

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDBOX MEDICAL, LLC,
Petitioner,

v.

NEOTECH PRODUCTS, INC.,
Patent Owner.

Case IPR2019-00246
Patent 6,958,050 B1

Before BENJAMIN D. M. WOOD, RICHARD H. MARSCHALL,
and JASON W. MELVIN, *Administrative Patent Judges*.

WOOD, Administrative Patent Judge.

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

I. INTRODUCTION

A. Background

Sandbox Medical, LLC (“Petitioner”) filed a Petition (Paper 3, “Pet.”) requesting *inter partes* review of claims 1–10 of U.S. Patent No. 6,958,050 B1 (Ex. 1001, “the ’050 patent”) on the following grounds (Pet. 6–7):

No.	Reference[s]	Basis	Claim[s] Challenged
1	Jackson, ¹ Kerwin, ² Behrstock, ³ Penny, ⁴ and Halligan ⁵	§ 103	1–6 and 8–10
2	Jackson, Kerwin, Behrstock, Penny, Halligan, and Shedlock ⁶	§ 103	7
3	Jackson, Kerwin, Behrstock, Penny, Halligan, and Perla ⁷	§ 103	10
4	Jackson “in view [of] the Common Knowledge of the POSA [person of ordinary skill in the art]”	§ 103	1–10

¹ U.S. Pat. No. 3,595,234 (iss. July 27, 1971) (Ex. 1003).

² U.S. Pat. No. 4,813,926 (iss. Mar. 21, 1989) (Ex. 1004).

³ U.S. Pat. No. 4,699,138 (iss. Oct. 13, 1987) (Ex. 1006).

⁴ U.S. Pat. No. 3,965,901 (iss. June 29, 1976) (Ex. 1009).

⁵ U.S. Pat. No. 3,319,628 (iss. May 16, 1967) (Ex. 1005).

⁶ U.S. Pat. No. 5,114,415 (iss. May 19, 1992) (Ex. 1007).

⁷ U.S. Pat. No. 5,496,268 (iss. Mar. 5, 1996) (Ex. 1010).

Neotech Products, Inc. (“Patent Owner”) did not file a Preliminary Response.

On May 10, 2019, we instituted *inter partes* review. Paper 9 (“Dec.”). Patent Owner subsequently filed a Patent Owner Response (Paper 13, “PO Resp.”), Petitioner filed a Reply to the Patent Owner Response (Paper 15, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 17, “PO Sur-reply”). A hearing was held on February 6, 2020, and a transcript of the hearing is included in the record. Paper 21 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing burdens of proof in *inter partes* reviews). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2012); 37 C.F.R. § 42.1(d) (2018). This decision is a Final Written Decision under 35 U.S.C. § 318(a). For the reasons discussed below, we hold that Petitioner has demonstrated by a preponderance of the evidence that claims 1–10 of the ’050 patent are unpatentable under 35 U.S.C. § 103(a).

B. Related Proceedings

Petitioner states that Patent Owner filed a patent infringement action asserting the ’050 patent against Petitioner in the Central District of California, but voluntarily dismissed the action prior to service. Pet. 4 (citing Ex. 1012 ¶ 8). The parties indicate that Patent Owner filed a new action in the District of Delaware, which was transferred to the District of Massachusetts. *Id.* (citing Ex. 1012 ¶ 8); Paper 6, 2. Petitioner disputes that

it has been served, but states that Patent Owner alleges that it effected service on November 14, 2017. Pet. 4 (citing Ex. 1012 ¶ 8). Petitioner informed us at the oral argument that the district-court action has been stayed pending the outcome of this proceeding. Tr. 6:10–12.

C. The '050 Patent

The '050 patent issued October 25, 2005 from an application filed June 18, 2002, and is titled “Nasal/Oral Aspiration Device.” Ex. 1001, codes (45), (22), (54). Figure 1, reproduced below, depicts a side elevation view of a preferred embodiment:

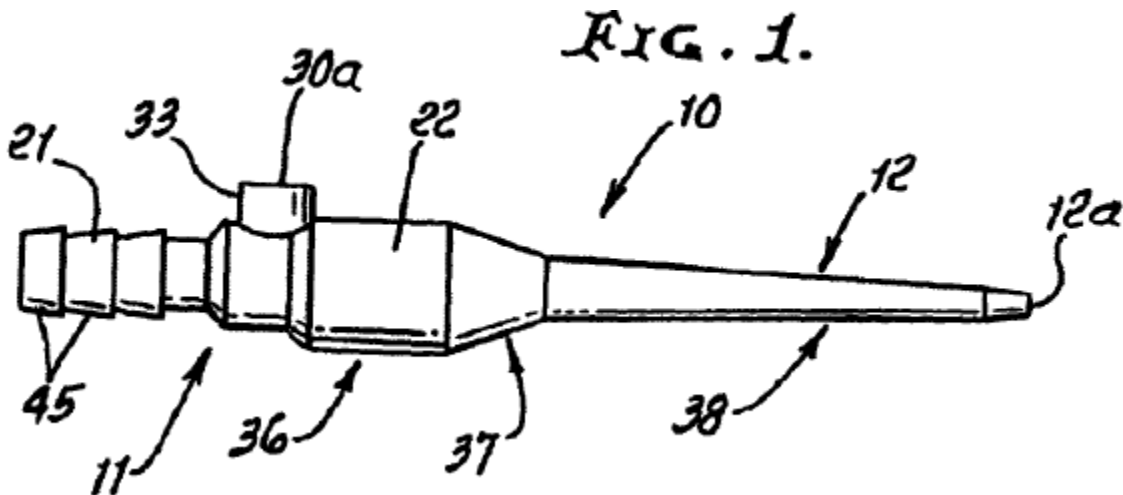


Figure 1 depicts two-part suctioning device 10 comprising first tubular body portion 11 connected end-to-end with second tubular portion 12. *Id.* at 2:31–34. First portion 11 is made from a “relatively hard non-deformable plastic material,” whereas second portion 12 is “flexibly and resiliently yieldably deformable, sidewardly.” *Id.* at 2:45–48. Flexible tapered tip 12a, located at the end of second portion 12, “flexes easily and helps provide better access to nasal and oral cavities.” *Id.* at 2:38–40, Fig. 4.

