

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PERMA PURE L.L.C.,  
Petitioner,

v.

MASIMO CORPORATION,  
Patent Owner.

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IPR2019-01583  
Patent 9,861,298 B2

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Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and  
DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

JUDGMENT  
Final Written Decision  
Determining No Challenged Claim Unpatentable  
*35 U.S.C. § 318(a)*

## I. INTRODUCTION

Perma Pure L.L.C. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 2, and 8–13 of U.S. Patent No. 9,861,298 B2 (Ex. 1001, “the ’298 patent”).<sup>1</sup> Paper 4, Corrected Petition (“Pet.”). Masimo Corporation (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).<sup>2</sup> We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that at least one of the challenged claims was unpatentable under 35 U.S.C. § 103(a) as obvious over the cited art. Pursuant to 35 U.S.C. § 314, the Board instituted trial on March 16, 2020. Paper 7 (“Institution Decision” or “Inst. Dec.”).

Following our Institution Decision, Patent Owner filed a Response to the Petition (Paper 9, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 12, “Reply”), and Patent Owner filed a Sur-Reply (Paper 13, “Sur-reply”). On December 15, 2020, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 17 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that claims 1, 2, and 8–13 of the ’298 patent are unpatentable.

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<sup>1</sup> Petitioner identifies Perma Pure L.L.C., a subsidiary of Halma PLC, as the only real party in interest. Pet. 1.

<sup>2</sup> Patent Owner identifies Masimo Corporation as the only real party in interest. Paper 5, 1.

*A. Related Proceedings*

Petitioner represents that it is not aware of any proceedings relating to the '298 patent. Pet. 1. Patent Owner represents that the following patents and patent applications claim priority to, or share a priority claim with the '298 patent: United States Patent Application No. 15/832,658, PCT/SE2009/051012, Swedish Patent No. 532,941, and European Patent No. 2,326,246. Paper 5, 1.

*B. The '298 Patent (Ex. 1001)*

The '298 patent issued January 9, 2018, identifying Anders Eckerbom and Robert Zyzanski as joint inventors. Ex. 1001, code (75). The patent relates to “a gas sampling line having a channel for conducting respiratory gases from a patient respiratory interface to a gas monitor, and to a gas analysis system comprising such a gas sampling line.” *Id.* at 1:5–8.

The '298 patent teaches that “[i]n respiratory care, it is often desirable to analyse and monitor the gas composition of a patient’s exhaled and/or inhaled breathing gases.” Ex. 1001, 1:15–17. This is typically done by “transferring a portion of [a patient’s] breathing gases through a sampling line to a suitable gas sensor or gas monitor.” *Id.* at 1:23–24. However, “[t]he patient’s exhaled breathing gases are usually saturated with moisture,” which may “result in inaccurate readings at the sensor or even adversely affect a delicate gas monitor.” *Id.* at 1:25–32. While the prior art taught various means for separating moisture from the air exhaled by patients (*see, id.* at 1:46–2:12), there was, according to the '298 patent, “a need for improvement of prior art solutions for respiratory gas analysis in respect of, e.g., low distortion, long lasting moisture and/or water removal, or low cost.” *Id.* at 2:13–16.

The '298 patent discloses:

[I]t has been surprisingly found that when passing a sample of respiratory gases through a gas sampling tube comprised of a polyether block amide material, the polyether segments of which comprise polyethyleneoxide, moisture and condensed water present in the gas sample permeate through the tube material to provide a dried gas sample, while components (such as CO<sub>2</sub> or anesthetic agents) of the gas sample passes the tube portion essentially undistorted (i.e. without being absorbed in or adsorbed to the tube material) to allow for an accurate reading at the gas monitor.

*Id.* at 2:62–3:5. Based on this discovery, the '298 patent discloses “a gas sampling line . . . for conducting respiratory gases from a patient respiratory interface to a gas monitor . . . comprising . . . a gas sampling tube . . . of polyether block amide material, the polyether segments of which comprise polyethyleneoxide.” *Id.* at 2:49–61.

### C. *Challenged Claims*

Petitioner challenges claims 1, 2, and 8–13 of the '298 patent.

Claim 1 is representative and is reproduced below.

