

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANI-TECH WEST, INC.,
Petitioner,

v.

MEISSNER FILTRATION PRODUCTS, INC.,
Patent Owner.

IPR2022-01123
Patent 7,373,825 B2

Before ZHENYU YANG, SHARON FENICK, and BRIAN D. RANGE,
Administrative Patent Judges.

YANG, *Administrative Patent Judge.*

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

I. INTRODUCTION

Sani-Tech West, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”), seeking an *inter partes* review of claims 1–11 of U.S. Patent No. 7,373,825 B2 (Ex. 1001, “the ’825 patent”). Meissner Filtration Products, Inc. (“Patent Owner”) filed a Patent Owner Preliminary Response. Paper 5 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is 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 provided below, we determine Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Accordingly, we deny institution of an *inter partes* review.

A. Related Matters

According to the parties, Patent Owner asserted the ’825 patent against Petitioner in *Meissner Filtration Products, Inc. v. Nordson Medical Corporation*, Case No. 2-20-cv-0178 (C.D. Cal.). Pet. 6–7; Paper 4, 1.

In addition, the ’825 patent is the subject of two other lawsuits, both of which were voluntarily dismissed. Pet. 6; Paper 4, 1.

B. The ’825 Patent and Related Background

The ’825 patent relates to “a new and improved gauge tee device for use in pressure measurement of fluids in disposable tubing. It is particularly useful in disposable sterile systems for filtering biopharmaceuticals.” Ex. 1001, 3:62–65.

The '825 patent acknowledges the existence of prior art devices for measuring pressure within disposable tubing. *Id.* at 1:17–2:29. But those devices, according to the '825 patent, are not ideal for use in the biopharmaceutical industry because they have various drawbacks and limitations, including, for example, significant hold-up volume and the occurrence of contamination. *Id.* at 1:23–2:29. The '825 patent states

[T]here is a need for a device that can accurately measure pressure of liquids in disposable tubing during various processes. Additionally, there is a need for a disposable device that allows for biopharmaceutical processing and eliminates batch cross contamination or expensive cleaning validation. Further, there is a need for a device that can be sterilized and allows for aseptic pressure monitoring of a process. There is a need for a device that reduces the amount of hold-up volume. Finally, there is a need for a device that provides measurement without product contact to the environment or the stainless steel gauge diaphragm.

Id. at 2:30–40.

The '825 patent discloses

A disposable sanitary gauge tee with no dead zone for use in pressure measurement of fluid in disposable tubing including a body having a main fluid passageway in fluid connection with a proximal end of a pressure fluid passageway, the main fluid passageway including a fluid port and a second fluid port, wherein a hose barb is operatively attached to the body at the fluid port and the second fluid port, wherein the disposable tubing can be removably attached to the hose barbs, and the pressure fluid passageway including a distal end for removable attachment of a sanitary pressure gauge and a biocompatible gauge protector for isolation of the fluid from the sanitary pressure gauge.

Id. at Abstract, 2:44–56.

It explains that to achieve the no dead zone, “the proximal end of the pressure fluid passageway is substantially the same diameter as the distal

end of the pressure fluid passageway, therein providing a total transfer of fluid within the pressure fluid passageway during fluid flow.” *Id.* at Abstract, 2:56–60.

C. Illustrative Claim

Independent claim 1 is illustrative of the claimed subject matter and is reproduced below:¹

1. A disposable sanitary gauge tee with no dead zone for use in pressure measurement of fluid in disposable tubing comprising:

[1.1] a body including a main fluid passageway in fluid connection with a proximal end of a pressure fluid passageway;

[1.2] said main fluid passageway including a fluid port and a second fluid port, wherein a hose barb is operatively attached to said body at said fluid port and said second fluid port, wherein said disposable tubing can be removably attached to said hose barbs;

[1.3] said pressure fluid passageway including a distal end for removable attachment of a sanitary pressure gauge and a biocompatible gauge protector for isolation of said fluid from said sanitary pressure gauge; and

[1.4] said proximal end of said pressure fluid passageway being substantially the same diameter as said distal end of said pressure fluid passageway, therein providing a total transfer of fluid within said pressure fluid passageway during fluid flow.

Ex. 1001, 8:8–28.