D. The Challenged Claims

Petitioner challenges claims 1–10. Pet. 1. Claim 1 is the sole independent claim, and is reproduced below:

1. A multi-purpose medical suctioning device, comprising:
 - a) a one piece first tubular body portion,
 - b) a one piece second tubular portion operatively connected to said first tubular body portion,
 - c) said second tubular portion having a flexible tip portion which is relatively soft and pliable and has an entrance of reduced area, said second tubular portion being easily maneuverable as by bending,
 - d) there being a side inlet associated with at least one of said first and second portions, to be manually blocked and unblocked to control suctioning of fluid from said tip portion entrance and through said second and first tubular portions,
 - e) and wherein said first tubular body portion consists of relatively hard plastic material, and said second tubular portion consists of relatively soft plastic material, the tip being maneuverable as by one hand of the user, while the user's other hand controls said side inlet,
 - f) said second tubular portion having primary secondary and tertiary [sic] lengthwise extending sections, said primary section fitting telescopically to said first tubular body portion, and with friction, said tertiary section being flexible and tapering toward said tip at a relatively lesser taper angle, and said secondary section extending between said primary and tertiary section, at a relatively greater taper angle, said primary section fitting over said first tubular body portion to define a device maximum diameter proximate the entrance of said side inlet and between said inlet and said flexible tip portion, for finger control of the device including finger control of said inlet and control of said primary section to control tip portion bending,

- g) said secondary and tertiary sections having respective lengths L_2 , [sic] and L_3 where L_3 is elongated and $L_3 > L_2$, flexibility of said tertiary section thereby being enabled along its major elongated length, to facilitate suctioning usage of the tertiary section as the tertiary section is easily bent in response to engagement with tissue of a patient,
- h) and wherein said device is characterized by one of the following:
 - i) said body portions are transparent
 - ii) said body portions are translucent
 - iii) at least one of said body portions is transparent
 - iv) at least one of said body portions is translucent.

E. Testimonial Evidence

In support of its asserted grounds of unpatentability, Petitioner enters into the record Declarations of Leslie H. Sherman (Ex. 1011) and Read McCarty (Ex. 1012), a Reply Declaration of Mr. Sherman (Ex. 1028), and a Second Declaration of Mr. McCarty (Ex. 1029). In support of the patentability of its claims, Patent Owner enters into the record a Declaration of James E. Moore, Jr., Ph.D. (Ex. 2001), a Declaration of Michael A. DiNardo (Ex. 2006), and a Sur-reply Declaration of Dr. Moore (Ex. 2007). Petitioner deposed Dr. Moore and entered the transcript of the deposition into the record (Ex. 1027).

F. Objective Indicia of Nonobviousness

Patent Owner has submitted evidence that it characterizes as objective indicia of nonobvious. PO Resp. 29–31 (citing Exs. 2003, 2004, 2006).

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art at the time of the '050 patent “would have been a mechanical technician having the equivalent of 4 years of undergraduate education in mechanical technology, or two years of education and two years of practical experience in industrial design.” Pet. 25 (citing Ex. 1011 ¶ 20). According to Petitioner, the level of skill “could be achieved through formal education, a combination of education and experience, or even purely through experience.” *Id.* (citing Ex. 1011 ¶ 20).

Patent Owner responds that one of ordinary skill in the art “must also have an understanding of fluid mechanics, i.e., fluid and mass transport, in order to have a greater understanding and recognition of the operational benefits of an aspirator conforming to the claimed inside diameter profile of the '050 patent.” PO Resp. 5–6 (citing Ex. 2001 ¶¶ 16, 41). Petitioner disagrees, arguing that Dr. Moore, on whose testimony Patent Owner’s definition of the ordinary skill level is based, is not sufficiently familiar with the relevant art. Pet. Reply 5.

The “level of skill in the art might be gleaned from the prior art itself.” *Litton Indust. Prods. V. Solid State Sys. Corp.*, 755 F.2d 158, 163–164 (Fed. Cir. 1985). The products described in the prior art of record are intended for the removal of bodily fluids in a controlled manner. *See, e.g.*, Ex. 1004, 1:13–15 (stating that surgical suction devices “are used for removing blood and other body fluids from surgical sites”); Ex. 1005, 1:10–15 (“This invention relates to . . . an improved regulator adapted to be used in combination with a suction catheter apparatus in which the fluid

flow therethrough is controlled by regulating the flow of a second fluid therethrough.”); Ex. 1009, 1:5–7 (“This invention relates to suction catheters for aspiration of mucus and other fluids from the tracheobronchial passages.”). It stands to reason, therefore, that, in addition to the skill level proposed by Petitioner, one of ordinary skill in the art would have sufficiently familiar with basic principles of fluid mechanics to understand the prior art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Therefore, we adopt Petitioner’s proposed definition of the level of ordinary skill, modified to clarify that one of ordinary skill in the art would also have an understanding of the basic principles of fluid mechanics. We note, however, that our claim construction and patentability analyses presented below would reach the same findings and determinations under either level of ordinary skill in the art.

B. Claim Construction

Because the Petition in this proceeding was filed before the effective date of the USPTO’s change to the claim-construction standard in trial proceedings before the Board,⁸ we construe the claims based on the “broadest reasonable construction” of the claims in light of the specification in which the claims appear. 37 C.F.R. § 42.100(b) (2018); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). Under this standard, claim

⁸ See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (changing claim construction standard for petitions filed on or after November 13, 2018); 37 C.F.R. § 42.100(b) (2019). The Petition in this case was filed November 9, 2018. Paper 4, 1.

terms are generally given their ordinary and accustomed meaning as understood by one of ordinary skill in the art, unless it appears from the specification, the file history, or other evidence asserted by the parties that the inventor used them differently. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Id.* We need only construe terms “that are in controversy, and only to the extent necessary to resolve the controversy.” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017), *cert. denied sub nom. Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 138 S. Ct. 1695, 200 L. Ed. 2d 951 (2018) (internal quotation marks and citation omitted).

