sets of levers and hinges to three servo-motors which collectively generate a resistive force along any direction. The forces provided to the instrument are modeled

after forces measured during an actual procedure and therefore accurately simulate the feel of a surgical procedure. The position and orientation of the instrument is transmitted to the SGI graphics computer which manipulates the eye based upon the position and motion of the instrument and updates the image of the eye to display a manipulated eye. The position of the instrument is also relayed to a second processing unit which provides the tactile feedback based upon the state of the instrument.

Id. at code [57].

4. Ground Based on Samosky, Mukherjee 2014, Mukherjee 2012

Petitioner contends that claims 1, 3, 4, 6, 10, 11, 15, 17, 18, and 21–24 of the '231 patent are unpatentable based on the combined teachings of Samosky, Mukherjee 2014, and Mukherjee 2012. Petitioner lays out in detail where it believes all the features of those claims reside in the prior art. Pet. 29–65. Petitioner also reasons that a person of ordinary skill in the art would have had adequate reasons to combine the teachings of the above-noted references. *Id.* at 25–28. Patent Owner disagrees with Petitioner. Patent Owner argues that the cited prior art is missing certain features of the challenged claims, focusing particularly on independent claims 1 and 6. PO Resp. 30–50, 57–62; PO Sur-reply 9–21. Patent Owner additionally contends that features required by claims 17, 23, and 24 are also absent from the prior art. PO Resp. 62–69; PO Sur-reply 21–26. Patent Owner further disputes that a skilled artisan would have had reason to combine Samosky and the Mukherjee articles, or a reasonable expectation of success in doing so. PO Resp. 50–57.

a) Claim 1

As to the alleged missing features of claim 1, Patent Owner focuses its arguments on an “outputting” step (that we designate in this Decision as beginning with limitation [ix]) required by claim 1.¹⁷ That outputting step requires a “graphical depiction” or “graphic depiction” that includes certain displayed content. Patent Owner contends that limitations associated with [ix], [x], [xi], and [xii] of the “outputting” step are not disclosed in the prior art. We evaluate whether those features are disclosed in Samosky and the Mukherjee articles.

(1) Limitation [ix]: “graphical depiction of the training injection”

Petitioner contends that the requirement of a “graphical depiction of the training injection” is satisfied by the “‘4D’ depiction of a needle trajectory from a training session” that appears in Figures 14A and 14B of Samosky. Pet. 40. Although Patent Owner disagrees with Petitioner, that disagreement is predicated on its construction of “graphical depiction” as being a “portrayal or likeness” of the injection that excludes displays of mathematical graphs, which we reject (*see supra*, § II.A.1). PO Resp. 33–35. Patent Owner’s general assertion, for instance that Samosky’s Figures 14A and 14B do not show a graphical depiction of the training injection because they “merely show graphs of needle trajectories,” is unavailing. *See id.* at 34.

Samosky’s Figures 14A and 14B are described as “4D graphs” of two examples of needle tip trajectories 1402 and 1404 tracking movement of a

¹⁷ Claim 6 requires a similar outputting step.

needle tip in three-dimensional space over a period of time from starting point “O” to target “T.” Ex. 1004 ¶ 74. Samosky also discloses that its system is associated with a “virtual anatomic model” that “can model an anatomic region associated with the clinical procedure” and is applicable to “training” a variety of medical procedures, including those involving needle injection. *Id.* at ¶¶ 38–39. We conclude that Petitioner has shown adequately that Samosky discloses “a graphical depiction of the training injection” as is required by claim 1. *See* Pet. 40–41.

(2) Limitation [x]: “wherein the graphic depiction includes a digital three-dimensional model of the anatomically-shaped apparatus”

Petitioner relies on Samosky as showing the required graphic depiction that may include a digital three-dimensional model of the anatomically-shaped apparatus. In particular, Petitioner points to various parts of Samosky’s disclosure including Figures 14A and 14B and Samosky’s description of its “virtual model” as being a “3D model derived from a medical imaging scan (e.g., magnetic resonance imaging (MRI), computed tomography (CT) data, or 3D ultrasound data, etc.) isomorphic to the physical model, etc.” Pet. 41–42 (quoting Ex. 1004 ¶ 31). As we noted above, Samosky also clearly provides that its “virtual anatomic model 104 can model an anatomic region associated with the clinical procedure.” Ex. 1004 ¶ 39.

Patent Owner discounts Samosky’s disclosure in accounting for the above-noted feature, arguing that neither Petitioner nor its declarant, Dr. Mukherjee, explains how the graphs of Samosky’s Figures 14A and 14B

are associated with Samosky's disclosure of a virtual model. *See, e.g.*, PO Resp. 34–35.

We find unavailing the basis for Patent Owner's discounting of Samosky's teachings. In that respect, we determine that Patent Owner has not accounted adequately for what a person of ordinary skill in the art would have understood from Samosky's teachings. "[A] prior art reference" stands for "all that it teaches to those of ordinary skill in the art." *In re Fritch*, 972 F.2d 1260, 1264–65 (Fed. Cir. 1992). Furthermore, a person of ordinary skill in the art is also a person of ordinary creativity. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Samosky clearly sets forth that its system contemplates use of a "3D" "virtual model" of an "anatomic region" that is "isomorphic" to a physical model, and used during the course of training for medical procedures. *See, e.g.*, Ex. 1004 ¶¶ 31, 38, 39. Samosky's "4D" graphs of Figures 14A and 14B are described as being associated with a "prototype system in accordance with the subject innovation" used to assist with "tutoring," "coaching" and providing "feedback" to a user of Samosky's system. *See, e.g., id.* ¶ 74. It follows from Samosky's explicit teachings that one of ordinary skill and creativity in the art would have appreciated that the graphs of Samosky's Figures 14A and 14B would be associated with a virtual model of an anatomic region on which a user is training for a medical procedure. We credit the testimony of Dr. Mukherjee in that respect as it is consistent with Samosky's own disclosure. *See, e.g.*, Ex. 1002 ¶ 130. We credit Dr. Mukherjee's testimony over the countervailing testimony of Dr. Pugh (*see, e.g.*, Ex. 2005 ¶ 87), as we conclude that Dr. Pugh's

testimony does not adequately reflect what a skilled artisan would have gleaned from Samosky's clear teachings.

Accordingly, we determine that Petitioner has shown how Samosky's teachings convey to a person of ordinary skill in the art a "graphic depiction" that "includes a digital three-dimensional model of the anatomically-shaped apparatus" as recited in claim 1.