¹ For ease of reference, Petitioner’s designations to reference the claim limitations are set forth in brackets. Herein, we refer to the claim limitations using Petitioner’s designations.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1–8	103(a)	Goebel ²
9, 10	103(a)	Goebel, Maurer ³
11	103(a)	Goebel, Maurer, FDA Guide ⁴
1–10	103(a)	Maurer, Milton ⁵
11	103(a)	Maurer, Milton, FDA Guide

Petitioner relies on the Declaration of Lyle W. Clem (Ex. 1003) to support its Petition.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term “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) (2020). Under that standard, the words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner argues that, for purposes of this Decision, no claim term needs specific construction beyond its plain and ordinary meaning. Pet. 7.

² U.S. Patent No. 3,352,158, issued Nov. 14, 1967 (Ex. 1004).

³ U.S. Patent No. 5,644,285, issued Jul. 1, 1997 (Ex. 1005).

⁴ FDA Guide to Inspection of Aseptic Processing and Packaging for the Food Industry, Feb. 2001 (Ex. 1007).

⁵ 2003 Milton Air Accessories and Fittings Catalog (Ex. 1006).

Petitioner, however, seeks to provide “some explanation” of the term “no dead zone,” which appears in the preamble of claim 1 and in claims 9 and 10. *Id.* at 7–8. According to Petitioner, the term at least includes “the two ends of the pressure fluid passageway are ‘substantially the same diameter.’” *Id.* at 8 (quoting Ex. 1001, Abstract, 2:56–60); 19–20, 33. Petitioner also argues that “[t]he phrase ‘with no dead zone’ is functional claiming, imposing no meaningful limitation on the claim.” *Id.* at 12.

Patent Owner does not directly address the meaning of the term “no dead zone;” instead, Patent Owner contends that Petitioner is wrong in “implicitly assert[ing] that the ‘diameter’ of the ‘pressure fluid passageway’ includes an exterior diameter of the pipe (or other structure) forming the fluid passageway.” Prelim. Resp. 8. According to Patent Owner, the “diameter” of the pressure fluid passageway refers to the interior diameter. *Id.* at 8–11.

For purposes of this Decision, we do not need to resolve these issues because, as explained below, Petitioner has failed to sufficiently address other limitations of the challenged claims. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (stating claim terms need only be construed to the extent necessary to resolve the controversy).

B. Level of Ordinary Skill

Petitioner asserts an ordinarily skilled artisan “would have a bachelor’s degree in mechanical engineering, physics, or food science, equivalent professional experience, or a similar level of education in a related field.” Pet. 9. “Graduate education,” Petitioner continues, “may substitute for professional experience or a different undergraduate background and vice versa.” *Id.*

Patent Owner states that for purposes of its Preliminary Response, it does not challenge Petitioner's definition of the skill level. Prelim. Resp. 6. Patent Owner, however, challenges the qualification and impartiality of Petitioner's declarant, Mr. Clem. *Id.* at 6–7.

For purposes of this Decision, we adopt Petitioner's definition of the skill level, as it is consistent with the disclosures of the '825 patent and the prior art of record. We do not need to address Patent Owner's concerns over Mr. Clem's qualification, because even if we give full credit to Mr. Clem's testimony, we find Petitioner has not met its burden for purposes of institution.

C. Alleged Obviousness over Goebel

Petitioner asserts that the challenged claims would have been obvious over Goebel, either alone or in combination with other prior art. Pet. 9–45. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Goebel

Goebel teaches a pressure gauge for pumps. Ex. 1004, 1:16–18.

Figure 2 of Goebel is reproduced below:

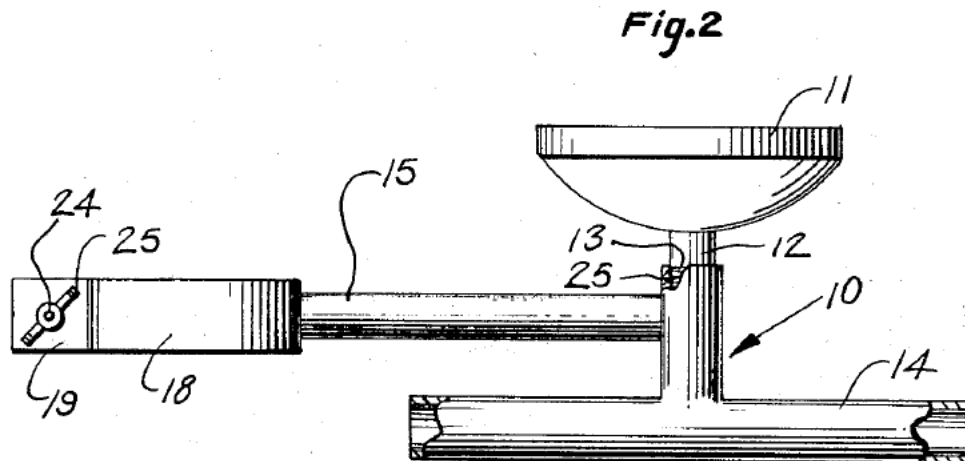


Figure 2 is a side elevational view of Goebel's invention. *Id.* at 1:46.