The parties dispute the construction of the following terms in claim 1: “relatively lesser taper angle,” “relatively greater taper angle,” and “device maximum diameter.” We construe these terms below, and determine that no other term requires express construction.

1. “*relatively lesser taper angle*”; “*relatively greater taper angle*”

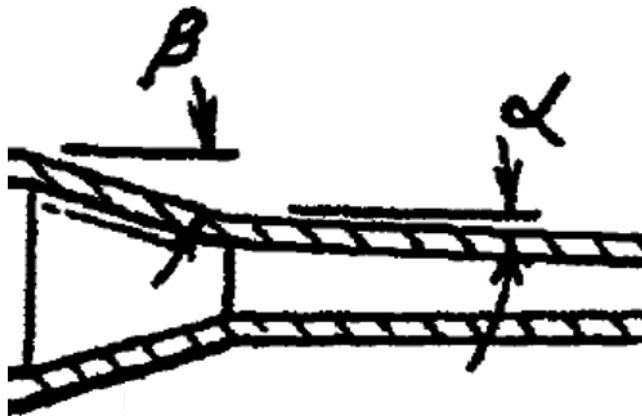
Claim 1 recites a “second tubular portion” having “primary secondary and tertiary lengthwise extending sections” and a “tip portion,” the tertiary section “tapering toward said tip at a *relatively lesser taper angle*,” the secondary section extending between the primary and tertiary sections “at a *relatively greater taper angle*.” Ex. 1001, 4:15–38 (emphasis added).

Petitioner contends that “‘relatively lesser taper angle’ refers to the angle of the tertiary section which is lesser than the angle of the secondary section,

and ‘relatively greater taper angle’ refers to the angle of the secondary section which is greater than the angle of the tertiary section.” Pet. 23.

Patent Owner agrees with Petitioner that “greater” and “lesser” mean in comparison with each other. Tr., 29:10–19. Patent Owner contends, however, that “taper angle” refers to the angle at which the inside profile of the secondary and tertiary sections tapers. PO Resp. 7–9; PO Sur-reply 3–6. Petitioner disagrees, asserting that the claimed taper angles refer to the tapering of the exterior profiles of the secondary and tertiary sections. Pet. Reply 6–13.

We discern nothing in claim 1 that directly addresses whether “taper angle” refers to the inside or outside profiles of the secondary and tertiary sections. The Specification of the ’050 patent, however, and particularly Figure 2, makes clear that “taper angle” refers to angles associated with the exterior of the secondary and tertiary sections. Depicted below is the relevant portion of Figure 2 illustrating angles designated α and β (the Figure modified to remove extraneous lead lines):



The portion of Figure 2 reproduced above depicts secondary section 37 on the left and a portion of tertiary section 38 on the right. Ex. 1001, 2:64–66, Fig. 2. According to the Specification, tertiary section 38 “tapers toward tip

12a at a relatively small or lesser tape[r] angle α ,” and secondary section 37 “extends between [primary section] 36 and [tertiary section] 38 at a relatively larger taper angle β .” *Id.* at 3:1–5. By comparing the description of taper angles α and β with limitation (f) of claim 1, it is clear that taper angles α and β correspond to the claimed lesser and greater taper angles, respectively, and are clearly depicted as representing the outside profiles of the tertiary and secondary sections, respectively. We have not found any reference to or depiction of a “taper angle” in the Specification that associates this term with the inside profiles of the tertiary and secondary sections.

Although Patent Owner asserts, without explanation, that taper angles α and β illustrate the interior diameters of the tertiary and secondary sections, PO Resp. 7, Patent Owner’s declarant, Dr. Moore, disagrees. According to Dr. Moore, Figure 2 “illustrates α and β relative to the exterior of the second tubular body.” Ex. 2001 ¶ 36. Dr. Moore attempts to explain this away, however, testifying that “[w]hile this FIG. 2 illustrates α and β relative to the exterior of the second tubular body, I believe that such was done for purposes of improved readability because of the relative scale of the drawing figure and the closeness of the interior lines.” *Id.* We give no weight to this testimony. First, it is unsupported by the record evidence or reasoned explanation. For example, Dr. Moore does not explain why the patentee could not have enlarged the scale of Figure 2—as was done with Figure 4—to illustrate interior angles, rather than to incorrectly (according to Dr. Moore) illustrate exterior angles. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (holding that “conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a

court”). Second, Dr. Moore’s opinion is not rendered from the perspective of one of ordinary skill in the art. Dr. Moore does not state that “taper angle” had any special meaning to one of ordinary skill in the art at the time of the invention, or otherwise explain how one of ordinary skill would have interpreted the α and β markings in Figure 2 to represent interior angles. See *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1375 (Fed. Cir. 2004) (rejecting expert opinion regarding interpretation of claim term because it was not established that term had a special meaning in the art).

Patent Owner argues that because the Specification teaches that the inside cross-sectional area of the device affects fluid flow through the device, one of ordinary skill in the art would have understood that the inside profiles must taper as claimed (i.e., the inside of the tertiary section must taper at a “relatively lesser taper angle,” and the inside of the secondary section must taper at a “relatively greater taper angle”) to optimize fluid flow through the device. PO Resp. 7–9; PO Sur-reply 4–5. For example, Patent Owner relies on the following excerpt from the Specification:

[T]he inside cross-section is typically smallest at the tip. Therefore, material that is sucked into the device encounters less resistance to flow once it enters the tip, due to highest flow velocity at lesser cross sectional area. Thus there will be no hang ups of, or blockages by, secretions, within the product.

