

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.

IPR2020-00937
Patent 10,290,232 B2

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

COCKS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No 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, 6–16, and 20–26 (“the challenged claims”) of U.S. Patent No. 10,290,232 B2 (Ex. 1001, “the ’232 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, 6–13, 15, 16, 20, 21, 24–26	103	Lampotang, ² Mukherjee 2014, ³ Mukherjee 2012 ^{4,5}
4, 22, 23	103	Lampotang, Mukherjee 2014, Mukherjee 2012, Dawson ⁶

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

² US Patent Application Publication No. 2012/0280988 A1 published Nov. 8, 2012 (Ex. 1008, “Lampotang”).

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 US Patent Application Publication No. 2004/0234933 A1 published Nov. 25, 2004 (Ex. 1038, “Dawson”).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
14	103	Lampotang, Mukherjee 2014, Mukherjee 2012, Samosky ⁷

Paper 11 (“Dec. on Inst.”).

Truinject Corp. (“Patent Owner” or “Truinject”) timely filed a Patent Owner Response. Paper 14 (“PO Resp.”).⁸ Petitioner filed a Reply (Paper 18, “Pet. Reply”) to which Patent Owner filed a Sur-reply (Paper 20, “PO Sur-reply”).

Oral argument was conducted on August 18, 2021. A transcript of the oral argument appears in the record. Paper 27.⁹

For the reasons set forth below, we determine that Petitioner has not shown by a preponderance of the evidence that any of the challenged claims are unpatentable based on the grounds of unpatentability proposed by Petitioner as a part of this proceeding. *See* 35 U.S.C. § 316(e).

B. Related Matters

The parties contend that the ’232 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 5, 1. The parties also reference

⁷ US Patent Application Publication No. 2013/0323700 A1 published Dec. 5, 2013 (Ex. 1004, “Samosky”).

⁸ Patent Owner relies on the Declaration of Dr. Carla M. Pugh (Ex. 2005) in support of its Patent Owner Response.

⁹ A consolidated oral argument was held for both the present proceeding and related proceeding IPR2020-00935 (“the ’935 IPR”).

IPR2020-00042 involving U.S. Patent No. 9,792,836 (“the ’836 patent”) and the ’935 IPR involving U.S. Patent No. 10,290,231 (“the ’231 patent”).¹⁰ Pet. 2; Paper 5, 1. Petitioner states that the ’836 patent and the ’231 patent have been asserted in the Delaware Action. Pet. 2.

C. The ’232 Patent

The ’232 patent is titled “Automated Detection of Performance Characteristics in an Injection Training System.” Ex. 1001, code (54). The ’232 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 1:36–38. 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 1:39–58. The ’232 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 2:6–28. The ’232 patent postulates that there is a need for “effective, efficient, and extensible training injection systems, methods, and devices.” *Id.* at 2:59–62. The Abstract of the ’232 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

¹⁰ Institution of *inter partes* review was denied in IPR2020-00042 on April 14, 2020. *See* IPR2020-00042, Paper 7. A Final Written Decision in IPR2020-00935 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 '232 patent is reproduced below.

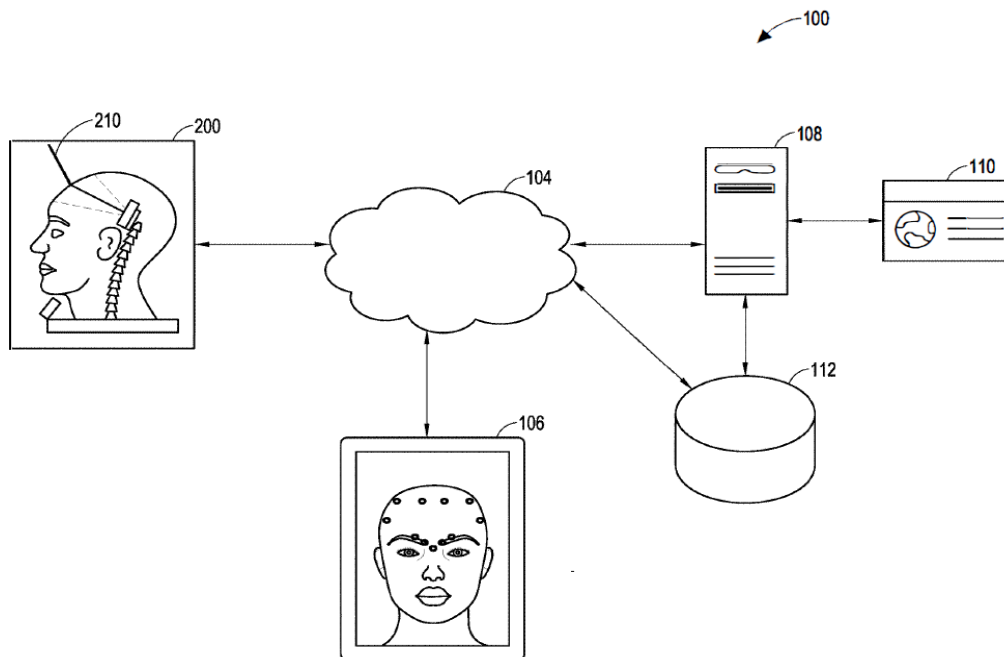


FIG. 1

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 Claim

Of the challenged claims, claims 1 and 20 are independent. Claim 1 is illustrative and is reproduced below:

1. [i] An injection training system configured for training of a facial injection technique, the system comprising:

[ii] a syringe having a syringe body and a plunger, the plunger configured to move relative to the syringe body, the syringe body comprising a proximal end and a distal end, the syringe further comprising a flange portion disposed at or near the proximal end, and a needle coupled to the distal end;

[iii] a training apparatus in the form of an anatomical model of a human head configured to receive a facial training injection performed by a user using the syringe, the training apparatus comprising a layer of synthetic or simulated tissue, the needle of the syringe configured to penetrate the layer of tissue;

[iv] a location sensing system including a first portion and a second portion, the first portion and the second portion working together to determine a position and orientation of the syringe needle, the first portion coupled to the syringe and configured to move with the syringe, the second portion being stationary relative to the training apparatus, wherein at least one of the first or second portion is at least configured to measure information corresponding to characteristics of a magnetic field; and

[v] a processing unit in electrical communication with the location sensing system, wherein the location sensing system is configured to determine and transmit to the processing unit information related to the position and orientation of the syringe needle,

[vi] the processing unit configured to calculate the position and orientation of the syringe needle relative to the training apparatus, the determined position and orientation including at least a depth and location of the injection associated with the layer of tissue of the training apparatus, and

[vii] the processing unit further configured to cause a display device to display feedback on how the user performed in the facial training injection, wherein the feedback comprises a three-dimensional graphical depiction of the training injection based at least in part on the calculated position and orientation of the syringe relative to the training apparatus,

[viii] wherein the three-dimensional graphical depiction comprises a digital model of the syringe and the digital model of the training apparatus, the digital model of the training apparatus comprising a plurality of different anatomical layers, [ix] the three-dimensional graphical depiction further comprising a simulated delivery of therapeutic agent to the digital model of the training apparatus and a dynamic position of the plunger in real-time.

Id. at 33:41–34:26 (with the Roman numerals i–ix added for ease of discussion (*see* Pet. 31–32)).

II. ANALYSIS

A. Claim Construction

In the Petition, Petitioner did not offer any particular construction for any claim term of the '232 patent, and stated that we do not need to expressly construe any claim term. *See* Pet. 18–19 (“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 20), and (2) “a simulated delivery of therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus” (claim 1). PO Resp. 17–21. In its Reply, Petitioner offers its own views on the meaning of the above-noted claim phrases. Pet. Reply 1–5. We address the noted claim phrases to the extent necessary.

1. “three-dimensional graphical depiction of the training injection” (claims 1 and 20)

At the outset, we note that the phrase “graphical depiction of the training injection” is at issue in the related ’935 IPR, and in both that proceeding and here, Patent Owner takes the view that such phrase excludes mathematical graphs.¹¹ In the ’935 IPR, the potential exclusion of mathematical graphs merited discussion as the question of whether Samosky’s mathematical graphs (Figures 14A and 14B) constituted “graphical depictions” was potentially material to the outcome of that proceeding. See IPR2020-00935, Paper 30, 8–11 (concluding that “graphical depiction” does not exclude mathematical graphs). Here,

¹¹ We note that the Specification in ’232 patent involved in this proceeding is substantively identical to the Specification of the ’231 patent involved in the ’935 IPR.

however, we do not discern that the outcome of this proceeding depends on whether or not a “graphical depiction” excludes mathematical graphs. Accordingly, we consider it unnecessary to further address the above-noted limitation as a part of this proceeding. *See 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))).

2. “a simulated delivery of the therapeutic agent to the digital three-dimensional model of the anatomically-shaped apparatus”
(claim 1)

Patent Owner represents the following:

As shown in the Joint Claim Construction Chart in the related district court litigation, Petitioner and Truinject have agreed that “a simulated delivery of therapeutic agent to the digital model of the training apparatus” in the ’232 Patent should be given its plain and ordinary meaning of “a simulated flow of therapeutic agent delivered from the digital model of the syringe to the digital model of the training apparatus.” Ex. 1011 at 7. Truinject respectfully asks that the Board apply the same construction.

PO Resp. 21.

Thus, Patent Owner proposes a construction of the above-noted phrase as “a simulated flow of therapeutic agent delivered from the digital model of the syringe to the digital model of the training apparatus.” Petitioner acknowledges that “the parties agreed to the construction of this term in the Delaware Action. No further construction of the term is required.” Pet. Reply 5.

In light of the parties’ mutually acknowledged agreement of the meaning of the noted-term, and given that we do not see reason on the

record before us to deviate from that meaning, we apply the same meaning of “a simulated flow of therapeutic agent delivered from the digital model of the syringe to the digital model of the training apparatus” to the noted claim phrase and consider no further construction to be necessary.

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 ’232 patent: (1) claims 1, 3, 6–13, 15, 16, 20, 21, and 24–26 as unpatentable over Lampotang, Mukherjee 2014, and Mukherjee 2012; (2) claims 4, 22, and 23 as unpatentable over Lampotang, Mukherjee 2014, Mukherjee 2012, and Dawson; and (3) claim 14 as unpatentable over Lampotang, Mukherjee 2014, Mukherjee 2012, and Samosky.

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 said 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).

2. Level of Ordinary Skill in the Art

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

The prior art discussed below and the declaration of Dr. Mukherjee (EX1002) demonstrate that a person of ordinary skill in the art (“POSITA”) as of the earliest claimed priority date of March 13, 2014[,] would have had at least a master’s degree in electrical engineering, robotics engineering, mechatronics, or a similar field. EX1002, ¶21. Alternatively, a POSITA may have had a lesser degree in one of those fields, but accompanied by 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.*, ¶22. 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. 17–18.

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 '232 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.

PO Resp. 16.

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.* 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) 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).