It shows

[P]ressure gauge 10 is provided with a sensitive air pressure gauging device 11 which is provided with a stem 12 suitably attached to the rear portion of gauging device 11 and being provided with a threaded portion 13. An inverted T-shaped pipe coupling 14 being provided with threaded portion 25 within its lateral extension for admitting the threaded portion[] 13 of stem 12. The longitudinal ends of pipe coupling 14 being adapted for insertion into the openings of pump hose 17 and 16. Hose clamps 20 and 22 are superimposed on the end portions of hose 16 and 17 for firmly securing the longitudinal ends of pipe coupling 14 to hose 16 and 17. An elongated clamp 15 is secured to the lateral portion of pipe coupling 14 by any suitable means, such as, welding.

Id. at 1:47–2:1.

2. Analysis

We focus our analysis on claim 1. Petitioner contends that Goebel teaches or suggests each limitation of claim 1. Pet. 11–20. Patent Owner counters that Petitioner fails to show Goebel teaches limitations [1.2], [1.3], and [1.4]. Prelim. Resp. 15–26. We find persuasive Patent Owner's argument with regard to limitation [1.2]. Because this issue is dispositive in rejecting the Goebel-based grounds, we do not reach Patent Owner's other arguments.

Limitation [1.2] recites “said main fluid passageway including a fluid port and a second fluid port, wherein a hose barb is operatively attached to said body at said fluid port and said second fluid port, wherein said disposable tubing can be removably attached to said hose barbs.” Petitioner argues Goebel teaches a “main fluid passageway,” shown as the inverted T-shaped pipe coupling 14 in Figure 2. Pet. 14 (citing Ex. 1004, 1:52–53,

Fig. 2). Petitioner maps the two claimed fluid ports to the two ends in Goebel's main fluid passageway. *Id.* at 15 (citing Ex. 1004, Fig. 2).

Petitioner acknowledges that Goebel's fluid ports do not include the claimed hose barbs for removably attaching disposable tubing to the barbs. *Id.* But, according to Petitioner, "'hose barbs' were remarkably well-known in application with plastic tubing and hoses." *Id.* (citing Ex. 1003 ¶¶ 94–97); *see also id.* (arguing that barb connections in disposable tubing are well within the knowledge of an ordinarily skilled artisan) (citing Ex. 1003 ¶ 81; Ex. 1006, 24, 34). Indeed, Petitioner points out even the '825 patent itself acknowledges that hose barbs are in the prior art. *Id.* (citing Ex. 1001, 1:34–35).

Accepting that hose barbs were well-known, on this record, we find, as Patent Owner argues, that Petitioner has not explained sufficiently why an ordinarily skilled artisan would have attached hose barbs to the ends of Goebel's pipe coupling 14. *See* Prelim. Resp. 15, 17. Indeed, other than asserting that hose barbs were well-known, Petitioner only refers to Goebel for "indicat[ing] that the hose to which it is connected at each end may be secured using a clamp." Pet. 16 (citing Ex. 1004, 1:60–2:3, claim 3). Without any explanation of its relevance to hose barbs by either Petitioner or Mr. Clem, however, we decline to speculate the significance of this teaching.

Obviousness requires more than a mere showing that each limitation in a challenged claim was independently known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Rather, a patent challenger must articulate a reason why an ordinarily skilled artisan would have modified the prior art. *Id.* at 418. Because Petitioner has failed to articulate a reason to modify Goebel to include the claimed hose barbs, there is no

reasonable likelihood that it would prevail in showing claim 1 and its dependent claims 2–8 would have been obvious over Goebel.

Petitioner contends that claims 9–11 would have been obvious over Goebel in combination with other prior art. Pet. 31–45. Here, Petitioner again relies on Goebel for “disclos[ing] a gauge tee as in claim 1.” *Id.* at 32, 39, 43. For the same reason explained above, there is no reasonable likelihood that Petitioner would prevail in showing claims 9–11 would have been obvious over the asserted Goebel combination.