PO Resp. 8 (quoting Ex. 1001, 3:52–57); *see also id.* (quoting Ex. 1001, 1:47–48, 3:1–3, 4:17–20); PO Sur-reply 4–5 (citing Ex. 1001, 4:23–25, 48–49). Patent Owner contends that “[a] person of ordinary skill in the art would also view the ‘Relatively Lesser Taper Angle’ of the tertiary section and the ‘Relatively Greater Taper Angle’ of the second section of the tubular portion to refer to the taper angles of the inside diameter or inside cross-

section of the secondary and tertiary sections of the second tubular portion, consistent with the illustrations and description in the Specification.” PO Resp. 8–9 (citing Ex. 2001 ¶¶36–38).

This is not persuasive. That the tip of the device may have the smallest inside cross-section does not specify the inside cross-sections of the secondary and tertiary sections, other than that they be larger than the tip’s inside cross-section. Stated differently, there is no reason to infer from this disclosure that the inside cross-section of the tertiary angle must taper any less than the inside cross-section of the secondary section in order to reduce flow resistance or prevent hang ups and blockages (a consistent taper through both sections would presumably obtain the same results). Even if this teaching would have suggested to one of ordinary skill in the art that the inside cross-sections taper as claimed, such suggestion would fall far short of contradicting the clear depiction in Figure 2 of taper angles with respect to the outside profile of the secondary and tertiary sections, rather than the inside profile. Thus, reading the Specification in its entirety, one of ordinary skill in the art would still have understood the claimed taper angles to refer to the outside profiles of these sections.

2. *device maximum diameter*

Petitioner contends that “device maximum diameter” should be construed as “the largest straight line between two points on the circumference of a circular portion of the device that passes through the center of the circle.” Pet. 22 (citing Ex. 1011 ¶ 45). Patent Owner appears to agree with this construction, but contends that it should apply to “the *inside circumference* of the circular portion of the device that passes through the center of the circular portion” of the device. PO Resp. 9 (emphasis

added).⁹ According to Patent Owner, the term must refer to the diameter measured at the inside of the device because: (1) to interpret the term as referring to the outside of the device would necessarily mean the width of the device at its side inlet; and (2) as with its construction of “taper angle,” “the dimensions of the device are described in the context of optimizing the flow cross-sectional area to avoid hang ups or blockages therein,” and “[a] POSA having the knowledge of fluid mechanics would have a greater understanding and recognition of the operational benefits of a medical suctioning device conforming to the claimed inside diameter profile of the ‘050 patent.” *Id.* at 10.

We disagree with Patent Owner that “device maximum diameter” refers to an inside diameter. Simply put, the inside diameter is, by definition, *not* the “maximum” diameter of the device, as it is necessarily less than the outside diameter. Further, construing the term to apply to the outside diameter would not require applying it to the side inlet, because the claim specifies that the device maximum diameter is located “proximate the entrance of [the] side inlet,” thereby excluding the side inlet from the term. Finally, we are not persuaded that considerations of fluid mechanics require the term to apply to the device’s inside diameter, for the reasons discussed above in connection with the “taper angle” limitations.

Accordingly, we construe “device maximum diameter” to mean the largest straight line between two points on the circumference of a circular portion of the device that passes through the center of the circle.

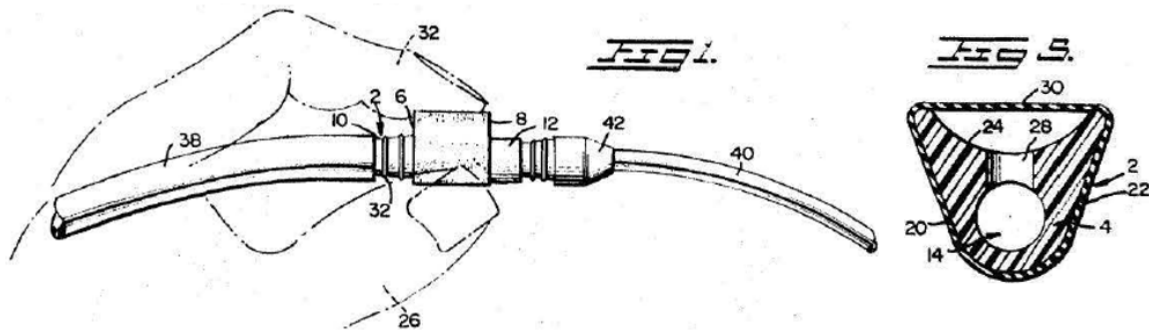
⁹ We agree with the parties (Pet. 22; PO Resp. 10) that the device maximum diameter does not refer to the width of the device at its side inlet.

C. *Ground 1: Claims 1–6 and 8–10—Obvious over Jackson, Kerwin, Behrstock, Penny, and Halligan*

Petitioner asserts that claims 1–6 and 8–10 would have been obvious over Jackson, Kerwin, Behrstock, Penny, and Halligan. Pet. 25–48.

1. *Jackson (Ex. 1003)*

Jackson describes a vacuum controller for a medicosurgical tube that can be used for the aspiration of mucus from the nose and mouth. Figures 1 and 5 depict perspective and cross-sectional views of a preferred embodiment, and are reproduced below:



Figures 1 and 5 depict vacuum controller 2 comprising central body portion 4 having a pair of opposed transverse ends 6 and 8. Ex. 1003, 3:14–16. Integral male connector portion 10 extends axially from end 6 and integral female connector portion 12 extends axially from end 8. *Id.* at 3:16–18. Bore 14 extends axially through vacuum controller 2. *Id.* at 3:18–20, Figs. 2–4. Body portion 4 has a triangular cross-section, including concave face 24, with elliptical opening 28 that extends through the face into bore 14. *Id.* at 3:34–36. Connector tube 38 is positioned over male connector 10 and is connected at the other end to a vacuum source (not shown). *Id.* at 3:65–67. Suction catheter 40 is inserted into female connector 12. *Id.* at 3:68–69. An operator controls suction through the device by placing a finger over

opening 28 to supply suction and removing the finger to release suction. *Id.* at 3:70–4:5.

2. *Kerwin (Ex. 1004)*

Kerwin describes a hand-held, fine tip medical suction device.