(3) Limitation [xi]: "a location of the needle relative to the digital three-dimensional model of the anatomically shaped apparatus"

In accounting for limitation [xi], Petitioner points to Samosky's Figure 8 and its description as showing "an instructional component that displays the location of a needle relative to the model of the anatomically-shaped apparatus." Pet. 42 (citing Ex. 1004 ¶ 66 ("As can be seen, the instructor interface can provide indicators identifying the anatomical feature (e.g., tissue type of structure, etc.) at the current needle tip location (the color-coded indicators to the left in FIG. 8).")). Petitioner also refers to Samosky's paragraph 74 and its description of the 4D graphs illustrated in Figures 14A and 14B. *Id.* As noted above, Samosky describes Figures 14A and 14B as showing graphs of "needle tip trajectories." Ex 1004 ¶ 74.

Patent Owner argues that the graphs of Figures 14A and 14B do not themselves show the location of a needle that is relative to the digital three-dimensional model of an anatomically-shaped apparatus. PO Resp. 35–36. As a part of that argument, Patent Owner also expresses that "Samosky does not explain how the needle trajectory graphs shown in Figures 14A and 14B could be combined with a medical imaging scan." *Id.* Patent Owner further contends that the indicators of Figure 8 are not displayed relative to any

digital three-dimensional model of an anatomically shaped apparatus. *Id.* at 36–38.

As discussed above, Samosky describes its “virtual model” as being a “3D model derived from a medical imaging scan (e.g., magnetic resonance imaging (MRI), computed tomography (CT) data, or 3D ultrasound data, etc.),” and which depicts an anatomic region that simulates a physical model. *See, e.g.*, Ex. 1004 ¶¶ 31, 39. Figures 14A and 14B show, in three dimensions, the trajectories or locations of a needle during a period of time. All of Samosky’s “virtual model” disclosures and its disclosures as to three-dimensional display of needle trajectories are associated with a system designed to provide medical procedure training for a user. Although Samosky does not show expressly the graphs of Figures 14A and 14B associated or overlaid with a virtual model of an anatomic region, such an understanding flows logically and directly from Samosky’s teachings.

We also do not find persuasive Patent Owner’s arguments that the location of a needle relative to a three-dimensional anatomically shaped apparatus is absent from Samosky’s teachings, including those of Samosky’s Figure 8. That figure shows an “instructor interface” that “can provide indicators identifying the anatomical feature (e.g., tissue type or structure, etc.) at the current needle tip location (the color-coded indicators to the left in FIG. 8)”. Ex. 1004 ¶ 66. Although Samosky may not directly associate the content of its Figure 8 with a three-dimensional model of an anatomically shaped apparatus, that is not dispositive where, as here, the question is one of obviousness. Indeed, in an obviousness analysis, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of

ordinary skill in the art would have employed can be taken into account. *KSR*, 550 U.S. at 418 (2007). Samosky is clear that its disclosed system as a whole “facilitates training in clinical procedures via mixed reality simulations” and contemplates a virtual model that is a three-dimensional representation of an anatomic region. *See, e.g.*, Ex. 1004 ¶¶ 7, 31. A person of ordinary skill and creativity in the art would have reasonably inferred from Samosky’s disclosure that one aspect of its training system, such as the instructor interface of Figure 8 showing needle tip location in connection with an anatomical feature, is associated with a three-dimensional display of needle tip location associated with an anatomically-shaped apparatus. We find persuasive Petitioner’s argument to that effect (*see, e.g.*, Pet. 42), and credit the testimony of Petitioner’s declarant, Dr. Mukherjee (Ex. 1002 ¶¶ 131–132), in part, because it is consistent with Samosky’s express disclosure.

We have considered Patent Owner’s arguments as to feature [xi], but find them unavailing. We are persuaded by Petitioner that Samosky’s disclosure, including its Figures 8, 14A, and 14B and their associated descriptions, accounts for limitation [xi].

(4) Limitation [xii]: “a dynamic position of the plunger in real time”

For limitation [xii], Petitioner relies on the disclosure of Samosky and the Mukherjee articles. Pet. 42–44. Figure 5 of Mukherjee 2012 describes that a “Virtual Instrument” display may show, among other things, “piston position and Aspiration indicators in real-time.” *See* Ex. 1006, 452. Mukherjee 2014 states that “[a] Lab VIEW[22]-based VI with an intuitive GUI provides the trainee with real-time feedback on the proximity and touch

of syringe to the EOM [extraocular muscles] and the rate of injection of anesthetic fluid.” Ex. 1005, 2. Petitioner contends that “Samosky teaches the benefits of providing a depiction of the needle position as well as information on ‘whether the user is pushing or pulling back on a plunger, amount of fluid injected into various tissue, etc.’” Pet. 43 (citing Ex. 1004 ¶¶ 50, 74). Petitioner concludes that:

[i]n view of these teachings and Mukherjee 2014 and Mukherjee 2012’s teachings of a sensor detecting syringe position, a POSITA would have found it obvious to provide a three-dimensional graphical depiction of a dynamic position of a plunger in real time, and would have had a reasonable expectation of success in making such modifications.

Id. at 43–44 (citing Ex. 1002 ¶¶ 82, 133–135).

Patent Owner contests Petitioner’s view that the prior art accounts for the graphical depiction of a dynamic position of the plunger in real time. *See* PO Resp. 43–50. According to Patent Owner, Petitioner relies only on the teachings of the Mukherjee articles for that requirement, and none of the figures in the Mukherjee articles displays a syringe plunger in real time. *See id.* Central to Patent Owner’s argument appears to be the premise that claim 1 requires that a “graphical depiction” that includes a “dynamic position of the plunger in real time” must constitute a computer-generated portrayal of likeness of a syringe that displays an image of a plunger moving in real time. *See id.*

As discussed above in connection with claim construction, we observe that claim 1 does not require a digital three-dimensional model of a syringe. Yet, that is what Patent Owner contends must be present in order to provide a depiction of a dynamic position of a plunger in real time. Petitioner points

to Figure 5 of Mukherjee 2012 as depicting a display of a syringe piston or plunger that is described as being shown in “real-time.” *See* Ex. 1006, 452.