D. Alleged Obviousness over Maurer and Milton

Petitioner asserts that claims 1–10 would have been obvious over the combination of Maurer and Milton, and that claim 11 would have been obvious over the combination of Maurer, Milton, and FDA Guide. Pet. 46–74. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in these assertions.

1. Prior Art Disclosures

Maurer teaches a pressure sensor die that provides media isolation between a fluid being measured and the internal components of a pressure sensor. Ex. 1005, Abstract. According to Maurer, “[t]he device is particularly useful in conjunction with applications where media isolation is required between the fluid being measured and the components of the pressure sensor, such as kidney dialysis machines.” *Id.*

Figure 14 of Maurer is reproduced below:

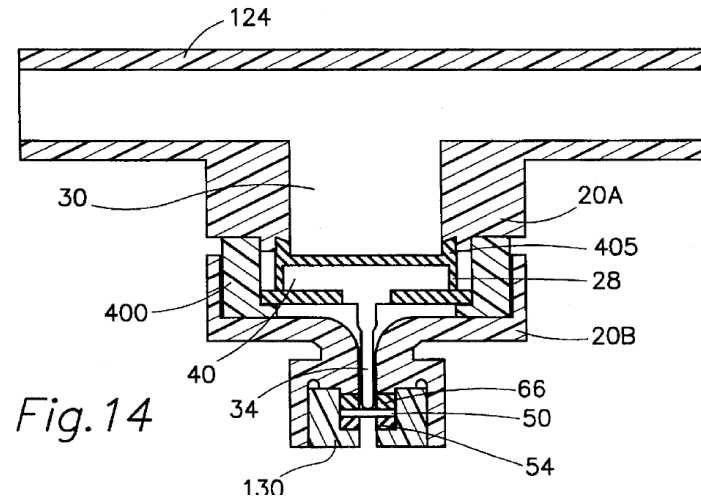


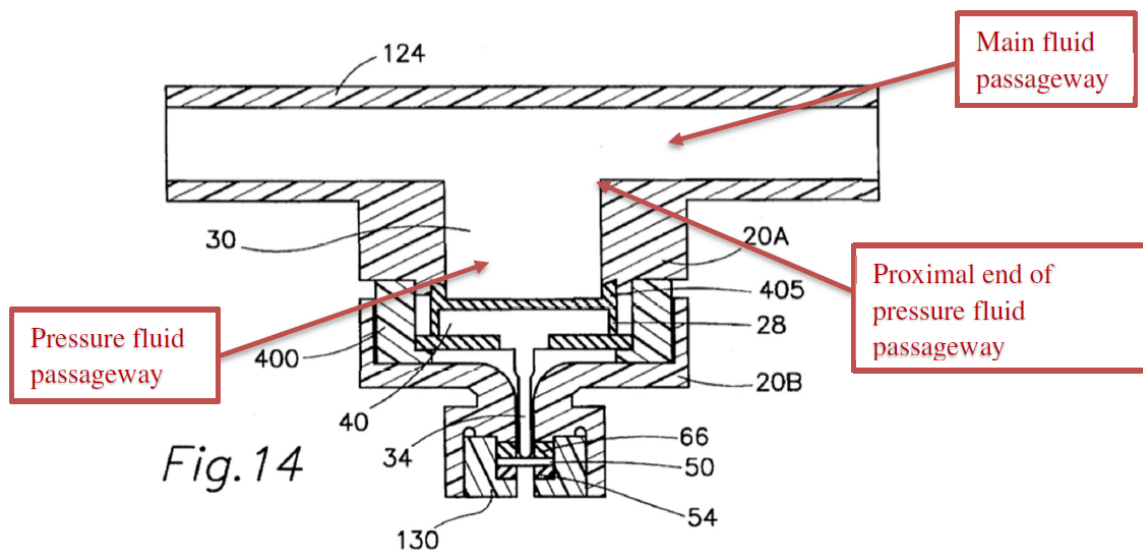
Figure 14 illustrates an embodiment of Maurer. *Id.* at 13:57–58. The device shown therein comprises plunger 34, flexible membrane 28, structure 400 and upper housing portion 20A, which “can possibly be contaminated during use.” *Id.* at 14:8–11. In Maurer, “[t]hose members, as a unitary structure, can be removed from the other components shown in FIG. 14 and washed.” *Id.* at 14:11–13. Put it another way, “[t]he lower housing portion 20B, in which the pressure sensor die 50 and related components are contained, can be removed from the other portions of the system shown in FIG. 14 and attached to another similar structure.” *Id.* at 14:20–24.