1. A gas sampling line having a channel for conducting respiratory gases from a patient respiratory interface to a gas monitor, the gas sampling line comprising:
  - a patient respiratory interface connector adapted to couple the gas sampling line to a patient respiratory interface;
  - a gas sampling tube adapted to conduct respiratory gases;and
  - a gas monitor connector adapted to couple the gas sampling line to a gas monitor,
  - wherein the gas sampling tube is comprised of a first polyether block amide material, wherein the first polyether block amide material comprises polyether segments and polyamide segments in a ratio of polyether to polyamide from about 60:40 to about 40:60, and the polyether segments comprise polyethyleneoxide; and

wherein a CO<sub>2</sub> component of the respiratory gases passes the gas sampling tube without being absorbed in or adsorbed to the tube material to allow for an accurate reading at the gas monitor.

Ex. 1001, 8:39–58.

*D. The Asserted Ground of Unpatentability*

Petitioner challenges the patentability of claims 1, 2, and 8–13 of the '298 patent on the following ground:

<b>Claim(s) Challenged</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>
1, 2, 8–13	§ 103(a) <sup>3</sup>	Norlien, <sup>4</sup> Sijbesma <sup>5</sup>

Petitioner submits the Declaration of Dr. Zane N. Frund (Ex. 1002) in support of the Petition. Patent Owner submits the Declaration of Mr. Len Czuba (Ex. 2002).

*E. Person of Ordinary Skill in the Art*

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071

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<sup>3</sup> The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '298 patent issued was filed before this date, the pre-AIA version of § 103 applies.

<sup>4</sup> Norlien et al., U.S. Patent No. 5,042,500, issued Aug. 27, 1991 (“Norlien”) (Ex. 1003).

<sup>5</sup> Sijbesma et al., *Flue Gas Dehydration Using Polymer Membranes*, 313 J. of Membrane Science 263–276 (2008) (“Sijbesma”) (Ex. 1004).

(Ct. Cl. 1975); *see also Orthopedic Equip. Co., v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner contends that the person of ordinary skill in the art (“POSA”) would be “a person holding a Bachelor of Science degree in an engineering discipline, most appropriately chemical engineering or mechanical engineering, or the equivalent knowledge gained through employment or other type of degree, and 3–5 years of experience in the field.” Pet. 6; Ex. 1002 ¶ 16 (Frund Declaration repeating same). Patent Owner contends that the POSA would be “a person holding a Bachelor of Science degree in an engineering discipline, such as chemical engineering or mechanical engineering, or the equivalent knowledge gained through employment or other type of degree, and 3-5 years of experience in the field of respiratory sampling or other relevant medical devices.” PO Resp. 19; Ex. 2002 ¶ 33 (Czuba Declaration repeating same).

These definitions differ in two ways. First, when discussing types of engineering degrees held by the POSA, Patent Owner’s definition substitutes “such as” in place of “most appropriately” in the phrase “most appropriately chemical engineering or mechanical engineering.” Second, Petitioner’s definition leaves the relevant field unspecified while Patent Owner’s definition specifies that the field is “respiratory sampling or other medical relevant devices.” We do not discern, and the parties do not argue, that either of the differences between these definitions impact our analysis in any way.

Both definitions are consistent with the level of skill reflected in the asserted prior art references and in the specification of the ’298 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art

itself can reflect the appropriate level of ordinary skill in the art). We adopt Patent Owner’s definition because it is more precise. In this regard, we note that Patent Owner’s definition of the relevant field is consistent with the field expressly identified in the ’298 patent and with the field implicitly proposed by Petitioner. Ex. 1001, 1:5–11 (portion of the ’298 patent defining the “technical field,” identifying the invention as relating to sampling respiratory gases); Pet. 13 (arguing that a POSA “would have known to look to other fields outside of respiratory sampling when looking to select a polymeric material for drying a gas stream”).

#### *F. Claim Construction*

We construe claims “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 (2019). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.* Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). For purposes of this decision, we determine that no claim terms require express construction.

## II. ANALYSIS

Petitioner asserts that claims 1, 2, and 8–13 of the '298 patent would have been obvious over the combination of Norlien and Sijbesma. Pet. 9–26. Patent Owner opposes. *See generally*, PO Resp. This case turns on whether Petitioner has carried its burden to establish that the POSA would have considered Sijbesma to be analogous art for purposes of determining whether the challenged claims would have been obvious. We have reviewed Petitioner's and Patent Owner's assertions, as well as the evidence of record. For the reasons discussed below, we conclude that Petitioner has not carried its burden to establish Sijbesma is analogous art, and thus, Petitioner has not established that claims 1, 2, and 8–13 of the '298 patent would have been obvious over the combination of Norlien and Sijbesma.

