

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.

IPR2020-00042
Patent 9,792,836 B2

Before JOSIAH C. COCKS, PATRICK R. SCANLON, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

SCANLON, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

SHDS, Inc. and Galderma Laboratories, L.P. (collectively “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–22 of U.S. Patent No. 9,792,836 B2 (Ex. 1001, “the ’836 patent”). TRUINJECT Corp. (“Patent Owner”) did not file a Preliminary Response.

We have authority under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). To institute an *inter partes* review, we must determine that the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons set forth below, we determine that the information presented in the Petition does not establish a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim. Accordingly, we do not institute an *inter partes* review of the ’836 patent.

II. BACKGROUND

A. Related Matters

The parties identify the following related matter: *Truinject Corp. v. Nestle Skin Health, S.A.*, Case No. 1:19-cv-00592-LPS-JLH (D. Del.). Pet. 2; Paper 5, 1. According to Petitioner, this action has been transferred to the Central District of California, *Truinject Corp. v. Nestle Skin Health, S.A.*, Case No. 8-18-cv-01851 (C.D. Cal.). Pet. 2–3. Petitioner notes that a pending patent application, U.S. Patent Application No. 15/700,648, “is a continuation of the ’836 patent.” *Id.* at 3.

B. Real Parties-in-Interest

Petitioner identifies SHDS, Inc. (formerly Nestlé Skin Health, Inc.), Galderma Laboratories, L.P., Nestlé Skin Health, S.A., and Galderma S.A. as the real parties in interest. Pet. 2. Petitioner notes that on October 2, 2019, “Nestlé S.A. sold Galderma S.A., Galderma Laboratories L.P., Nestlé Skin Health, Inc. (now SHDS, Inc.), and Nestlé Skin Health S.A. to an investment consortium of: EQT Partners, AB; PSP Investments; and Luxinva, a wholly owned subsidiary of Abu Dhabi Investment Authority.” *Id.* Patent Owner identifies itself, TRUINJECT Corp., as the real party in interest. Paper 5, 1.

C. The '836 patent

The '836 patent, titled “Injection Training Apparatus Using 3D Position Sensor,” issued on October 17, 2017, with claims 1–22. Ex. 1001, code (54), code (45), 36:51–38:35. The '836 patent relates to systems and methods for practicing injection techniques through an injectable apparatus. *Id.* at code (57). Figure 1, reproduced below, illustrates injection apparatus 100 used for injection training.

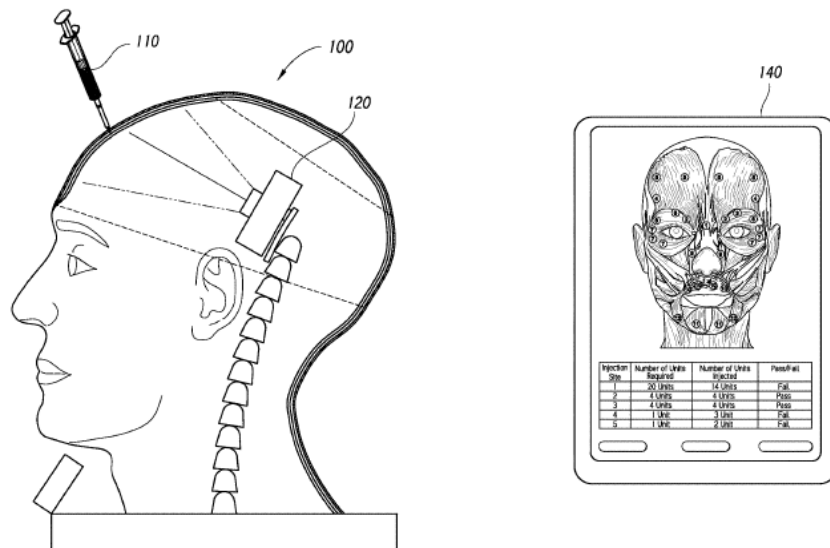


FIG. 1

Figure 1 depicts injection apparatus 100, which may consist of a simulated skull with layers of muscle and skin. *Id.* at 11:60–12:7. Testing tool 110, which may simulate injection equipment such as a needle, catheter, or cannula, is used with injection apparatus 100 and camera 120 located within injection apparatus 100. *Id.* at 12:8–13. Testing tool 110 includes a light source to aid in obtaining visual indications detectable by camera 120. *Id.* at 12:18–21. As testing tool 110 is injected through the outer layers of injection apparatus 100, the “resulting light detected by camera 120 can be used to determine the location of the injection, the pressure exerted by the user, the angle of injection, or the depth of the injection.” *Id.* at 12:34–39. This information can be communicated from camera 120 to user interface device 140 for testing and certification purposes. *Id.* at 12:39–41.