Figure 5 of Mukherjee 2012 is reproduced below:

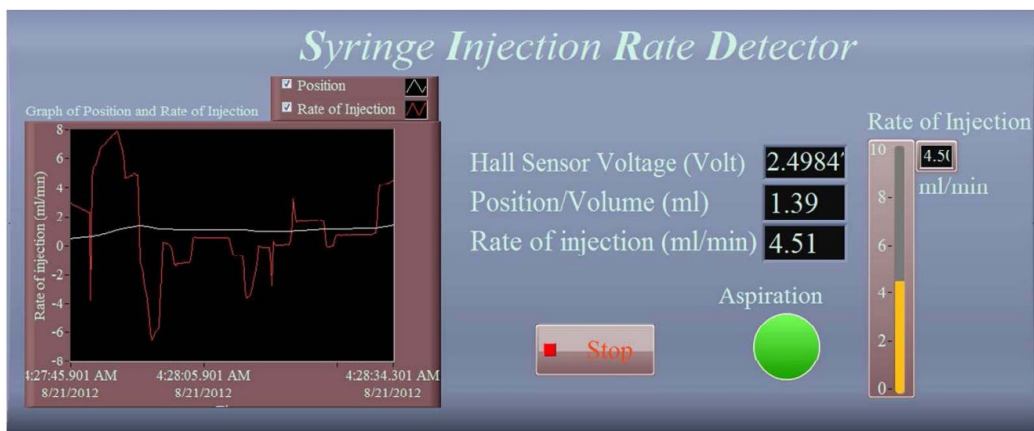


Figure 5 above shows a “LabVIEW based Virtual Instrument front panel showing the rate of injection, *piston position* and Aspiration indicators *in real-time*.” *Id.* at 452 (emphasis added). The left side of Figure 5 shows a “Graph of Position and Rate of Injection.” It is clear from that graph that the position of a syringe “piston,” i.e., plunger, is charted over a defined period of time. *See, e.g.,* Ex. 1002 ¶ 83. The middle portion of Figure 5 also includes an indicator of “Position/Volume (ml),” which is understood to reflect movement of the syringe position in real-time. *See id.* Mukherjee 2012 further describes its system as including a “Hall effect sensor along with a permanent magnet” that “sense the position of the syringe piston relative to the syringe body.” *Id.* at 450 (Abstract). Additionally, Mukherjee 2012 explains the following:

As the piston is moved, the distance between the Hall sensor and the magnets change. Thus the magnetic field strength experienced by the Hall sensor changes according to the position of the piston in relation to the syringe body. As a result the output

of the Hall sensor is a function of the piston position and in turn, the volume of liquid expelled in ml.

Id. at 452 (Measurement Scheme).

We also take note of Dr. Mukherjee’s credible testimony, for example, that “displaying the dynamic position of the syringe plunger in real time as taught by Mukherjee 2012 would provide the trainee with feedback as to the trainee’s injection technique, particularly as to the rate of injection.” Ex. 1002 ¶ 135. It further is clear from the record at hand, including Samosky’s Figures 14A and 14B, that real-time digital display of syringe components, such as needle tip position, during an injection procedure was known. *See also id.* (“Samosky illustrates the benefits of providing a depiction of the needle position, as well as the utility of monitoring whether the plunger of a syringe has been pulled back or pushed” (citing Ex. 1004 ¶¶ 50, 74)).

Patent Owner characterizes Figure 5 of Mukjherjee 2012 as simply being a “mathematical graph” that “does not provide a computer-generated portrayal or likeness of the plunger.” PO Resp. 46. It is apparent from such characterization that Patent Owner largely bases its argument on its claim construction position that a “graphical depiction” must be a computer-generated portrayal or likeness that excludes mathematical graphs. *See, e.g.*, PO Resp. 46–47. As we have discussed above, however, that is a position with which we do not agree.

Having reviewed the record, we conclude that Samosky’s teachings along with those of the Mukherjee articles reasonably would have conveyed to a skilled artisan that a virtual graphical display of a training injection exercise shows the syringe’s plunger position in real-time. We, thus, are persuaded that Petitioner, in relying on the teachings of Samosky and the

Mukherjee articles, in particular Mukherjee 2012, demonstrates that a graphical depiction that displays a dynamic position of a syringe plunger in real-time does not distinguish claim 1 from the teachings of the prior art.

(5) Remaining Limitations of Claim 1

Petitioner persuasively explains where all of the limitations of claim 1 are found in the prior art, including those that have been discussed specifically above. Pet. 29–65. Other than the limitations addressed above, Patent Owner does not argue that any of the remaining limitations of claim 1 are absent from the prior art. In light of the record before us, we conclude that Petitioner has demonstrated where all of the limitations of claim 1 are found in the prior art.

(6) Reasons to Combine

Petitioner contends that one of ordinary skill in the art “would have been motivated and had reason to combine the relevant teachings of Samosky, Mukherjee 2014, and Mukherjee 2012 to arrive at the features of the challenged claims.” Pet. 25. Petitioner characterizes the three references as “analogous art” to the ’231 patent and that “[e]ach reference, like the ’231 patent, is directed to the same problem of providing a simulated injection training system to reduce human error by practitioners.” *Id.* Petitioner also contends that “a POSITA would have been motivated to employ a simulated syringe in Samosky’s simulation-based training system based on Mukherjee 2014 and Mukherjee 2012 in order to provide feedback as to the rate of anesthesia being injected as a particular target site.” *Id.* at 26 (citing Ex. 1002 ¶¶ 99–101, 111–112). Petitioner offers the following additional reasoning:

Further, a POSITA would have found it obvious to have included with Samosky's system a display of dynamic position of the plunger in real time during a training exercise. *See* EX1002, ¶¶102-104. For example, as shown above, Samosky, Mukherjee 2012, and Mukherjee 2014 teach that it was well known to display to a trainee information relating to injection parameters, such as flow rate, to assist with training in real time and to evaluate the trainee after conclusion of a training session. Further, Mukherjee 2012 and Mukherjee 2014 each show that it was known to display the dynamic position of the plunger (specifically, the piston portion of the plunger) during an injection exercise. Mukherjee 2014, p. 1; Mukherjee 2012, p. 450.

Thus, displaying position of the plunger over time would simply have involved the use of known techniques to improve a known device to yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416-419 (2007); *see* EX1002, ¶¶94-104, 133-135. Notably, nothing in the '231 patent suggests that there is any new or unexpected result associated with display of plunger position in real time. In fact, the '231 patent fails to describe how this result is achieved or even to illustrate that feature in the drawings.