Ex. 1004, 1:9–10. Figures 1 and 2 are reproduced below:

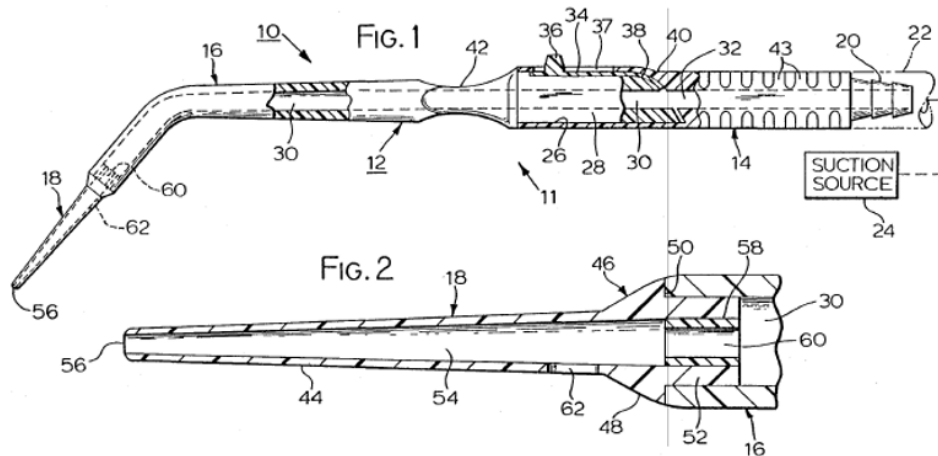
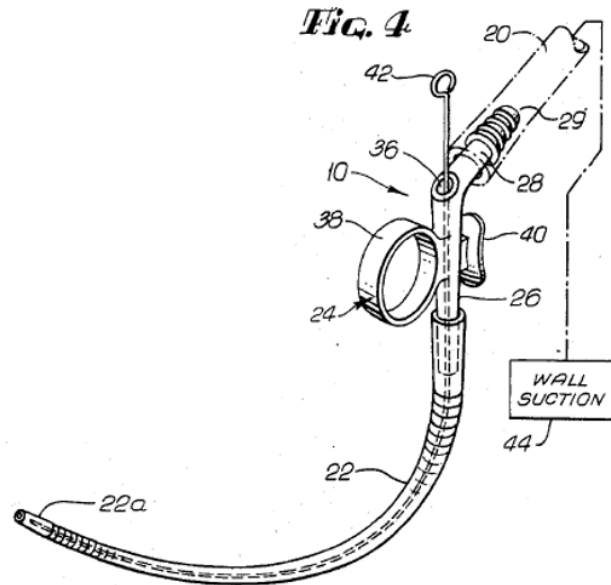


Figure 1 depicts Kerwin’s medical hand-held suction device 10; Figure 2 is an enlarged view of the distal end of the device depicted in Figure 1. *Id.* at 2:11–15. Suction device 10 comprises handle 14 connected to probe 16, which has flexible suction tip 18 at its distal end. *Id.* at 2:29–32. Tip 18 includes longitudinally extending tapered portion 44 with integral enlarged connector portion 46 at its proximal end. *Id.* at 3:4–7. Handle 14 and probe 16 may be made of a relatively rigid plastic material, whereas tip 18 is preferably formed of a flexible plastic material. *Id.* at 6:17–23. The tip “may be formed of a polyvinyl chloride that is soft and flexible but which supports itself and is resilient enough to return to its original shape after being bent during use.” *Id.* at 6:24–28.

3. *Behrstock (Ex. 1006)*

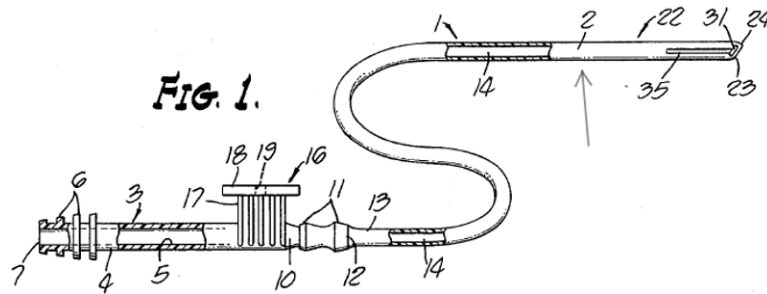
Behrstock describes an endotracheal intubation device that can be inserted into a baby's mouth or nose to remove meconium at birth. Ex. 1006, 1:8–10, 33–41. Figure 4 of Behrstock is reproduced below:



As shown in Figure 4, Behrstock's device 10 is attached at one end to suction tubing 20, which in turn is attached to wall suction device 44. *Id.* at 3:55–56, 4:13–15. Device 10 is attached at the other end to endotracheal (E-T) tube 22. *Id.* at 4:18–20. “E-T tube 22 is a commonly used stock item in the art” that is “made of a variety of clear plastic material as is also commonly known in the art.” *Id.* at 4:21–26. An operator controls suction by placing or removing a finger over port 36. *Id.* at 5:3–7, 53–54.

4. *Penny (Ex. 1009)*

Penny describes a suction catheter for aspiration of mucus and other fluids from tracheobronchial passages. Ex. 1009, 1:5–7. Figure 1 of Penny is reproduced below:



As shown in Figure 1, suction catheter 1 comprises flexible tubular body 2 attached to rigid connector 3 and tubular body 4. *Id.* at 2:50–52. “The end of connector 3 opposite suction port 7 has a tubular extension 10 with external retaining ribs 11 over which the proximal end section 13 of flexible tubular member 2 is telescoped.” *Id.* at 58–61. Connector 3 includes regulator 16 having upstanding cylindrical body 17 and atmospheric port 19 connected to axial passage 5 via a passage through body 1. *Id.* at 2:52–53, 2:65–3:1. An operator controls the degree of suction through tubular member 2 by opening or closing port 19 with a finger. *Id.* at 3:1–4.