Injection apparatus 100 includes a surrounding layer divided into three separate simulated human skin and muscle layers 410, 420, 430. *Id.* at 15:56–59, Fig. 4A. For instance, first layer 410 may represent the epidermis as opaque, second layer 420 may represent the dermis as tinted, and third layer 430 may represent the muscle as clear. *Id.* at 15:66–16:3. Base layer 400, which can be a clear plastic shell, holds the components of the injectable muscle and skin layer in place. *Id.* at 18:39–41, 18:57–58, Fig. 4A.

Figure 29 of the '836 patent is reproduced below.

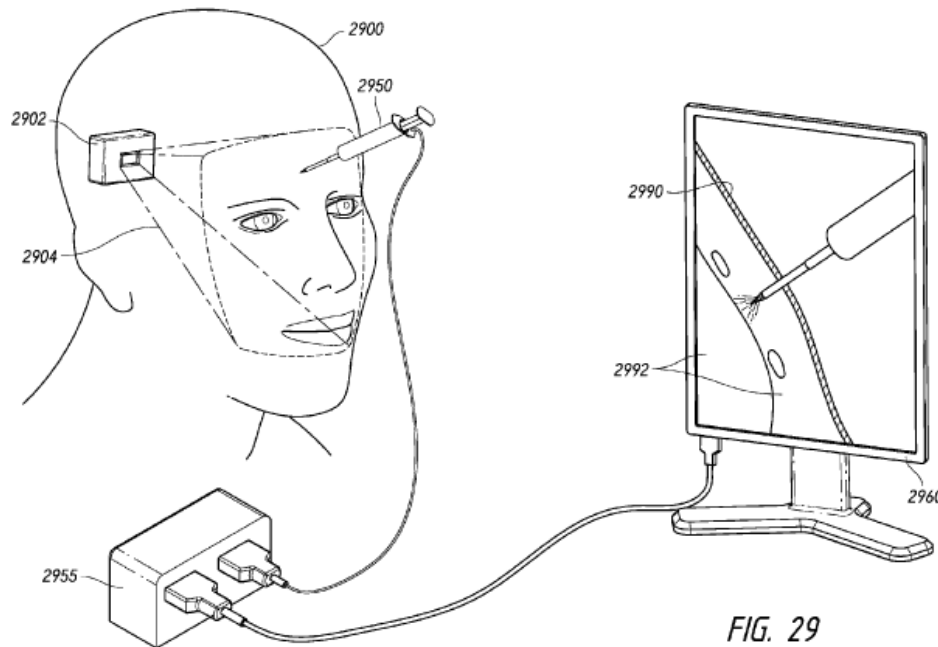


Figure 29 shows an alternative injection apparatus 2900. *Id.* at 30:20–23. Injection apparatus 2900 is hollow and has three-dimensional (3D) sensor 2902 positioned inside. *Id.* at 30:34–35. Testing tool 2950 and 3D sensor 2902 are coupled with signal processing and display interface 2955. *Id.* at 30:48–50. When the needle tip of testing tool 2950 passes through the opaque outer skin of injection apparatus 2900, 3D sensor 2904 is configured to detect the light from the needle tip and determine an X-Y-Z position of the needle tip, and this position information is transmitted to signal processing and display interface 2955. *Id.* at 30:54–61. Interface 2955 communicates with display device 2960, which presents a visual representation of the needle tip position vis-à-vis the injection site so that the trainee may gauge the actual needle position with respect to the ideal position. *Id.* at 30:64–31:3.

D. Challenged Claims

Of the challenged claims, claims 1 and 18 are independent. These independent claims are illustrative of the claimed subject matter and are reproduced below:

1. An anatomically shaped injection training apparatus comprising:

an at least partially hollow base configured to provide structural support;

a clear layer of elastomer coating at least partially covering a base layer;

an opaque layer at least partially covering the clear layer, wherein the base, clear layer, and opaque layer form an anatomical shape; and

a three-dimensional (3D) tracking system positioned inside the base and configured to determine a location of a needle inserted into the clear layer of elastomer.