Samosky and Mukherjee 2014 show that it would have been obvious to apply Samosky's teachings to an application involving a model of human facial features. As set forth above, Samosky expressly states that its system and method may be used for other procedures. *See, e.g.*, Samosky, ¶¶34, 36, 38, 61, 63, 64. Mukherjee 2014 describes the benefits of a simulation based training system for ocular anesthetic injection. Mukherjee 2014, p. 1. Accordingly, a POSITA would have found it obvious to apply Samosky's position detection and training feedback techniques to training procedures involving facial injection, and would have had a reasonable expectation of success in doing so. *See* EX1002, ¶¶94-104, 133-135.

Id. at 27–28.

Patent Owner initially focuses on the claim feature of “a dynamic position of the plunger in real time,” and contends that one of ordinary skill

in the art “would not have been motivated to modify Samosky in view of Mukherjee 2014 and Mukherjee 2012 to arrive at this feature.” PO Resp. 50. Pointing to a statement at page 44 of the Petition, Patent Owner contends that “Petitioner merely relies on the claim limitation itself to allege motivation to combine the asserted references.” *Id.* at 50–51 (quoting Paper 1, 44 (“[A] POSITA would have been motivated to display ‘*a dynamic position of the plunger in real time*’ in order to provide this information to a user during a training injection.”)). That contention, in our view, does not adequately consider Petitioner’s expressed reasoning for combining the teachings of the prior art. Patent Owner’s myopic focus on a single statement in the Petition does not address adequately Petitioner’s analysis (for instance, that which is reproduced above) that a person of ordinary skill in the art would have had multiple reasons to combine the teachings of Samosky and the Mukherjee articles.

Patent Owner also generally is of the view that the deposition testimony of Dr. Mukherjee is inadequate to provide suitable reasons to modify Samosky based on the teachings of the Mukherjee articles. PO Resp. 51–53 (citing Ex. 2020, 92:18–93:22, 63:22–64:12, 76:2–73:11). According to Patent Owner, “[n]either Petitioner nor its expert explain why the proposed modification would provide better feedback to the user than Samosky’s display.” PO Resp. 51. Patent Owner also contends Samosky and Mukherjee 2014 have aspirator indicators that are “simple” or “easily interpretable” and that “[a] person of skill would have no motivation to convert this easy to interpret indicator to a graphical depiction of a dynamic position of the plunger in real time.” *Id.* at 51–53.

We find Patent Owner’s arguments unavailing. That Samosky’s and Mukherjee 2014’s indicators may be “simple” or “easily interpretable” does not mean that any modification is precluded. The prior art clearly sets forth that it was known in the art that providing “real-time feedback” in dispensing a therapeutic agent during a training exercise is desirable “[t]o give the trainee a realistic training environment.” *See, e.g.*, Ex. 1005, 1; Ex. 1006, 450. It is also clear that one known mechanism for providing that feedback is through real-time indication of the position of a syringe piston or plunger during a training exercise. *See* Ex. 1006, 452, Fig. 5. We find sufficiently persuasive and credible Petitioner’s and Dr. Mukherjee’s views that the desire to provide that feedback provides adequate reason to implement display of the dynamic position of a syringe plunger in real-time into other types of known virtual training simulations, such as that of Samosky, so as to enhance the training experience. *See* Pet. 25–28 (citing various paragraphs of Ex. 1002 (Mukherjee Declaration)).

We find that Patent Owner’s arguments and Dr. Pugh’s testimony (*e.g.*, PO Resp. 50–55; Ex. 2005 ¶¶ 34–36, 97–105, 108) do not appropriately take into account what a skilled artisan would have regarded as clear and adequate reason to combine the teachings of the prior art, and specifically to implement the display of a dynamic position of a plunger into a virtual training simulation. We conclude that the record conveys adequate reason to combine the teachings of Samosky, Mukherjee 2014, and Mukherjee 2012.

(7) Reasonable Expectation of Success

Patent Owner contends that a person of ordinary skill in the art “would not have had a reasonable expectation of success in combining Samosky, Mukherjee 2014, and Mukherjee 2012 to display a graphical depiction including ‘a dynamic position of the plunger in real time.’” PO Resp. 55. Patent Owner bases that contention on the theory that Dr. Mukherjee has offered insufficient evidence “that a person of skill would have been able to turn the two-dimensional graphs, such as shown in Figure 5 in Mukherjee 2012, into a three-dimensional display of a dynamic position of a syringe plunger in combination with a three-dimensional model of the anatomically-shaped apparatus.” *Id.* at 55–56. We discern, however, that Dr. Mukherjee bases his testimony concerning the “dynamic position of the plunger in real time” claim feature on disclosure in each of Samosky, Mukherjee 2012, and Mukherjee 2014. *See* Ex. 1002 ¶¶ 133–135 (citing Mukherjee 2014 (Ex. 1005) § II, p. 2; Mukherjee 2012 (Ex. 1006) Fig. 5, 452; Samosky (Ex. 1004) ¶¶ 50, 74).

Taken together, those references describe, among other things: (1) displaying a syringe plunger position in real time (e.g., Ex. 1005 § II, 2; Ex. 1006, Fig. 5, 452); (2) tracking of syringe needle trajectory as a part of a three-dimensional display (*see, e.g.*, Ex. 1004, Figs. 14A, 14B, ¶ 74); and (3) simulation based training for medical procedures that incorporates a physical model and an associated three-dimensional virtual model (*see, e.g.*, Ex. 1004 ¶¶ 31, 38, 39). Moreover, in connection with a discussion of “a digital three-dimensional model of the syringe,” Dr. Mukherjee also points to disclosure of Samosky at Figs. 15, 16A, and 16B, and paragraph 83.

Ex. 1002 ¶ 167.¹⁸ Paragraph 83 of Samosky describes, in part, the following:

A laryngoscope was fitted with the tracking sensor attached via a custom-made adapter to the end of the hand, and a 3D model of the laryngoscope was generated, as can be seen in the display in FIG. 15. The system was able to display a “target” position for the laryngoscope—set, for example, by a clinical teacher. As seen in FIG. 16, a learner or user of the system can see both the fixed, target laryngoscope position, rendered as a 3D virtual laryngoscope on a computer display, and a current, “live” laryngoscope position. As the live laryngoscope is aligned to the target position, positional error metrics can be displayed as visual cues (e.g., color coded, etc.) to guide the user. When the positional error drops below a preset threshold, a visual alert and audio tone can signal the user that he or she has successfully targeted the reference position. Although this prototype related specifically to a laryngoscope, this technique can be applied to any tool or device and can permit both quantification of proper manipulation and visual feedback to guide a learner to achieving correct target positioning.