Milton is a catalogue of fittings and other components used primarily in the automotive industry related to filling and maintaining automobile tires. Ex. 1006.

2. Analysis

We, again, focus our analysis on claim 1. Petitioner contends that the combination of Maurer and Milton⁶ teaches or suggests each limitation of claim 1. Pet. 47–55. Patent Owner counters that Petitioner fails to show the asserted prior art teaches limitations [1.2] and [1.3]. Prelim. Resp. 30–37. We find persuasive Patent Owner’s argument with regard to limitation [1.2]. Because this issue is dispositive in rejecting the grounds based on Maurer and Milton, we do not reach Patent Owner’s other arguments.

Petitioner maps the structural limitations of claim 1 to the components in the embodiment of Maurer’s Figure 14, as shown below.



The figure above is Maurer’s Figure 14 as annotated by Petitioner. See Pet. 49. Petitioner maps the two claimed fluid ports to the two ends in of the main fluid passageway in Maurer. *Id.* at 50 (citing Ex. 1005, Fig. 14).

⁶ Petitioner relies on Milton primarily “to provide context for readily-known fittings, connections and sizes of tubing components widely in use as of the Priority Date.” Pet. 46.

Petitioner acknowledges that Maurer’s fluid ports do not include the claimed hose barbs for removably attaching disposable tubing to the barbs. *Id.* Petitioner argues here, as it does in the Goebel-based grounds, that “‘hose barbs’ were remarkably well-known in application with plastic tubing and hoses.” *Id.* (citing Ex. 1003 ¶¶ 94–96); *see also id.* at 51 (“Hose barbs were in widespread use, for example, in automotive air systems as of the Priority Date and well before.”) (citing Ex. 1003 ¶ 82; Ex. 1006, 24, 34). Petitioner refers to Milton for teaching that its disposable tubing “[c]an be used with hose barbs.” *Id.* at 51 (quoting Ex. 1006, 82). We are not persuaded by this argument for the same reasons explained above in addressing the Goebel-based grounds. *See supra* Section II.C.2. Furthermore, we are not persuaded by this argument for the following additional reasons.

“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). Thus, even though an ordinarily skilled artisan could have modified Maurer’s fluid ports to include the claimed hose barbs for removably attaching disposable tubing to the barbs, Petitioner has not explained sufficiently why an ordinarily skilled artisan would have done so.

In fact, Petitioner’s argument appears to support the opposite conclusion. According to Petitioner, “barb fittings are known by POSAs to be particularly poorly suited to sterile and aseptic processing because they incorporate pockets where bacteria and contaminants may reside.” *Id.* at 46–47 (citing Ex. 1003 ¶ 96). This statement appears consistent with Maurer’s teaching.

Indeed, Maurer teaches “it is advantageous if the design avoids the creation of cavities or pockets in which contaminated material can collect.” Ex. 1005, 14:16–18. This is especially important because, as Petitioner points out, Maurer envisions using its device “in pressure measurement in kidney dialysis machines.” Pet. 30 (citing Ex. 1005, Abstract, 14:6–20).

Given Maurer’s goal to avoid contamination (*see* Ex. 1005, 1:24–31, 8:33–36, 9:50–56), and Petitioner’s acknowledgement that barb fittings are “particularly poorly suited to sterile and aseptic processing because they incorporate pockets where bacteria and contaminants may reside” (Pet. 46–47), we find Petitioner has not explained sufficiently why an ordinarily skilled artisan would have incorporated hose barbs into Maurer’s device. Thus, there is no reasonable likelihood that Petitioner would prevail in showing claim 1 would have been obvious over Maurer and Milton.

For the other challenged claims, Petitioner relies on the same argument to account for the limitation of hose barbs. Thus, for the same reason explained above, there is no reasonable likelihood that Petitioner would prevail in showing claims 2–11 would have been obvious over Maurer and Milton.

III. CONCLUSION

Based on the current record, and for the reasons explained above, we find Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and we do not institute *inter partes* review of any claim of the '825 patent based on the grounds asserted in the Petition.

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