Ex. 1001, 36:51–62.

18. A method of manufacturing an anatomically shaped injection training apparatus, the method comprising:

forming an at least partially hollow based configured to provide structural support for a target injection test area;

coating at least a portion of the base with a clear layer of elastomer;

coating at least a portion of the clear layer with an opaque layer, wherein the base, clear layer, and opaque layer form an anatomical shape; and

affixing a three-dimensional (3D) tracking system within a hollowed portion of the base, wherein the three-dimensional tracking system provides a field of view of the clear layer covering the target injection test area.

Id. at 38:4–17.

E. Evidence

Petitioner relies on the following prior art references in the asserted grounds of unpatentability:

Reference	Exhibit No.
U.S. Patent No. US 6,485,308 B1, issued November 26, 2002 (“Goldstein”)	Ex. 1004
U.S. Patent Application Publication No. US 2005/0084833 A1, published April 21, 2005 (“Lacey”)	Ex. 1006
U.S. Patent Application Publication No. US 2012/0280988 A1, published November 8, 2012 (“Lampotang”)	Ex. 1009
U.S. Patent No. US 9,017,080 B1, issued April 28, 2015 (“Placik”)	Ex. 1010
Wierinck et al., <i>Expert Performance on a Virtual Reality Simulation System</i> , Journal of Dental Education, vol. 71, no. 6, 759–66 (June 2007) (“Wierinck”)	Ex. 1031

Petitioner also relies on the Declaration of Biswarup Mukherjee, Ph.D. (Ex. 1002).

F. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 3–6, 9–11, 16–20	103	Goldstein, Lacey
2, 7, 8, 21	103	Goldstein, Lacey, Wierinck
12–15	103	Goldstein, Lacey, Lampotang
22	103	Goldstein, Lacey, Placik

Pet. 7.

III. ANALYSIS

A. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of

ordinary skill in the pertinent art at the time of the invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.*

Relying on the testimony of Dr. Mukherjee, Petitioner submits that a person of ordinary skill in the art would have had at least a bachelor's degree in electrical engineering, robotics engineering, mechatronics, or a similar field, or, alternatively, may have had a lesser degree in one of those fields accompanied by practical experience in designing medical training or similar systems. Pet. 17–18 (citing Ex. 1002 ¶ 27). Petitioner further submits that a person of ordinary skill in the art 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.* at 18 (citing Ex. 1002 ¶ 27). In addition, Petitioner submits that a person of ordinary skill in the art would have experience in designing and producing realistic anatomical models or lifelike mannequins and would have a strong working knowledge of mannequin design, computer-aided design and manufacturing (CAD and CAM), materials selection, human anatomy, and related special effects, and may have collaborated with others of skill in the art, such that the individual or the

team collectively would have had experience and/or knowledge of medical simulators. *Id.* (citing Ex. 1002 ¶ 28).

Patent Owner does not dispute this contention at this stage of the proceeding, nor does Patent Owner offer its own definition of the level of ordinary skill in the art.

We find, based on our review of the record before us, that Petitioner’s stated level of ordinary skill in the art is reasonable because it is consistent with the evidence at this stage of the proceeding, including the asserted prior art and, for the purposes of this Decision only, we adopt Petitioner’s definition.

B. Claim Construction

“In an *inter partes* review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019).¹ That standard “includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Petitioner proposes constructions for the claim terms “injection” and “3D tracking system.” Pet. 19–22. In view of our analysis below, however, we do not discern a need to expressly construe any claim phrase or term for purposes of this Decision. *See, e.g., Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (holding claim terms need only be construed “to the extent necessary to resolve the

¹ The Petition was filed October 11, 2019. *See* Paper 3, 1.

controversy”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

C. Asserted Obviousness Based on Goldstein and Lacey

Petitioner contends claims 1, 3–6, 9–11, and 16–20 are obvious over Goldstein and Lacey. Pet. 22–38.

1. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness 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 ordinary skill in the art; and (4) when in evidence, objective indicia (also called secondary considerations) of non-obviousness, such as commercial success, long-felt but unsolved needs, and failure of others. *Graham*, 383 U.S. at 17–18. We analyze this ground based on obviousness in accordance with the above-stated principles.²

2. Overview of Goldstein

Goldstein “pertains to models and devices used to train manual needle biopsy procedures,” particularly models of the human female breast. Ex.