Lampotang also describes that its system is an “interactive combined physical and virtual (i.e., mixed) system,” and incorporates “a patient mannequin, a tool and/or instrument to interact with the patient mannequin, and a virtual model of internal anatomy that can be associated with the patient mannequin and instantiated on a display.” *Id.* ¶¶ 12, 15.

Lampotang’s Figure 2 is reproduced below:

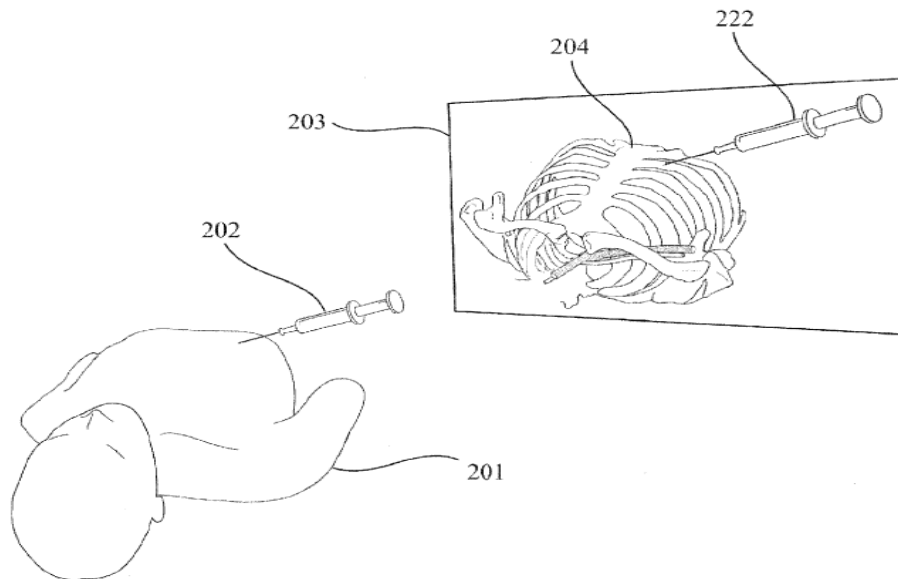


FIG. 2

Figure 2 above “shows a representation of an interactive mixed simulator system that can be used for the simulation of inserting a needle into a proper vessel.” *Id.* ¶ 78. The system includes “physical model 201,”

“instrument 202,” “display 203,” “virtual model 204,” and “virtual instrument 222.” *Id.*

Lampotang’s Figure 3 is reproduced below:

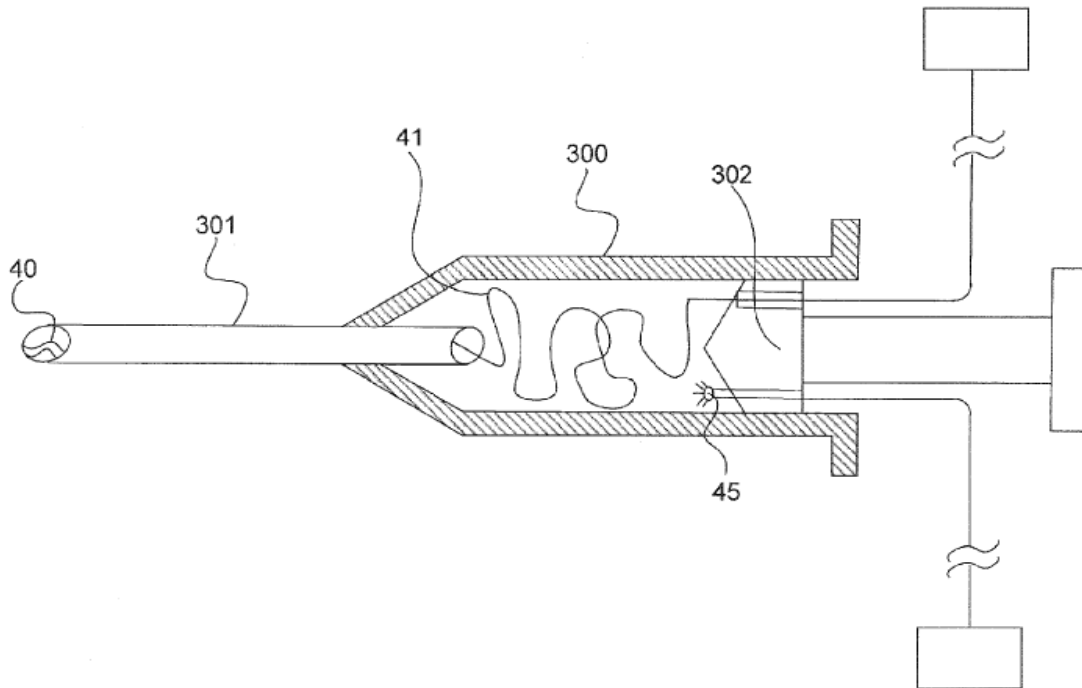


FIG. 3

Figure 3 above “shows a syringe instrument according to one embodiment of the invention.” Syringe 300 can include electromagnetic tracking sensor 40 at needle 301. *Id.* ¶ 91. One or more LEDs 45 that are, for example, red or blue can be included on the plunger. *Id.* Lampotang describes:

During conducting of a central venous access a user is usually pulling back on the plunger of a syringe. If the needle tip is in tissue, the plunger cannot be pulled back. If the needle tip is in the artery or vein, the plunger can be pulled back and red (oxygenated) or blue (de-oxygenated) blood is aspirated respectively. . . . The red or blue blood flashback can be simulated with red or blue LEDs that light up or by allowing red or blue colored water to enter the syringe.