Ex. 1004 ¶ 83.

Thus, Samosky describes a system in which a “user of the system can see a fixed, target laryngoscope, rendered as a 3D virtual laryngoscope on a computer display and a current ‘live’ laryngoscope position.” *Id.* Samosky also describes that the disclosed “technique” may be applied to any tool or device to facilitate the goal of providing “proper manipulation and visual feedback.” *Id.* It follows readily from the teachings of the prior art that a skilled artisan would have recognized a syringe as the type of device ripe for application of the noted technique in connection with an injection procedure to harness the state benefits of “proper manipulation and visual feedback.”

¹⁸ Referenced on page 58 of the Petition.

Relying on the testimony of Dr. Pugh, Patent Owner argues that “it was not well-known for simulation-based medical training systems to display a three-dimensional real time animation of an interaction of a syringe and an anatomical model, in which the plunger of the digital three-dimensional model of the syringe moves according to the dynamic position of the plunger in real time.” PO Resp. 56 (citing Ex. 2005 ¶ 109). That argument is misplaced, however, because, even accepting Dr. Pugh’s testimony as true, claim 1 does not require an “animation” or a “digital three-dimensional model of the syringe.” Furthermore, Dr. Pugh offers no more than general and unsupported statements as to what was well-known. Dr. Pugh does not cite to any tangible or credible evidence that substantiates this testimony. *See* Ex. 2005 ¶ 109.

Dr. Pugh also opines, without citing supporting evidence, that the “LabVIEW . . . virtual instrument GUI” of the Mukherjee articles would be incapable of a “three-dimensional rendering of the dynamic movement of the syringe plunger” that is displayed in real time. *See* Ex. 2005 ¶ 110; *see also* PO Resp. 56–57 (relying solely on Ex. 2005 ¶ 110). Yet, even if true, claim 1 does not require a “three-dimensional rendering” of the dynamic movement of the syringe plunger.

Moreover, Patent Owner’s own assessment of the level of ordinary skill in the art conveys that such person has a degree in “Electrical Engineering, Biomedical Engineering, or any similar type of engineering or biomedical degree” and also has “at least one year experience in designing sensor-based motion tracking and simulators for evaluating clinical performances.” *See* PO Resp. 20–21. It is difficult to reconcile Patent Owner’s and Dr. Pugh’s view that a skilled artisan with such a background

would have found it beyond their skill to implement an approach of displaying real-time data as a part of a three-dimensional rendering, particularly given the evidentiary record at hand that includes the teachings of Samosky, Mukherjee 2012, and Mukherjee 2014.

We have considered Patent Owner’s arguments suggesting that a person of ordinary skill in the art would not have had a reasonable expectation of success in combining the teachings of the prior art, including Samosky, Mukherjee 2012, and Mukherjee 2014. We, however, find them unavailing.

(8) Conclusion—Claim 1

In light of the record that has been developed during trial, including the parties’ filings and the underlying supporting evidence, we conclude that Petitioner has shown: (1) where all the features of claim 1 are found in the prior art, specifically Samosky, Mukherjee 2012, and Mukherjee 2014; (2) that a person of ordinary skill in the art would have had adequate reasons to combine the teachings of Samosky, Mukherjee 2012, and Mukherjee 2014; and (3) a person of ordinary skill in the art would have had a reasonable expectation of success in so combining those teachings. Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence that claim 1 would have been unpatentable over the combined teachings of Samosky, Mukherjee 2014, and Mukherjee 2012.

b) Claim 6

Petitioner also contends that claim 6 is unpatentable over Samosky, Mukherjee 2014, and Mukherjee 2012. Pet. 49–59. Claim 6 is drawn to a “method to analyze a collection of injection training data using one or more

signal processors of an injection training system having an anatomically-shaped apparatus and a syringe[.]” Claim 6 includes many of the same or similar features as claim 1 including an “outputting” step. That outputting step is reproduced below:

outputting from the one or more signal processors, for displaying on a display device during and/or after the training injection, a graphical depiction of the training injection, wherein the graphic depiction includes a digital three-dimensional model of the anatomically-shaped apparatus, a digital three-dimensional model of the syringe, a dynamic position of the plunger in real time, and a location of the needle relative to the digital three-dimensional model of the anatomically-shaped apparatus, the digital three-dimensional model of the anatomically-shaped apparatus comprising a plurality of anatomical layers.

Ex. 1001, 35:30–41.

Thus, claim 6, like claim 1, requires: (1) “a graphical depiction of the training injection” (corresponding to limitation [ix] of claim 1); (2) “wherein the graphic depiction includes a digital three-dimensional model of the anatomically-shaped apparatus” (corresponding to limitation [x] of claim 1); (3) “a location of the needle relative to the digital three-dimensional model of the anatomically-shaped apparatus” (corresponding to limitation [xi] of claim 1; and (4) “a dynamic position of the plunger in real time” (corresponding to limitation [xii] of claim 1). For the same reasons discussed above with respect to claim 1, we conclude that Petitioner has accounted adequately for those features in the prior art.

Unlike claim 1, the outputting step of claim 6 expressly recites a “three-dimensional model of the syringe.” Patent Owner disputes that the requirement is described or suggested by the prior art teachings of Samosky, Mukherjee 2014, and Mukherjee 2012.

With respect to the above-noted requirement, Petitioner focuses on disclosure in Samosky as to discussion, in the context of a virtual training procedure, of providing a laryngoscope position “rendered as a 3D virtual laryngoscope,” and also providing such rendering for other devices. Pet. 58–59 (citing Ex. 1004 ¶ 83). Petitioner reasons the following:

A POSITA would have understood that the “virtual” instrument would be based on a virtual model of an actual instrument, utilizing known techniques, such as described by Samosky with respect to the virtual model of the training apparatus. *See* [Ex. 1004 ¶ 83], ¶¶ 31, 32; *see also* EX1002 ¶167. A POSITA would have recognized the benefit of displaying other types of virtual instruments, such as an injection syringe. *See* EX1002 ¶¶ 40, 167.

Pet. 58.