² We address the level of ordinary skill in the art in Section III.A., *supra*. The record does not include any evidence of objective indicia of non-obviousness at this point in the proceeding.

1004, 1:5–9. According to Goldstein, manual breast examination has been an effective method of early breast cancer detection. *Id.* at 1:13–15. Fine needle biopsy often is used to investigate breast tissue abnormalities revealed by self-examination or other methods. *Id.* at 1:22–27. Goldstein states that “[p]roper biopsy needling training requires that a trainee gain the ability to distinguish and locate specific target lesions by tactile means alone and the ability to guide a biopsy needle through breast tissue to penetrate these target tissues.” *Id.* at 3:31–35.

As a training aid for teaching fine needle biopsy of the human breast, Goldstein “provides breast models having lifelike properties providing accurate tactile sensation during palpation of the breast that enable a trainee to learn to locate internal lesions and similar anomalous tissues in the breast” and “allow trainee learning of tactile sensations that indicate relative position and motion of biopsy needles during biopsy needling procedures.” *Id.* at 2:24–32. Goldstein discloses a “blinded” model that includes an opaque skin that blocks the trainee’s view of a target lesion, while allowing viewing by a second party such as an instructor. *Id.* at 2:32–44. With this model, “a trainee may practice needling based solely on simulated tactile information while an instructor observes internal events, enabling real-time comment and instruction.” *Id.* at 2:44–47. Goldstein also discloses an alternative model that is sufficiently transparent to allow viewing of modeled lesions from any position, thereby providing “error-free” training in which a trainee learns proper tactile indicators of accurate needling techniques. *Id.* at 2:58–64.

Figure 1 of Goldstein is reproduced below.