Id. ¶ 89.

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:

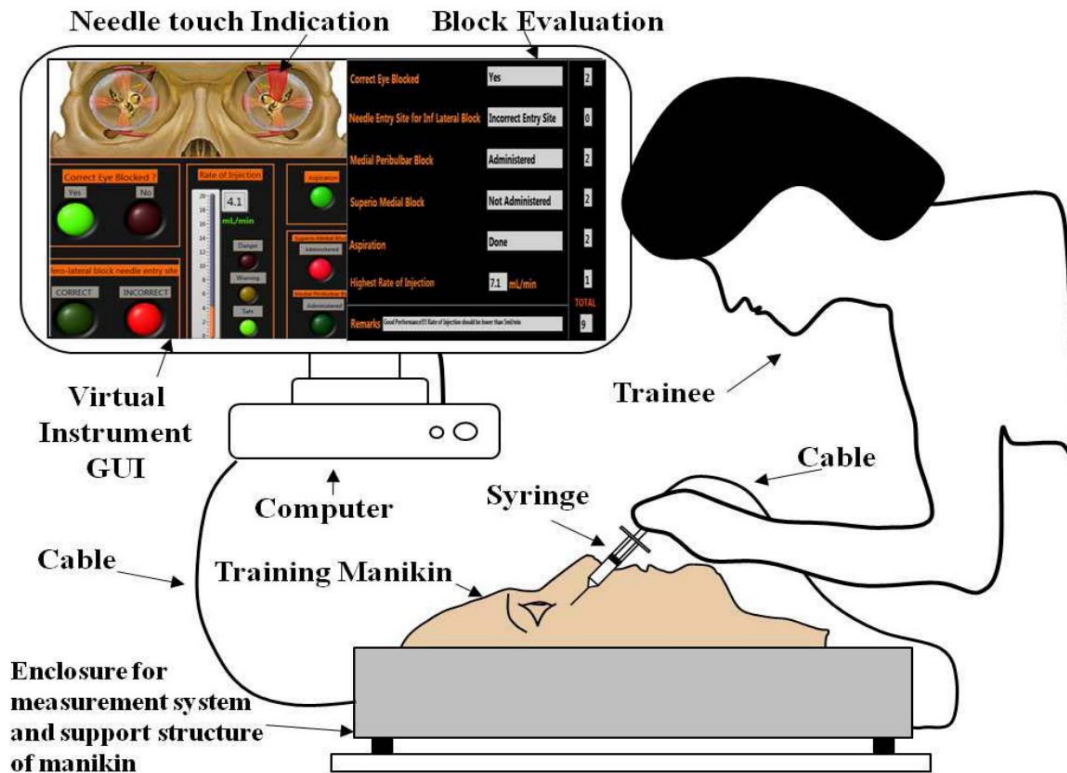


Figure 2 above is a “[c]onceptual diagram of the ophthalmic regional anesthesia training system showing the trainee with a modified syringe administering a block on the manikin.” *Id.* at 1. “A VI shows real-time

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:

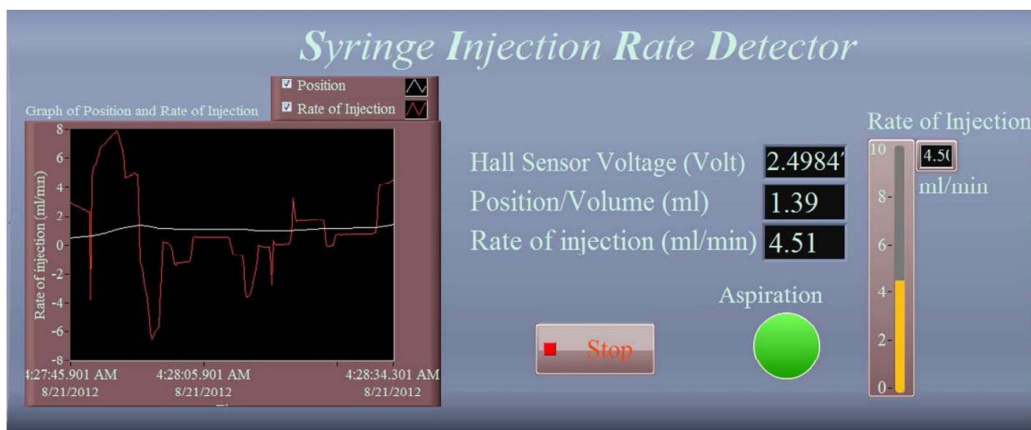


Figure 5 is described as showing a "LabVIEW based Virtual Instrument front panel showing the rate of injection, piston position and Aspiration indicators in real-time." *Id.* at 452.

d) Dawson

Dawson is titled "Medical Procedure Training System." Ex. 1038, code (54). Dawson's Abstract is reproduced below:

A medical procedure training system includes a mannequin having internal and external anatomical characteristics, such as body contour and organs, derived from medical imaging of an actual patient. The system can includes [sic] an instrument tracking system for monitoring the position of an instrument in relation to the mannequin anatomical components, which can be registered in relation to a reference point.

Id. at code (57).

e) 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 date, etc.) isomorphic to the physical model, etc.), mechatronics and spatial tracking.

Id. ¶ 31.

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

Petitioner contends that claims 1, 3, 6–13, 15, 16, 20, 21, and 24–26 of the ’232 patent are unpatentable based on the combined teachings of Lampotang, Mukherjee 2014, and Mukherjee 2012. *See* Pet. 33–65.