We find Petitioner’s reasoning persuasive. We also credit Dr. Mukherjee’s testimony in that regard (e.g., Ex. 1002 ¶¶ 40, 167). It is clear from record evidence, including, for instance, Samosky’s paragraph 83, that it was known in the art to display “virtual” instruments in the form of a three-dimensional rendering of the instrument. It also is abundantly clear that an injection syringe is a known device employed in training simulations. *See, e.g.*, Ex. 1004 ¶¶ 66–67; Ex. 1005, Fig. 2; Ex. 1006, 450. Whether any of the prior art references expressly discloses a three-dimensional model of a syringe is not dispositive, where, as here, the question is one of obviousness. Indeed, in an obviousness analysis, it is not necessary to find precise teachings in the prior art directed to the specific subject matter claimed because inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account. *KSR*, 550 U.S. 418 (2007). In this case, it is a ready inference from the record that an injection syringe is the type of device contemplated by Samosky as being suitable to be displayed as

a virtual instrument via three-dimensional rendering in a training simulation. *See, e.g.*, Ex. 1004 ¶ 83, ¶¶ 31, 32; Ex. 1002 ¶¶ 40, 167.

Furthermore, we agree with Petitioner that although claim 6 recites each of “a dynamic position of the plunger” and a “three-dimensional model of the syringe,” there is no requirement of “a three-dimensional depiction that shows both a syringe and movement of the plunger.” Pet. Reply 14. With respect to what claim 6 does require, the record includes ample evidence that providing and displaying real-time information to a user during a training procedure (*see generally* Exs. 1004, 1005, 1006) and also presenting virtual three-dimensional images as a part of such training (*see, e.g.*, Ex. 1004, Figs 14A, 14B ¶¶ 31, 39, 74, 83) were known in the art. The record reasonably conveys that a skilled artisan would have contemplated providing such real-time information in connection with a dynamic three-dimensional image. *See, e.g.*, Ex. 1002 ¶¶ 135–137. The record suggests that such is true even if the implementation is “difficult and computationally complex” as is urged by Patent Owner. *See, e.g.*, PO Sur-reply 20 (citing Ex. 2005 ¶ 119). We share Petitioner’s view that it is notable that, despite what Patent Owner and Dr. Pugh characterize as “difficult” in nature, the ’231 patent itself provides little, if any, explanation or guidance as to the specifics of overcoming such difficulty. *See* Pet. Reply 12–14. That such explanation is omitted as being unnecessary in the ’231 patent does not lend itself to a conclusion that addressing such issues would have been outside of, or beyond, the skill of a person of ordinary skill in the art.

For the reasons set forth above, we conclude that Petitioner has accounted adequately in the prior art for the recitation in claim 6 of a “three-dimensional model of the syringe.” We further conclude that Petitioner has

shown adequately where all other features of claim 6 are found in the prior art. *See* Pet. 49–59.

Accordingly, as with claim 1, we conclude that Petitioner has shown: (1) where all the features of claim 6 are found in the prior art, specifically Samosky, Mukherjee 2012, and Mukherjee 2014; (2) that a person of ordinary skill in the art would have had adequate reasons to combine the teachings of Samosky, Mukherjee 2012, and Mukherjee 2014; and (3) a person of ordinary skill in the art would have had a reasonable expectation of success in so combining those teachings. Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence that claim 6 would have been unpatentable over the combined teachings of Samosky, Mukherjee 2014, and Mukerjee 2012.

c) Claim 17

Claim 17 depends from claim 6. Claim 6 includes a requirement that the three-dimensional model of the anatomically-shaped apparatus includes “a plurality of anatomic layers.” Ex. 1001, 35:39–41. Claim 17 adds the following “[w]herein altering the view of the training injection comprises causing to be displayed different ones of the plurality of anatomical layers as a needle tip of the syringe penetrates each one of the anatomical layers.” *Id.* at 37:8–12.

With respect to claim 6 and its “anatomical layers” requirement, the Petition set forth the following:

In particular, Samosky discloses that “[t]he virtual anatomic model 104 can be a 3D model and can virtually represent the anatomical region corresponding to the physical anatomic model 102, and can comprise information associating or co-registering anatomical features or tissue types (e.g., blood vessels, nerves,

etc.) with locations in the physical anatomic model 102.” [Ex. 1004], ¶40. Samosky further discloses “showing an internal view of the four layers of the physical model of the arm—skin at 1102, fat at 1104, fascia [connective tissue] at 1106, and soft tissue (muscle) at 1108—along with the bone structure 1110.” *Id.*, ¶70. Samosky further discloses simulating a nerve-block procedure with a model that “utilized a translucent cylindrical silicone phantom cylindrical phantom ‘limb’ 502 and corresponding virtual model.” *Id.*, ¶65. Thus, Samosky demonstrates that it was known to create a virtual model that includes various anatomical layers. *See also* EX1002, ¶172.

Pet. 60.¹⁹

Thus, Petitioner relies on Samosky’s disclosure that its virtual model may be a three-dimensional model that corresponds to a physical model. Petitioner also points to Samosky’s disclosure that the physical model may incorporate multiple “layers” and that the virtual model is “co-register[ed]” to the physical model. *Id.*; *see also* Ex. 1004 ¶ 70 (“Nerves, blood vessels, fascia, skin, and other relevant anatomy were segmented . . . to create a virtual model that was registered to the physical model to track needle distance.”).

With respect to claim 17, the Petition expresses the following:

Samosky discloses that “details of both the physical anatomic model 102 and the virtual anatomic model 104 will vary.” Samosky, ¶40. Samosky further discloses that a determined “response of the physical anatomic model 102, virtual anatomic model 104, or clinical instruments 106” can include “changes in the virtual anatomic model 104.” *Id.*, ¶45.

Samosky further discloses that an instructor interface shows the “current tissue type the needle is located in (air, tissue, vessel, nerve, bone).” Samosky, ¶67. Samosky discloses

¹⁹ The quoted portion comes from the Petition addressing claim 11, but is referenced in connection with the corresponding feature of claim 6. *See* Pet. 59.

providing “indicators identifying the anatomical feature (e.g., tissue type or structure, etc.) at the current needle tip location (the color-coded indicators to the left in FIG. 8)” and that “other indicators can display the volume of fluid that has been injected into each tissue type (shown in FIG. 8 via the gray indicators).” *Id.*, ¶66. At least because the interface depicts the “current” tissue type that a needle is located in, Samosky teaches display of the anatomical layer as the needle penetrates that layer during training injection. *See* EX1002, ¶¶175-176.

Pet. 61–62.