5. Halligan (*Ex. 1005*)

Halligan discloses a regulator for a catheter for suctioning tracheal, bronchial, oral, or nasal passages. *Ex. 1005*, 1:10–17. Figure 1 is reproduced below:

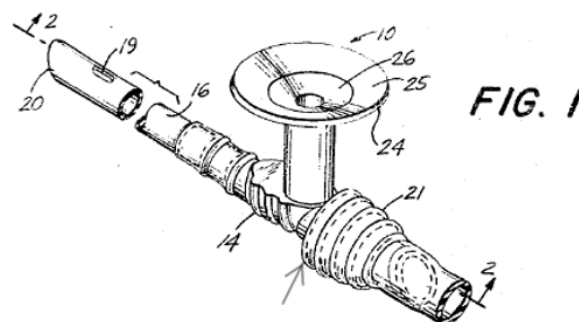


Figure 1 depicts regulator 10. *Id.* at 2:26–28. “The regulator is preferably formed of nylon, although other plastics having rigid properties may be used.” *Id.* at 2:29–31. Regulator 10 is attached to “flexible tubular member 16 such as a suction catheter.” *Id.* at 2:33–36. “It is convenient to use a tubing which is translucent or transparent as opposed to an opaque tubing.” 2:52–53.

6. *Principles of Law*

“A patent for a claimed invention may not be obtained though the invention is not identically disclosed or described as set forth in [35 U.S.C. § 102], if the differences between the subject matter sought to be patented 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 the subject matter pertains.” 35 U.S.C. § 103(a) (2011).¹⁰ Obviousness is a question of law based on underlying factual considerations that “include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations” of non-obviousness, including commercial success of the patented product or method, a long-felt but unmet need for the functionality of the patented invention, and the failure of others to accomplish what the patentee has achieved. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). The obviousness analysis should not be

¹⁰ Because the ’050 patent issued from an application filed before March 16, 2013, the effective date of the amendments to 35 U.S.C. § 103 enacted by the Leahy-Smith America Invents Act, we apply the pre-AIA version of the statute. See Leahy-Smith America Invents Act (AIA), Pub. L. No. 112–29, § 3(n)(1), 125 Stat. 284, 293 (2011).

conducted “in a narrow, rigid manner,” but should instead focus on whether a claimed invention is merely “the result[] of ordinary innovation,” which is not entitled to patent protection. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

7. *Claim 1*

a. The Combined References Teach All of the Limitations of Claim 1

Petitioner contends that “[t]he vast majority of the claimed elements can be found explicitly in [Jackson].” Pet. 25. Specifically, Petitioner contends that Jackson teaches: (1) a one-piece first tubular body portion; (2) a one-piece second tubular portion operatively connected to said first tubular body portion; (3) a side inlet associated with at least one of the first and second portions that can be manually blocked and unblocked to control suction from a tip through the first and second portions; (4) the second tubular portion having primary, secondary, and tertiary sections; (5) the primary section fitting telescopically to the first tubular body portion; (6) the secondary section extending between the primary section at a relatively greater taper angle; (7) the tertiary section length $L_3 \gg \gg$ the secondary section length L_2 ; and (8) a device maximum diameter located proximate the side inlet entrance and between the inlet and the flexible tip portion. *Id.* at 27–37 (citing Ex. 1003, 1:6–19, 64–73, 2:52–55, 3:57–61, 4:64–66, Figs. 1–3; Ex. 1011 at 29–39).

Based on our review of the record, and specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by

a preponderance of the evidence that Jackson teaches the above limitations.¹¹

Regarding the limitations requiring the second tubular portion to have a relatively soft, pliable, flexible, single-handedly maneuverable tip with an entrance of reduced area, Petitioner relies on, *inter alia*, Kerwin. Pet. 28–29. Petitioner specifically relies on Kerwin’s “fine tip 18” shown in Figures 1 and 2, which “is preferably formed of a suitable flexible plastic material,” and which is “soft and flexible” but “resilient enough to return to its original shape after being bent during use.” *Id.* at 29 (citing Ex. 1004, 6:17–20, 22–32, Figs. 1–2). Petitioner relies on Kerwin and Jackson to teach the second tubular portion being “maneuverable as by bending,”¹² (*id.* (citing Ex. 1003, Fig. 1; Ex. 1004, 6:17–20, 2232)), and the tertiary section of the second tubular portion being bendable and flexible (*id.* at 29, 31–32, 34 (citing Ex. 1004, 6:17–20, 22–32, Fig. 2)). Petitioner asserts that one of ordinary skill in the art would have used Kerwin’s flexible tip with Jackson’s vacuum controller because Jackson teaches that its vacuum controller can be used “with any form of medicosurgical suction tube,” which vary in size and shape depending on the medical application. *Id.* 29 (quoting Ex. 1003, 1:6–19).

¹¹ Petitioner asserts that many of these limitations are also taught by other cited references. *See, e.g.*, Pet. 28 (asserting that Penny, Halligan, Behrstock, and Kerwin also teach a one-piece second tubular portion).

¹² Petitioner also contends that Behrstock teaches this limitation (Pet. 29 (citing Ex. 1006, 5:16–33)) and that Penny teaches that suction catheters have “[t]raditionally” consisted of a “flexible” plastic tube (*id.* at 32 (quoting Ex. 1009, 1:12–17)).

Based on our review of the record, and specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by a preponderance of the evidence that the combination of Kerwin and Jackson teaches the limitations discussed above, and that one of ordinary skill in the art would have had reason to combine teachings from Jackson and Kerwin. Jackson teaches that all forms of suction tubes can be used with its vacuum controller, including those used for surgical operations. Ex. 1003, 1:13–22. Kerwin teaches a suction tip used in connection with a suction tube on a surgical suction device. Ex. 1004, 1:13–50. Thus, combining Kerwin’s suction tip with Jackson’s vacuum controller amounts to no more than the combination of prior art elements according to known methods to yield predictable results. *See KSR*, 550 U.S. at 416 (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

Regarding the requirement that the primary section of the second tubular portion “fit[] over” the first tubular body portion, Petitioner acknowledges that Jackson’s primary section fits inside of, not over, Jackson’s first tubular body portion (i.e., the primary section uses a male connection to connect to a female connection on the first tubular body portion). Pet. 36. Petitioner asserts, however, that Penny teaches this limitation. *Id.* at 36 (citing Ex. 1009, 2:58–62). Petitioner asserts that it would have been obvious to one of ordinary skill in the art to use a female connector to connect to a male connector on the first tubular body portion as taught in Penny because deciding between a male or female connection “was merely a design choice and male and female connections were well known in the art.” *Id.* 37 (citing Ex. 1011 at 37–39).