Petitioner also reasons that a person of ordinary skill in the art would have had adequate reason to combine the teachings of the above-noted references.

Id. at 28–31. 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 20. PO Resp. 23–33, 37–40; PO Sur-reply 5–9, 13–16. Patent Owner additionally contends that features required by claim 9 are also absent from the prior art. PO Resp. 45–47; PO Sur-reply 16–18. Patent Owner also disputes that a skilled artisan would have had reason to combine Lampotang and the Mukherjee articles. PO Resp. 33–37, 40–45; PO Sur-reply 9–13.

a) Claim 1

As to the proposed missing features of claim 1, Patent Owner focuses its arguments on the following features: “the three-dimensional graphical depiction further comprising a simulated delivery of therapeutic agent to the digital model of the training apparatus and a dynamic position of the plunger in real-time.”¹² PO Resp. 23. More specifically, Patent Owner contends that none of the cited references includes (1) “a simulated delivery of therapeutic agent to the digital model of the training apparatus” (PO Resp. 37–40; PO Sur-reply 13–16) (claim 1), or (2) “a dynamic position of the plunger in real time” (PO Resp. 25–33; PO Sur-reply 7–13) (claims 1 and 20).

(1) “a simulated delivery of therapeutic agent to the digital model of the training apparatus.”

We consider first whether the prior art that has been relied upon by Petitioner in this proceeding in urging the unpatentability of claim 1 discloses “a three-dimensional graphical depiction” that comprises “a simulated delivery of therapeutic agent to the digital model of the training

¹² These features are identified as a part of Roman numeral [ix] in this Decision.

apparatus.” As noted above the parties agree that the above-noted claim phrase means “a simulated flow of therapeutic agent delivered from the digital model of the syringe to the digital model of the training apparatus.” Thus, claim 1 requires a three-dimensional graphical depiction of a simulated flow of therapeutic agent from a digital model of a syringe to a digital model of a training apparatus.

For this limitation, Petitioner relies initially on the disclosure of Lampotang, and, specifically, its Figure 2 (reproduced *supra*) and paragraph 89. Pet. 48–49. Petitioner states the following:

As shown above, Fig. 2 of Lampotang illustrates a virtual syringe used for injection in relation to the virtual model and illustrates a simulated delivery of a therapeutic agent to a digital model of the training apparatus. For example, Lampotang indicates that the system of Fig. 2 can be used for simulated injection into a central venous line (CVL), in which application the tool comprises a syringe with a needle and plunger that simulates aspiration into an artery or vein. Lampotang, ¶89; *see* EX1002, ¶132.

Id.

Thus, it is clear that a central tenet of the Petition in accounting for the noted limitation pertaining to simulated delivery of therapeutic agent is the illustration of Lampotang’s Figure 2 coupled with disclosure at Lampotang’s paragraph 89, which is stated to describe simulated aspiration into an artery or vein.

Patent Owner challenges Petitioner’s above-noted reliance on Lampotang’s disclosure on several fronts. Patent Owner first disputes that Lampotang’s Figure 2 illustrates any display of a therapeutic agent, or any simulated delivery of therapeutic agent to a training apparatus. PO Resp. 38–39 (citing Ex. 1008 ¶ 78; Ex. 2021, 126:1–8). Patent Owner also

contends that Lampotang's paragraph 89 is limited to "describing physically simulating withdrawal of blood in a *physical syringe*." *Id.* at 39. In that respect, Patent Owner expresses that "Lampotang does not disclose a *digital model* of the syringe delivering a flow of therapeutic agent to a digital model of a training apparatus." *Id.*

We conclude that Patent Owner has identified inconsistencies in Petitioner's characterization of Lampotang's disclosure in the Petition as compared with Lampotang's actual disclosure. Although Lampotang's Figure 2 does appear to illustrate virtual syringe 222 associated with display 203, there is nothing in that figure or its associated description that conveys disclosure of a simulated depiction of a therapeutic agent, or simulated delivery of that agent. *See* Ex. 1008 ¶ 78. Rather, Lampotang simply characterizes Figure 2 as showing "a representation of an interactive mixed simulator system that can be used for the simulation of inserting a needle into a proper vessel." *Id.* We also are mindful of the deposition testimony of Petitioner's declarant, Dr. Mukherjee, in which he acknowledged that Lampotang's Figure 2 does not shown an illustration of therapeutic agent. *See* Ex. 1021, 136:1–8; PO Resp. 10. We further take note of the Declaration testimony of Patent Owner's declarant, Dr. Pugh, who testifies as follows:

Lampotang's disclosure with reference to Figure 2 focuses on the CVL technique, which involves withdrawing blood from a blood vessel rather than injecting medication into the patient's body. Ex. 1008 ¶¶ 89-90. The CVL technique is not concerned with visualizing a simulated flow of therapeutic agent delivered from a digital model of the syringe to the digital model of the training apparatus.

Ex. 2005 ¶ 102; *see* PO Resp. 41.

We credit Dr. Pugh’s testimony on this matter, as we find it consistent with Lampotang’s disclosure as to the content of its Figure 2 and Lampotang’s description of the CVL technique. *See, e.g.*, Ex. 1008 ¶¶ 78, 89–90.