Thus, Petitioner points to Samosky’s teachings concerning a virtual model coupled with other of Samosky’s teachings pertaining to “indicators identifying the anatomical feature (e.g., tissue type or structure, etc.) at the current needle tip location (the color-coded indicators to the left in FIG. 8).” *Id.*

Patent Owner disputes that Samosky’s teachings account for the requirements of claim 17. According to Patent Owner, Petitioner is combining multiple embodiments of Samosky and has not explained adequately how those embodiments are being combined. *See* PO Resp. 62–65; PO Sur-reply 13–14.

We are not satisfied that Patent Owner accounts adequately for what Samosky’s teachings would have suggested to one of ordinary skill in the art. Samosky is clear in its teachings of a virtual model that is structured to mimic a physical model that includes multiple anatomical “layers,” e.g., tissue, blood vessels, nerves, and bones. Samosky is also clear in its teachings of using “indicators” to convey real-time information to a user engaged in a training exercise as to the “current” location of a needle tip in relation to a given layer. *See* Ex. 1004 ¶ 66. Although Samosky discusses those “indicators” in the context of the instructor interface panel of Figure 8,

which is not itself a virtual model of an anatomic region (*see* Ex. 1004 ¶ 66), Samosky does not limit its teachings pertaining to needle tip location solely to Figure 8. Given Samosky's disclosures of a "virtual model" of anatomic layers of a physical model and the recognized usefulness of providing current needle tip location with respect to those layers, a person of ordinary skill and creativity would have reasonably inferred that information of the needle tip location is associated with the virtual model. *See, e.g.*, Ex. 1002 ¶ 176.

We agree with Petitioner that Patent Owner does not appropriately consider the full nature of Samosky's teachings when it comes to the technological disclosure of a physical-virtual model based training system. *See* Pet. Reply 9–10. A prior art reference must be considered for everything it teaches by way of technology. *See EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). In our view, Petitioner's position is better aligned with what a person of ordinary skill in the art would have understood from the full nature of Samosky's teachings. We further agree with the following assessment offered by Petitioner:

Samosky explains that "FIGS. 5 through 8 tracked the replica ultrasound probe and the needle tip, and the student or trainee interface or application was capable of ***displaying the virtual ultrasound image that corresponds to the cylindrical phantom anatomy*** and calculating the needle to nearest target nerve distance (which was also displayed on the screen)." EX1004, ¶67. If the phantom anatomy data is "cylindrical"—i.e., three dimensional—the virtual ultrasound image is also cylindrical/three-dimensional. This is consistent with Samosky's indication that the virtual ultrasound image may be derived from "3D ultrasound data." *See, id.*, ¶¶31, 67. Nerves and tissue are three-dimensional structures. Thus, to provide "needle to nerve distance" and "current tissue type the needle tip is located in,"

the location of the needle in Samosky must be tracked relative to the digital three-dimensional model of the anatomically-shaped apparatus, e.g., as shown in Figure 14. *Id.*, ¶74. Thus, contrary to Truinject’s assertions, there is no need to “explain how the indicators shown in Figure 8 of Samosky could be combined with a three-dimensional model of the anatomically shaped apparatus.” Samosky already does this.

Pet. Reply 9–10.

Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence that claim 17 would have been unpatentable over Samosky, Mukherjee 2014, and Mukherjee 2012.

d) Claims 23 and 24

Claim 23 depends from claim 1 and claim 24 depends from claim 6. Each of claim 23 and claim 24 adds the following feature: “wherein the graphical depiction further comprises a simulated delivery of therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus.” Ex. 1001, 38:14–21. The Petition sets forth the following with respect to that feature:

Samosky teaches “provid[ing] a ‘bull’s-eye’ visualization of the needle tip approaching the nerve.” Samosky, ¶67. Samosky further discloses providing indicators to “display the volume of fluid that has been injected into each tissue type” (*id.*, ¶66.), and Figs. 7-8 depict example displays including a distance to nerve (*id.*, Figs. 7-8) and whether a plunger is pulled or pushed back (*id.*, Fig. 8). These portions of Samosky thus teach “*the graphical depiction further comprises a simulated delivery of therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus.*” See EX1002, ¶180.

Further, Mukherjee 2014 shows, in Fig. 12, a graphical user interface depicting a syringe being inserted into an eyeball

for a simulated delivery. Mukherjee 2014, Fig. 12; *see* EX1002, ¶181.

Pet. 64.

Thus, Petitioner points to disclosure in Samosky as to displaying: (1) fluid volume that has been injected; (2) distance to nerve information; and (3) the positioning of a plunger, i.e. pulled or pushed back. In its Petitioner Reply, Petitioner additionally expresses that “[t]hese three parameters—volume of injected fluid, distance from needle tip to nerve, and whether the plunger is pulled or pushed back—sufficiently define a simulated delivery of therapeutic agent.” Pet. 24 (citing Ex. 1002 ¶ 180). Petitioner and Dr. Mukherjee (Ex. 1002 ¶ 181) also characterize Mukherjee 2014’s Figure 12 as showing a syringe inserted into an eyeball for simulated delivery. *Id.*

Patent Owner contends that Petitioner has mischaracterized Samosky’s Figures 7 and 8 and its teachings with respect to those figures. PO Resp. 65; *see* PO Sur-reply 24–25. According to Patent Owner, neither of those figures “shows a computer generated portrayal or likeness of a therapeutic agent.” PO Resp. 65; PO Sur-reply 25. Patent Owner also argues that neither figure shows a three-dimensional image of a virtual model (each being allegedly limited to a “two dimensional image”), and thus cannot convey “a simulated delivery of therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus.” PO Resp. 66–67; *see* PO Sur-reply 25–26 (citing Ex. 2005 ¶ 130) (emphasis omitted). Lastly, Patent Owner discounts Petitioner’s and Dr. Mukherjee’s assessment as to what is shown in Figure 12 of Mukherjee 2014. *Id.* at 67–69.

Initially, we note that Patent Owner appears, in part, to premise its argument on the requirement that a “graphical depiction” be a “computer

generated portrayal or likeness.” That is a premise with which we do not agree. *See supra*, § II.A.1. In any event, as we have discussed above, we do not conclude that Samosky limits its teachings, or any of its figures, strictly to two-dimensional images. *See, e.g., supra*, § II.B.4.c. We, thus, do not find persuasive Patent Owner’s arguments and Dr. Pugh’s testimony (e.g., Ex. 2005 ¶ 130) that attempts to minimize aspects of Samosky’s teachings as being limited to two-dimensional images. Rather, the record establishes that Samosky contemplates a three-dimensional virtual model, and also three-dimensional simulated devices, as a part of its physical-virtual training simulation. *See, e.g.*, Ex. 1004 ¶¶ 31, 39, 83.