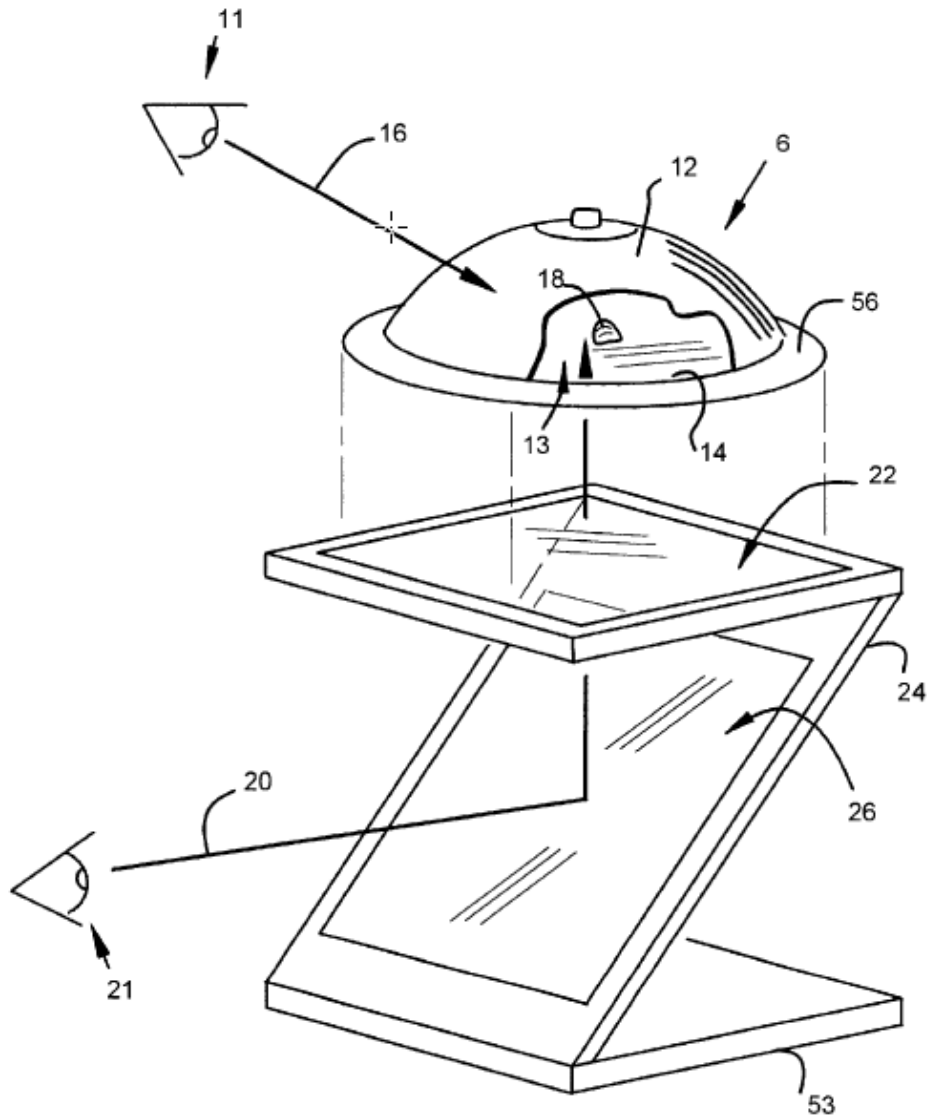


Fig. 1

Figure 1 shows blinded breast model 6, partially cut-away to reveal internal elements. *Id.* at 4:23–26. Model 6 has opaque outer skin 12, cavity 13, and transparent backing 14. *Id.* at 4:26–27. Viewing path 16 from a trainee positioned at first location 11 to needling target 18 in cavity 13 is blocked by

opaque outer skin 12. *Id.* at 4:28–31. Cavity 13 is filled with a transparent simulated adipose tissue medium (not depicted in Figure 1). *Id.* at 7:13–16.

Training stand 24 supports model 6 and includes transparent surface 22 and reflective surface 24, which is oriented to reflect an internal image of cavity 13 to second location 21. *Id.* at 4:32–36. Thus, “[a]n instructor . . . positioned at the second location 21 is able to view the internal cavity of the breast model, as well as any events therein, while the trainee’s view is obscured.” *Id.* at 4:48–51.

Figure 2 shows blinded breast model 6 supported by an alternative stand that uses video-capable camera 40 instead of a reflective surface. *Id.* at 4:60–64. Camera 40 is connected to monitor 42, which displays image 44 produced by the camera. *Id.* at 4:64–66. This arrangement allows the image to be transmitted to a remote location where several people may observe the training events. *Id.* at 4:66–5:3.

Figures 3 and 4 depict transparent model 8 that provides for “error-free” training in which a trainee is allowed to practice in a non-blinded mode before proceeding to the blinded mode. *Id.* at 5:50–55. Transparent model 8 includes transparent outer skin 32, but is otherwise constructed in the same fashion as blinded model 6. *Id.* at 5:56–59, 6:44–46. Figures 3 and 4 also show transparent simulated adipose tissue medium 54 filling cavity 13, which is not depicted in Figures 1 and 2. *Id.* at 7:13–16.

3. *Overview of Lacey*

Lacey relates to a simulator for laparoscopic surgical training. Ex. 1006 ¶¶ 1, 4. Figure 1 of Lacey is reproduced below.