In light of the record that has developed during trial, we conclude that Patent Owner correctly contends that Lampotang’s paragraph 89 describes aspects of a physical syringe that is operated by a user, rather than any three-dimensional digital depiction of a syringe. The discussion of “simulation” as a part of that paragraph pertains to simulation components such as red and blue light emitting diodes (LEDs) or red and blue colored water that are physically associated with an actual syringe and not a digital display of the syringe. *See* Ex. 1008 ¶ 89. Such a physical syringe is shown, for instance, at Lampotang’s Figure 3, in which syringe 300 that is operated by a user includes red and blue LEDs 45 for providing the noted “simulation.” *See id.* ¶ 91. It is not apparent that such “simulation” is directed to the delivery of therapeutic agent. Nevertheless, even if it is, Petitioner does not explain persuasively how providing for simulation features as a part of an actual, physical syringe, teaches or suggests providing a simulated flow of therapeutic agent from a digital model of a syringe that is part of a three-dimensional graphical depiction, as required by claim 1. Simply put, a physical syringe and a three-dimensional model of such a syringe are not the same.

Perhaps recognizing the apparent deficiency in the Petition’s reliance on Lampotang’s paragraph 89, Petitioner attempts to expand its proposed ground, and uses the Petitioner Reply to do so. To that end, Petitioner turns to specific disclosure of Samosky at paragraph 67 as providing an

evidentiary basis to conclude that depiction of a simulated delivery of a therapeutic agent “would have been obvious.” Pet. Reply 14.

A reply provides an opportunity for a party to respond to arguments made, for instance, in a patent owner response. 37 C.F.R. § 42.23(b). A reply, however, is not an appropriate vehicle to reconfigure a proposed ground based on new or additional evidence that is not reasonably tied to a ground advanced in the Petition, which is what Petitioner seeks to do here. The Petition does not set forth an adequate basis to conclude that Petitioner relied on Samosky’s teachings to account for features of claim 1 of the ’232 patent. As Patent Owner points out (PO Sur-reply 13–14), it is impermissible and untimely for Petitioner to now attempt to do so as a part of the Reply. *See, e.g., Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330–31 (Fed. Cir. 2019) (“[A]n [*inter partes* review] petitioner may not raise in reply ‘an entirely new rationale’ for why a claim would have been obvious.”) (citing *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1370 (Fed. Cir. 2016)).

In the Reply, Petitioner also seeks to rely on additional content of Lampotang stated to be part of Lampotang’s “background section” and appearing at paragraph 9 of that reference. Here, too, the Petition did not rely on content of Lampotang that the reference describes as constituting material that is “background” to Lampotang’s own disclosed invention. Petitioner additionally attempts to connect Lampotang’s background discussion of paragraph 9 with Lampotang’s paragraph 60. Pet. Reply 15–16. The referenced portion of paragraph 60 reads “[w]hen the needle nicks an artery or vein, the virtual representation can indicate a flashback of blood or warning to simulate the damage.” Ex. 1008 ¶ 60.

Petitioner, however, does not provide adequate or meaningful explanation as to why that disclosure amounts to the required three-dimensional graphical depiction of the simulated delivery of therapeutic agent from a digital model of the syringe to a digital model of the training apparatus as is required by claim 1.

We are cognizant that Petitioner also relies on the Mukherjee articles as a part of its discussion pertaining to the limitation of claim 1 that encompasses the “simulated delivery of therapeutic agent” feature. *See* Pet. 49–51. For instance, Petitioner points to Mukherjee 2014’s disclosure of “[a] Lab VIEW[22]-based VI with an intuitive GUI provides the trainee with real-time feedback on the proximity and touch of syringe needle to the [extraocular muscles (EOM)] and the rate of injection of anesthetic fluid.” Pet. 49 (quoting Ex. 1005, 2). Petitioner also points to Mukherjee 2012’s disclosure at Figure 5 of a “Virtual Instrument” display that shows a “piston position and Aspiration indicators in real-time.” *Id.* (quoting Ex. 1006, 452). Petitioner, however, does not explain adequately why those identified teachings in the Mukherjee articles themselves give rise to teachings of presenting a three-dimensional graphical depiction for a simulated delivery of a therapeutic agent from a digital model of a syringe to a digital model of a training apparatus. Rather, the principle basis of Petitioner’s reliance on the Mukherjee articles appears rooted in accounting for other aspects of claim 1, in particular, the dynamic display of a plunger in real-time. Petitioner also does not rely on the content of the Mukherjee articles to make-up for Petitioner’s inaccurate assessments of Lampotang’s disclosure, which are noted above.

Accordingly, in view of the record that is before us in this proceeding, we conclude that, as a part of its proposed ground in the Petition, Petitioner has not accounted adequately for the requirement in claim 1 directed to a “three-dimensional graphical depiction” that shows “a simulated delivery of therapeutic agent to the digital model of the training apparatus,” as that phrase is understood in the context of the ’232 patent.

(2) Remaining Limitations of Claim 1

Because we determine that the Petition does not account adequately for the above-discussed limitation required by claim 1, we conclude that it is unnecessary to further consider the Petition’s assessment of other features of claim 1, including the requirement of a three-dimensional depiction showing a “dynamic position of the plunger in real-time.” Whether or not those features have been shown to be present in the prior art does not remedy the deficiencies noted above when it comes to the requirements surrounding the “simulated delivery of therapeutic agent” feature of claim 1.