Samosky also clearly provides that “indicators can display the volume of fluid that has been injected into each tissue type.” *Id.* ¶ 66. In the Petitioner Reply, Petitioner additionally notes the following:

Samosky states, with reference to Figure 8, “[v]olume and location of fluid injected was displayed on the instructor interface, although in other embodiments, ***the measured injected fluid volume can be used to provide feedback in other manners, such as using it as a real-time input parameter to model a visible bolus of fluid in the vicinity of the needle tip on the simulated ultrasound display.***

Pet. Reply 24 (quoting Ex. 1004 ¶ 67).

Thus, Samosky clearly contemplates modeling of injected fluid as a part of a simulated display. It follows readily that a skilled artisan would have regarded simulated delivery of a therapeutic agent as being encompassed as a part of Samosky’s disclosed physical-virtual training simulation. Also, as discussed above, we conclude that a person of ordinary skill in the art would have recognized that such simulation incorporates

delivery of therapeutic agent as a part of a three-dimensional virtual model including a three-dimensional model of a syringe.²⁰

We are cognizant of Patent Owner’s contention that, with respect to page 24 of the Reply, “Petitioner did not present the argument in the Petition,” and that it is “newly raised argument.” PO Sur-reply 25–26. We, however, view it as a permissible reply argument (*see* 37 C.F.R. § 42.23(b)) made in response to Patent Owner’s contentions in the Patent Owner Response as to proposed inadequacies in Samosky’s teachings, because the argument points to teachings of Samosky that are consistent with disclosures that Petitioner relied on in the Petition. Indeed, as generally discussed in this Decision, throughout the Petition, Petitioner relies on Samosky’s teachings pertaining to its physical-virtual simulation based training that encompasses a three-dimensional model of anatomy derived from a medical imaging scan and three-dimensional modeling of devices or tools, which includes injection syringes. *See, e.g.*, Pet. 14–18 (citing, among other content, Ex. 1004 ¶¶ 7, 31, 55, 65 66, 67, 74); *id.* at 41–42 (citing Ex. 1004 ¶ 31); *id.* at 58 (citing Ex. 1004 ¶¶ 31, 32, 83); *id.* at 61–62 (citing Ex. 1004 ¶¶ 40, 45, 66, 67).

Furthermore, Patent Owner had opportunity to address Petitioner’s Reply Brief as a part of its Sur-reply, and did so. According to Patent Owner, “even if considered,” the content of Samosky identified at page 24 of the Reply does not establish that Samosky’s Figure 7 discloses the requirements of claims 23 and 24 including a “digital three-dimensional model of the anatomically-shaped apparatus” or “a simulated delivery of the

²⁰ We note, however, that when it comes to claim 23, as we discussed in connection with claim construction, there is no requirement of a “three-dimensional syringe.”

therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus.” PO Sur-reply 25–26. Yet, as discussed above, we conclude that Petitioner does not rely solely on Samosky’s Figure 7 in that respect. Instead, Petitioner’s reliance is more broadly premised on that figure taken in the context of Samosky’s overall disclosure as to its physical-virtual simulation device, and also in combination with the teachings of the Mukherjee articles.

In our view, given the extent of the evidentiary record, and what a person of ordinary skill in the art would have reasonably understood from that record, we cannot conclude that a “graphical depiction” of “a simulated delivery of therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus” establishes a distinction over the prior art. We credit Dr. Mukherjee’s testimony to that effect (Ex. 1002 ¶¶ 180, 181), as it is consistent with what a skilled artisan would have understood from the full extent of the teachings of the prior art, including Samosky’s teachings.

We conclude that Petitioner has shown by a preponderance of the evidence that claims 23 and 24 would have been unpatentable over Samosky, Mukherjee2014, and Mukherjee 2012.

e) Claims 3, 4, 10, 11, 15, 18, 21, and 22

We have reviewed the Petition with respect to all the limitations required by claims 3, 4, 10, 11, 15, 18, 21, and 22. *See* Pet. 46–49, 59–64. Patent Owner does not offer any arguments directed specifically to those claims. We determine that Petitioner has shown where all the limitations of those claims are found in Samosky and the Mukherjee articles. *See id.* We

also conclude that Petitioner has shown by a preponderance of the evidence that those claims are unpatentable.

5. Other Grounds

Petitioner also challenges the patentability of (1) claim 12 based on Samosky, Mukherjee 2014, Mukherjee 2012, and Toly, and (2) claims 16 and 19 based on Samosky, Mukherjee 2014, Mukherjee 2012, Lampotang, and Sinclair. Pet. 65–69. Patent Owner does not present any arguments directed specifically to either of those grounds, or any of claims 12, 16, and 19.²¹ Rather, Patent Owner simply references its arguments as to claims 1 and 6. *See* PO Resp. 69–70. As discussed above, we do not find those arguments availing. In considering the record before us, we find Petitioner’s showing for both of the noted grounds to be persuasive. *See* Pet. 65–69. Accordingly, we conclude that Petitioner has shown by a preponderance of the evidence that claims 12, 16, and 19 are unpatentable.

²¹ Claims 12 and 16 depend from claim 6. Claim 19 depends from claim 1.

III. CONCLUSION²²

For the foregoing reasons, we conclude that Petitioner has met its burden to show by a preponderance of the evidence that claims 1, 3, 4, 6, 10–12, 15–19, and 21–24 are unpatentable over the prior art.

In summary,

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 3, 4, 6, 10, 11, 15, 17, 18, 21–24	103	Samosky, Mukherjee 2014, Mukherjee 2012	1, 3, 4, 6, 10, 11, 15, 17, 18, 21–24	
12	103	Samosky, Mukherjee 2014, Mukherjee 2012, Toly	12	
16, 19	103	Samosky, Mukherjee 2014, Mukherjee 2012. Lampotang, Sinclair	16, 19	

²² Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
Overall Outcome			1, 3, 4, 6, 10–12, 15–19, 21–24	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1, 3, 4, 6, 10–12, 15–19, and 21–24 of the '231 patent are unpatentable; and

FURTHER ORDERED because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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