Based on our review of the record, and specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by a preponderance of the evidence that Penny teaches the claimed connector arrangement and that using Penny's connector arrangement with Jackson would have been obvious to one of ordinary skill in the art at the time of the invention, because it would merely have been a simple substitution of one known element—a female/male connection—for another—a male/female connection—to obtain predictable results. *See KSR*, 550 U.S. at 416 (holding that “when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field the combination must do more than yield a predictable result”).

Regarding the requirement that at least one of the first and second tubular portions be transparent or translucent, Petitioner relies on Behrstock, and particularly Behrstock's teaching that it was “commonly known in the art” to use a “clear plastic material[]” to make an endotracheal suction tube. Pet. 38 (citing Ex. 1006, 1:6–19, 4:22–27). Petitioner further notes Halligan's teaching that “[i]t is convenient to use a tubing which is translucent or transparent as opposed to an opaque tubing” for suction catheter tubing, “although an opaque tubing may be used.” *Id.* (citing Ex. 1005, 2:52–55). Petitioner contends that “[i]t would have been obvious to a POSA to use any number of clear or translucent materials for both primary and secondary sections” of the second tubular portion because “transparent and/or translucent materials were well known in the prior art and used routinely in suction devices.” *Id.* at 39 (citing Ex. 1011 at 39–41).

Based on our review of the record, and specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by

a preponderance of the evidence that Behrstock and Halligan teach this limitation, and that one of ordinary skill in the art would have combined Behrstock and Halligan with Jackson. The record indicates that transparent suction tubes were well-known and could have been used in place of opaque tubes to accomplish the result of providing suction. Ex. 1005, 2:52–55; Ex. 1006, 1:6–19, 4:22–27; *see KSR*, 550 U.S. at 416.

b. Patent Owner’s Arguments Are Unpersuasive

Patent Owner’s primary argument is that none of the references discloses the claimed “inside diameter profile.” PO Resp. 24. This argument is premised on Patent Owner’s incorrect construction of the “taper angle” limitations as referring to the inside profiles of the secondary and tertiary sections. Because these limitations are properly construed as applying to the outside profiles of these sections, this argument is unavailing.

Patent Owner also contends that none of the prior art references discloses “the claimed relative rigidities.” *Id.* at 25. Patent Owner acknowledges that the references may disclose using “hard plastic” and “soft plastic,” but argues that the references “fail[] to disclose those materials properties coordinated with the claimed structures, relative taper angles, and relative lengths,” which “impact the relative flexibilities of each section just as much as the materials properties.” *Id.* at 28.

We disagree. The combination of Jackson and Kerwin teaches a relatively hard plastic first tubular body portion and a relatively soft plastic second tubular portion, as well as the claimed “relative lengths” of the secondary and tertiary sections. Ex. 1003, 2:51–55, 3:57–61, 4:64–66, Fig. 1; Ex. 1004, 6:17–26; Ex. 1011 ¶ 53; *see also* Ex. 1005, 1:71–2:2

(Halligan) (teaching “a regulator for a suction catheter apparatus which includes in combination a relatively elongated flexible tube having a regulator made of substantially rigid plastic material”); Ex. 1009 (Penny) (“Traditionally, suction catheters having consisted of a flexible plastic tube.”). Further, as discussed above, one of ordinary skill in the art would have combined Jackson, Kerwin, Halligan, and Penny. Indeed, Patent Owner does not substantively argue otherwise.¹³ Patent Owner also does not dispute that Jackson teaches the relative “outside” taper angles and the relative lengths of the secondary and tertiary sections.

c. Patent Owner’s Evidence of Copying is Unpersuasive

Patent Owner asserts “objective evidence of Petitioner’s intentional copying of [Patent Owner’s] products.” PO Resp. 30. This evidence “relates to the parties’ respective packaging, namely the instructions printed thereon.” *Id.* (citing Ex. 2004, Ex. 2006 ¶ 3). According to Patent Owner:

In Petitioner’s original packaging, Petitioner copied the words on [Patent Owner’s] packaging—to the point of leaving [Patent Owner’s] common law trademark “Suction Caddy” in instruction number 5—even down to the capitalization. . . . In addition to using [Patent Owner’s] common law trademark, Petitioner copied [Patent Owner’s] instructions verbatim, with the exception of one word.

¹³ Patent Owner merely asserts that because the references fail to disclose “the inside diameter profile of the second tubular body portion” and “the transition from rigid to flexible tubular body portions,” “no POSA at the time of the invention would have combined the cited prior art references without the benefit of hindsight reconstruction from the disclosure of the ‘050 patent.” PO Resp. 18.

Id. at 30–31 (citing Ex. 2006 ¶¶4–5). Petitioner responds, *inter alia*, that “copying user instructions from a label is irrelevant to secondary considerations.” Pet. Reply 21.

We agree with Petitioner. Evidence of secondary considerations is relevant only to the extent that its proponent establishes a nexus between the evidence and “the merits of the claimed invention.” *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). Patent Owner has not offered evidence that a product embodying the claims of the ’050 patent has been copied, only that certain packaging has allegedly been copied. Therefore, Patent Owner has not established the required nexus, and we accord no weight to this evidence.

d. Summary as to Claim 1

For the reasons discussed above, we find that the combination of Jackson, Kerwin, Behrstock, Penny, and Halligan teaches all of the limitations of claim 1, that one of ordinary skill in the art would have had reason to combine the references to achieve the subject matter of claim 1, and Patent Owner’s evidence of secondary considerations is deserving of no weight. We therefore conclude that claim 1 would have been obvious over Jackson, Kerwin, Behrstock, Penny, and Halligan.