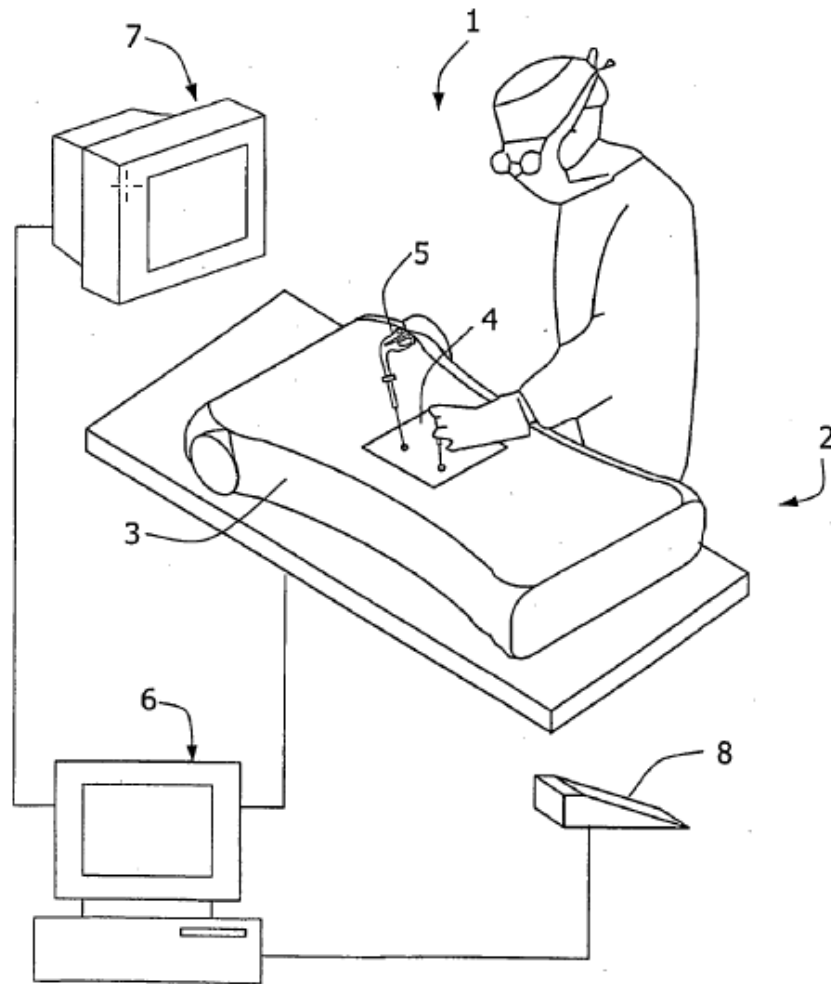


Fig.1

Figure 1 is a perspective view of a surgical training simulator in use. *Id.*

¶ 36. In particular, surgical training simulator 1 includes body form apparatus 2 having torso body form 3 and panel 4 of a flexible material that simulates skin. *Id.* ¶ 41. Body form apparatus 2 is connected to computer 6, which is connected in turn to output display monitor 7. *Id.*

Body form apparatus 2 contains three cameras 10 located to capture images of surgical instruments 5 extending through panel 4. *Id.* ¶¶ 42, 44, Figs. 2–3. Computer 6 uses stereo triangulation techniques with calibration of the internal space of body form 3 to track location of each instrument 5 in

three dimensions. *Id.* ¶ 44. Specifically, cameras 10 feed video into motion analysis engine 35 and processor 40. *Id.* ¶ 48, Fig. 5. Motion analysis engine 35 generates 3D position data for each instrument using stereo triangulation. *Id.* ¶ 48. Processor 40 may receive training images and/or graphical templates (in addition to the video from cameras 10), and outputs displays of actual video, positional metrics, graphical simulations, or combinations thereof. *Id.* ¶ 49.

4. *Independent Claim 1*

Petitioner provides analysis purporting to show where each limitation recited in independent claim 1 is disclosed by Goldstein or would have been obvious in view of Goldstein combined with Lacey. Pet. 25–29. Petitioner asserts that Goldstein discloses an at least partially hollow base in that blinded breast model 6 is supported on transparent restraining surface 22 of stand 24, where stand 24 and its base 53 form a partially hollow base. *Id.* at 26 (citing Ex. 1004, 4:63–64, 5:29–31, Fig. 2). Petitioner also asserts that transparent backing 14 of model 6 corresponds to the claimed base layer, and adipose tissue medium 54 filling cavity 13 corresponds to the claimed clear layer of elastomer. *Id.* (citing Ex. 1004, 4:26–27, 5:10–14, 5:57, 7:13–16, Figs. 1–4). In addition, Petitioner asserts that opaque outer skin 12 of model 6 corresponds to the claimed opaque layer. *Id.* at 26–27 (citing Ex. 1004, 4:26–27, 7:13–15).

Regarding the claim 1 recitation that “the base, clear layer, and opaque layer form an anatomical shape,” Petitioner argues that “Goldstein’s ‘clear layer’ (transparent simulated adipose tissue medium 54) and ‘opaque layer’ (‘an opaque outer skin 12’) ‘form an anatomical shape’, i.e., the shape of a female breast.” *Id.* at 27. Petitioner acknowledges, however, that

Goldstein does not describe explicitly a base that forms part of the anatomical shape. *Id.* at 28. Thus, Petitioner argues that one of ordinary skill in the art

would have been motivated to modify Goldstein's system to incorporate a larger body torso form (mannequin) as taught by Lacey as a support for the breast model 6 in order to construct an anatomically-shaped training apparatus that provide[s] a more realistic simulation (of a human and human tissues) for training. *Id.* at 28–29 (citing Ex. 1002 ¶¶ 71–75).

We are not persuaded that Petitioner has demonstrated sufficiently that one of ordinary skill in the art would have been led to modify Goldstein's blinded breast model 6 by combining it with the larger torso body form of Lacey. First, neither the Petition nor Dr. Mukherjee adequately explains why the proposed modification would provide a simulation of human tissues for training that is more realistic than Goldstein's training apparatus. Dr. Mukherjee's testimony merely repeats the Petition's assertion and does not offer objective evidence or analysis to support the assertion. *See* Ex. 1002 ¶ 75. For this reason, we do not credit the testimony of Dr. Mukherjee on this point. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."); *see also Nobel Biocare Services AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1382 (Fed. Cir. 2018) (explaining that the Board can reject arguments based on expert testimony that lacks specificity or detail).