(3) Conclusion—Claim 1

Because Petitioner has not accounted adequately in this proceeding for all the features required by claim 1, we conclude that Petitioner has not shown by a preponderance of the evidence that claim 1 would have been unpatentable based on Lampotang, Mukherjee 2014, and Mukherjee 2012.

b) Claims 3, 6–12, 15, and 16

Each of claims 3, 6–12, 15, and 16 ultimately depends from independent claim 1, and thus each dependent claim requires all the features of that independent claim. We also conclude that Petitioner has not shown

by a preponderance of the evidence that claims 3, 6–12, 15, and 16 would have been unpatentable based on Lampotang, Mukherjee 2014, and Mukherjee 2012.

c) Claim 20

Similar to claim 1, independent claim 20 is drawn to “[a]n injection training system configured for training of a facial injection technique.” Ex. 1001, 35:29–30. Among other limitations, claim 20 requires a “three-dimensional graphical depiction” comprising a digital model of a syringe with “the digital model of the syringe comprising a digital model of the plunger moving in real-time relative to the digital model of the syringe needle based on the dynamic position of the plunger relative to the syringe needle during the facial training injection.” *Id.* at 36:16–21. Patent Owner argues that those features are not accounted for in Petitioner’s proposed ground of unpatentability for claim 20. *See* PO Resp. 25–37; PO Sur-reply 7–13.¹³

The Petition sets forth only the following in accounting for the above-noted requirement of claim 20: “*See* Sections IX.A.1 and IX.A.2.ix. *See* EX1002, ¶ 170.” Pet. 64. Section “IX.A.1” is a portion of the Petition that spans pages 19 to 31 and constitutes Petitioner’s summary of the disclosures of Lampotang and the Mukherjee articles as well as arguments that it would have been obvious to combine those disclosures. *Id.* at 19–31. That section provides only generalized discussion of each reference as a whole and does

¹³ In the noted sections of the Patent Owner Response and the Sur-reply, Patent Owner also submits arguments tied to features required by claim 1. Here, however, we focus on features required by claim 20.

not provide specific or directed discussion reasonably viewed as being focused on the above-noted feature of claim 20.

Section “IX.A.2.ix” is a portion of the Petition spanning pages 48 to 51 and addresses element “[ix]” of claim 1. As discussed above, that element reads “the three-dimensional graphical depiction further comprising a simulated delivery of therapeutic agent to the digital model of the training apparatus and a dynamic position of the plunger in real-time.” *Id.* at 48. As claim 20 does not require features pertaining to a simulated delivery of therapeutic agent, it is clear that, in referencing section “IX.A.2.ix,” Petitioner is drawing attention to the discussion in that section as to requirements in claim 1 of a three-dimensional graphical depiction that comprises “a dynamic position of the plunger in real time.” *Id.* at 50–51.

The referenced paragraph 170 of Dr. Mukherjee’s testimony recites simply that, with respect to the pertinent of claim 20, “[t]hese features would have been obvious, as I discussed regarding claim 1.” Ex. 1002 ¶ 170.

At the outset, we note that claim 1 and claim 20 include different phrasing as to the particular, noted feature in each claim. In that regard, where claim 1 only generally recites that its three-dimensional graphical depiction comprises “a dynamic position of the plunger in real-time” (Ex. 1001, 34:25–26), claim 20 is decidedly more detailed in reciting that its three-dimensional graphical depiction comprises “a digital model of the plunger moving in real-time relative to the digital model of the syringe needle based on the dynamic position of the plunger relative to the syringe needle during the facial training injection” (*id.* at 36:16–21). Although the Petition evidently equates the pertinent requirement of each of those claims, the Petition provides no explanation as to why, despite the clear differences

in the language of the claims, there is, nevertheless, no distinction in the scope of the claims.

In our view, the different expressions in claim 1 and claim 20 as to the three-dimensional depiction of plunger position gives rise to different requirements as between those two claims. It is clear that claim 20 is explicit in its requirement of a three-dimensional graphical depiction that shows movement of a digital model of the plunger in real-time relative to a syringe needle of a digital model of a syringe, and also further specifies that such movement is based on the dynamic position of the plunger relative to the syringe needle. Those are not requirements in claim 1. Patent Owner contends that “[n]owhere does Lampotang disclose a three-dimensional graphical depiction of a dynamic position of the plunger in real-time or a digital model of the plunger moving in real-time.” PO Resp. 25–26. In response, Petitioner expresses that “[i]t is undisputed that Lampotang’s system provides for a three-dimensional graphical depiction of the entire syringe, including the plunger, and the syringe needle as shown, for example in Figure 2.” Pet. Reply 6 (citing Ex. 1008 ¶ 12; Ex. 1002 ¶ 128).

Petitioner’s representation that the noted matter is “undisputed” is, in our view, not entirely accurate. We discern that disclosure of Lampotang as to aspects of a digital plunger is clearly in dispute, as is apparent from Patent Owner’s Response as well as its Sur-reply. *See, e.g.*, PO Resp. 25–26; PO Sur-reply 7–8. Lampotang’s Figure 2 does illustrate a digital model of a syringe, however, neither that figure nor its description shows or describes a plunger or associates motion of a digital model of a plunger relative to a digital model of a syringe and syringe needle. In support of its position of unpatentability, Petitioner now cites to Lampotang’s paragraph 12 in its

Petitioner Reply. Pet. Reply 6. That paragraph is part of a brief summary of Lampotang's invention and only generally describes that a "3D virtual model is registered invisibly and/or internally to a physical model," and that a user may interact with the physical model using "a physical tool or implement that may be tracked in a 3D space." Ex. 1008 ¶ 12. There is no discussion in paragraph 12 of a three-dimensional depiction of a model of a syringe and syringe plunger in which the syringe plunger is shown moving relative to a syringe needle. The testimony of Dr. Mukherjee at paragraph 128 of his declaration (Ex. 1002) that Petitioner references in its Reply (Pet. Reply 6) only describes Lampotang's Figure 2. As noted above, however, that figure also does not describe or show real-time motion of a digital model of a plunger with respect to a digital model of a syringe and syringe needle.