8. Claims 2–6 and 8–10

For claims 2–6 and 8–20, which depend directly or indirectly from claim 1, Petitioner identifies specific excerpts from Jackson, Kerwin, Behrstock, Halligan, and Penny that teach the additional limitations of these claims. Pet. 39–48 (citing Ex. 1003, 1:6–19, 3:28–36, 61–69, Fig. 1; Ex. 1004, 2:46–60, 3:20–23, Figs. 1–4; Ex. 1005, 2:11–15, 29–32, 52–55; Ex. 1006, 3:31–34, 4:22–27, Fig. 4; Ex. 1009, 2:58–62, 2:65–3:4, Figs. 1, 10;

Ex. 1011, 32, 41–47). Patent Owner does not separately argue any of the dependent claims. Based on our review of the record, specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by a preponderance of the evidence that the additional limitations of claims 2–6 and 8–10 are taught by the cited references, and conclude that claims 2–6 and 8–10 would have been obvious over Jackson, Kerwin, Behrstock, Penny, and Halligan.

9. *Summary as to Ground 1*

For the above reasons, we determine that claims 2–6 and 8–10 would have been obvious over Jackson, Kerwin, Penny, Behrstock, and Halligan.

D. *Ground 2*

Petitioner contends that claim 7 would have been obvious over Jackson, Kerwin, Penny, Behrstock, Halligan, and Shedlock. Pet. 48–49. Claim 7 depends from claim 1 and additionally recites “a soft pliable flange on said tertiary section near said tip.” The Specification explains that “a soft pliable flange” is placed near the tip of the device “for sideward positioning engagement with a nostril inner wall, and [to] seal off (or partially seal off) the nostril, increasing suction in the nostril.” Ex. 1001, 3:25–29. Petitioner relies on Shedlock to teach this limitation. Pet. 48–49. Shedlock discloses a hand-held, oral and nasal suctioning device for infants. Ex. 1007, 1:42–51. The device comprises a nozzle, which may be conical and “tapered very gradually,” that “abuts the entrance to the baby’s nostril while suctioning takes place.” *Id.* at 1:54–63. A “flange having air passage holes may be included to partially block the oropharynx and nasopharynx openings when using the apparatus.” *Id.* at 1:67–2:2. According to Petitioner, “[i]t would have been obvious to a POSA to include a soft pliable flange on the tertiary

section near the tip as flanges were well known in the prior art and used routinely in suction devices.” Pet. 49 (citing Ex. 1011, 46). Patent Owner does not dispute Petitioner’s contentions or otherwise raise any arguments specific to this proposed ground of unpatentability.

Based on our review of the record, and specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by a preponderance of the evidence that Shedlock teaches the additional limitation of claim 7, and that one of ordinary skill in the art would have had reason to combine Shedlock with the other cited references. Therefore, we determine that claim 7 would have been obvious over Jackson, Kerwin, Penny, Behrstock, Halligan, and Shedlock.

E. Ground 3

Petitioner contends that claim 10 would have been obvious over Jackson, Kerwin, Penny, Behrstock, Halligan, and Perla. Pet. 49–51. Claim 10 depends from claim 1 and additionally recites “said body portions consist of molded plastic material that excludes vinyl and latex.” Petitioner relies on Perla to teach this additional limitation. Pet. 50. Perla teaches an aspirating device formed from “flexible, transparent, non-irritating plastic material, such as polyethylene.” Ex. 1010, 4:3–7, Figs. 1, 3. Petitioner contends that “[i]t would have been obvious to a POSA to use any number of plastic materials including plastic materials that exclude vinyl and latex as catheters made of plastic material that excludes vinyl and latex were well known in the prior art.” Pet. 50–51 (citing Ex. 1011, 48–49). Patent Owner does not dispute Petitioner’s contentions or otherwise raise any arguments specific to this proposed ground of unpatentability.

Based on our review of the record, and specifically relying on the evidence cited by Petitioner, we determine that Petitioner has established by a preponderance of the evidence that Perla teaches the additional limitation of claim 10, and that one of ordinary skill in the art would have had reason to combine Perla with the other cited references. Therefore, we determine that claim 10 would have been obvious over Jackson, Kerwin, Penny, Behrstock, Halligan, and Perla.

F. Ground 4

Petitioner asserts that “Jackson modified by the Common Knowledge of the skilled artisan renders all the claims unpatentable.” Pet. 51. In support of this Ground, Petitioner appears to rely on the same references discussed above in connection with Grounds 1–3. *Id.* at 51–55. Unlike with the previous grounds, however, Petitioner substitutes attorney argument for precise citations to the references, and fails to explain why one of ordinary skill in the art would have combined the references. It is Petitioner’s burden to “specify where each element of the claim is found in the prior art patents or printed publications relied upon,” and “identif[y] specific portions of the evidence that support the challenge.” 37 C.F.R. § 42.104(b)(4), (5).

Petitioner has failed to do so here in connection with Ground 4. We decline Petitioner’s implicit invitation to incorporate Petitioner’s citations and analysis from Grounds 1–3 into this Ground. Accordingly, we determine that Petitioner has failed to show unpatentability of claims 1–10 under Ground 4.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–10 of the '050 patent are unpatentable under 35 U.S.C. § 103(a),¹⁴ as set forth in the following table:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–6, 8–10	103	Jackson, Kerwin, Behrstock, Penny, and Halligan	1–6, 8–10	
7	103	Jackson, Kerwin, Behrstock, Penny, Halligan, and Shedlock	7	
10	103	Jackson, Kerwin, Behrstock, Penny, Halligan, and Perla	10	
1–10	103	Jackson in view of Common Knowledge of POSA		1–10
Overall Outcome			1–10	

¹⁴ 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).

IV. ORDER

For the reasons given, it is

ORDERED that claims 1–10 of U.S. Patent 6,958,050 B1 have been shown to be unpatentable;

and

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

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