Second, we do not agree that one of ordinary skill in the art would have considered combining Goldstein's model with a torso body form useful or desirable given the nature of Goldstein's training process. That is, Goldstein's training technique relies on the trainee palpating the breast

model to locate the target lesion and to guide the aspiration needle to the target. Ex. 1004, 3:53–59. Thus, “[t]he lifelike characteristics *of the breast model* provide tactile training of these events and allow the trainee to accumulate sensory knowledge of successful technique.” *Id.* at 3:60–62 (emphasis added). Petitioner fails to explain adequately why including a human torso form would have made palpating the breast model more realistic or otherwise enhanced this technique in any way.

Furthermore, Goldstein states that a benefit of the disclosed breast models is “their small size and simplicity which encourage their availability and use.” *Id.* at 5:13–15. Petitioner’s proposed modification, however, would result in a larger, more expensive training apparatus that would defeat Goldstein’s stated benefit. As such, we are not persuaded that one of ordinary skill in the art would have been led to modify Goldstein’s training apparatus in the manner proposed by Petitioner.

For the reasons discussed above, we find that Petitioner has not met its burden to show a reasonable likelihood that claim 1 is unpatentable over the combination of Goldstein and Lacey.

5. *Independent Claim 18*

Petitioner contends that independent claim 18 would have been obvious to one of ordinary skill in the art over the combination of Goldstein and Lacey for substantially the same reasons set forth in connection with claim 1. Pet. 36–37 (citing Ex. 1002 ¶¶ 94–97).

Thus, Petitioner’s challenge to claim 18 is based on the same deficient assertions as to the rationale for combining Goldstein and Lacey as discussed above in the analysis of the challenge to independent claim 1. For these same reasons, we find that Petitioner has not met its burden to show a

reasonable likelihood that claim 18 is unpatentable over the combination of Goldstein and Lacey.

6. *Dependent Claims 3–6, 9–11, 16, 17, 19, and 20*

Claims 3–6, 9–11, 16, and 17 depend from claim 1 and, thus, contain all the limitations of claim 1. Claims 19 and 20 depend from claim 18 and, thus, contain all the limitations of claim 18. Petitioner’s challenges to dependent claims 3–6, 9–11, 16, 17, 19, and 20 do not overcome the deficient assertions as to the rationale for combining Goldstein and Lacey as discussed above in the analysis of the challenge to independent claims 1 and 18. Pet. 29–36, 37–38. Accordingly, for the same reasons discussed above in connection with claims 1 and 18, we find that Petitioner has not met its burden to show a reasonable likelihood that claims 3–6, 9–11, 16, 17, 19, and 20 are unpatentable over the combination of Goldstein and Lacey.

D. Remaining Grounds

Petitioner challenges claims 2, 7, 8, and 21 as obvious under 35 U.S.C. § 103(a) over Goldstein, Lacey, and Wierinck; claims 12–15 as obvious over Goldstein, Lacey, and Lampotang; and claim 22 as obvious over Goldstein, Lacey, and Placik. Pet. 38–49. Each of claims 2, 7, 8, 12–15, 21, and 22 depends from claim 1 or claim 18 and, thus, contains all the limitations of claim 1 or claim 18. Thus, for each of these grounds, Petitioner relies in large part on the same assertions presented in the challenge of independent claims 1 and 18 based on Goldstein and Lacey, discussed above, in support of its contentions that claims 2, 7, 8, 12–15, 21, and 22 are obvious over Goldstein and Lacey in combination with Wierinck, Lampotang, or Placik. *Id.*

Accordingly, each of these additional grounds suffers from the same deficiencies noted above (*see supra* Section III.C.4) with respect to the proposed combination of Goldstein and Lacey. Therefore, for the same reasons discussed above, we determine that the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail in showing that claims 2, 7, 8, 12–15, 21, and 22 are unpatentable.

IV. CONCLUSION

For the foregoing reasons, we do not institute *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '836 patent; and

FURTHER ORDERED that no *inter partes* review is instituted.

IPR2020-00042
Patent 9,792,836 B2

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