Petitioner additionally relies on the Mukherjee articles as a part of its Petition addressing the pertinent feature of claim 1. *See* Pet. 49–51. It is apparent that at least Mukherjee 2012 describes that a virtual display may show the position of a syringe piston, i.e., a plunger, in real-time. In particular, Mukherjee 2012's Figure 5 shows a two-dimensional virtual display in which plunger position is shown in real-time in connection with a graph of the position (left side of Figure 5) as well as numerical values indicative of that position (right side of Figure 5). *See* Ex. 1006, 452. We do not discern, however, any disclosure in the Mukherjee articles, and Petitioner points to none, which establishes an association of that plunger position with a three-dimensional depiction in which the real-time movement of a digital model of a plunger is specifically depicted relative to a digital model of a syringe and a syringe needle.

As discussed above, claim 20 requires “a three-dimensional graphical depiction” showing “a digital model of the plunger moving in real-time relative to the digital model of the syringe needle based on the dynamic position of the plunger relative to the syringe needle during the facial training injection.” The Petition is silent as to those particular requirements. The Petition’s silence on those requirements is a substantial impediment to Petitioner’s view that claim 20 is unpatentable based on the teachings of Lampotang, Mukherjee 2014, and Mukherjee 2012.¹⁴ The burden is on Petitioner to demonstrate unpatentability. *See Dynamic Drinkware*, 800 F.3d at 1378. In light of the record that is now before us, we conclude that Petitioner has not accounted adequately in its Petition for all of the features required by claim 20, and thus has not met its burden. Accordingly, we conclude that, on the record of this proceeding, Petitioner has not shown by a preponderance of the evidence that claim 20 would have been unpatentable over Lampotang, Mukherjee 2014, and Mukherjee 2012.

¹⁴ It is apparent from Patent Owner’s briefing that Patent Owner is of the view that the features in each of claim 1 and 20 pertaining to the movement of the plunger in real time are not satisfied by the combined teachings Lampotang, Mukherjee 2014, and Mukherjee 2012. *See, e.g.*, PO Resp. 25–33; PO Sur-reply 7–13. As noted above, claims 1 and 20 include different recitations pertaining to that feature. Because, as discussed above, we conclude that Petitioner has not accounted adequately for other limitations required by claim 1, we find it unnecessary to also assess claim 1’s more general recitation of simply depiction of “a dynamic position of the plunger in real-time” in connection with either that recitation’s scope or its presence in the prior art.

d) Claims 21 and 24–26

Claims 21 and 24–26 depend from claim 20. Claims 21 and 24–26, thus, include all the limitations required by claim 20. As discussed above, Petitioner has not accounted adequately for all the features required by claim 20. Accordingly, we conclude that Petitioner has not shown that claims 21 and 24–26 are unpatentable based on Lampotang, Mukherjee 2014, and Mukherjee 2012.

5. Other Grounds

Petitioner also challenges the patentability of (1) claim 4, 22, and 23 based on Lampotang, Mukherjee 2014, Mukherjee 2012, and Dawson, and (2) claim 14 based on Lampotang, Mukherjee 2014, Mukherjee 2012, and Samosky. Pet. 65–68.

a) Claims 4, 22, and 23

Claim 4 depends from claim 1. Claim 22 depends from claim 20. Claim 23 depends from claim 22. As noted above, Petitioner contends that claims 4, 22, and 23 are unpatentable over Lampotang, Mukherjee 2014, Mukherjee 2012, and Dawson. Petitioner does not rely on Dawson to overcome any of the deficiencies that we have noted when it comes to claims 1 and 20. Accordingly, we also conclude that Petitioner has not shown by a preponderance of the evidence that claims 4, 22, and 23 are unpatentable over Lampotang, Mukherjee 2014, Mukherjee 2012, and Dawson.

b) Claim 14

Claim 14 depends from claim 1. Petitioner contends that claim 14 is unpatentable over Lampotang, Mukherjee 2014, Mukherjee 2012, and Samosky. Thus, the ground applied to claim 14 includes application of some teachings of Samosky.¹⁵ Pet. 67–68. We, however, do not discern that, with respect to claim 14, the Petition addresses the shortcomings that we identify above when it comes to claim 1, namely, the shortcomings in connection with the requirement of “a three-dimensional graphical depiction” that comprises “a simulated delivery of therapeutic agent to the digital model of the training apparatus.” Accordingly, we conclude that on the record of this proceeding, Petitioner has not met its burden to show by a preponderance of the evidence that claim 14 is unpatentable.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not met its burden to show by a preponderance of the evidence that claims 1, 3, 4, 6–16, and 20–26 are unpatentable based on the grounds that were presented in the Petition.

In summary,

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 3, 6–16, 21, 24–26	103	Lampotang, Mukherjee 2014, Mukherjee 2012		1, 3, 6–16, 21, 24–26

¹⁵ Samosky is the reference that Petitioner, in its Reply, belatedly seeks to incorporate into its ground of unpatentability applied to claim 1.

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
4, 22, 23	103	Lampotang, Mukherjee 2014, Mukherjee 2012, Dawson		4, 22, 23
14	103	Lampotang, Mukherjee 2014, Mukherjee 2012, Samosky		14
Overall Outcome				1, 3, 4, 6–16, 20–26

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not shown by a preponderance of the evidence that claims 1, 3, 4, 6–16, and 20–26 of the '232 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.

IPR2020-00937
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