### A. *Disclosure of Sijbesma*

Sijbesma discloses that “[c]oal-fired power plants produce . . . large volume flows of flue gas.” Ex. 1004, Abstract. “To prevent condensation of the water present in this flue gas stream, water has to be removed before emission to the atmosphere.” *Id.* Sijbesma discloses the use of membranes to remove water from flue gas. *Id.* According to Sijbesma, simulations indicate that it is important that the membrane material have “very high water vapor permeabilities combined with very low inert gas fluxes.” *Id.* Inert gases produced in connection with flue gas include N<sub>2</sub>, O<sub>2</sub>, and CO<sub>2</sub>. *Id.* at 263. Sijbesma “identified and characterized” “[t]wo promising membrane materials (PEBAX<sup>®</sup> 1074 and sulfonated poly(ether ether ketone) (SPEEK)) . . . with respect to their mixed nitrogen and water vapor permeation properties.” *Id.* at 264.

*B. Applicable Legal Principles*

“To be considered within the prior art for purposes of the obviousness analysis, a reference must be analogous.” *Circuit Check Inc., v. QXQ INC.*, 795 F.3d 1331, 1335 (Fed. Cir. 2015). Whether a prior art reference is analogous is question of fact. *Id.* “Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992).

*C. Determination of Whether Sijbesma is in the Same Field of Endeavor as the '298 patent*

The '298 patent identifies the “technical field” of the invention as relating to “the use of a tube for sampling of respiratory gases, and to a method for sampling of respiratory gases.” Ex. 1001, 1:5–11. Sijbesma describes a study regarding “the viability of flue gas dehydration” using polymer membranes for flue gas from “[c]oal-fired power plants.” Ex. 1004, Abstract. Accordingly, Sijbesma is not directed to the same field of endeavor as the '298 patent. Petitioner does not contend otherwise. Pet. 13 (arguing that a POSA “would have known to look to other fields outside of respiratory sampling when looking to select a polymeric material for drying a gas stream”); *see also*, PO Resp. 25 (asserting that “Petitioner does not argue Sijbesma is from the same field of endeavor as the '298 Patent”); Sur-reply 2–13 (presenting arguments that Sijbesma is “reasonably pertinent” without challenging Patent Owner’s assertion that “Petitioner

does not argue Sijbesma is from the same field of endeavor as the '298 Patent”).

*D. Determination of whether Sijbesma is Reasonably Pertinent to the Problem Faced by the Inventors*

1. Identification of the Problem Faced by the Inventors

We begin our analysis of whether Sijbesma is “reasonably pertinent” by considering the problem addressed by the inventors of the '298 patent. Petitioner contends that the problem faced by the inventors was removing water from a gas stream. Reply 4–5 (“Like the '298 patent, Sijbesma’s problem is ‘To prevent condensation of the water vapor present in this flue gas stream, water has to be removed before the emission [of the gas].’”); 7 (“Sijbesma and the '298 patent are both directed to drying a gas stream”). Patent Owner contends that Petitioner oversimplifies the problem, explaining that the “prior art in the field of the '298 Patent already taught ‘drying a gas stream.’” Sur-reply 3. According to Patent Owner, the problem faced by the inventors was to dry a gas stream while “preventing distortion of the gas sample during a drying process.” *Id.* at 3–4; *see also*, PO Resp. 23–24. Having considered the arguments presented and the evidence of record, we agree with Patent Owner that the problem faced by the inventors of the '298 patent was not merely drying a gas stream, but doing so without distorting the gas to be analyzed.

This is consistent with the disclosure of the '298 patent, which identifies as a problem, not only the presence of moisture in exhaled respiratory gases, but also the potential distortion of the gas to be analyzed as it is transmitted to the gas monitor. For example, in discussing the

“Background Art,” the specification teaches that exhaled gases may be distorted by “adsorption on and/or absorption in the tube material of one or more components of the gas sample.” Ex. 1001, 1:37–40. The specification further teaches that this distortion is a problem because “[t]he accuracy of the gas concentrations obtained from a respiratory gas monitor . . . depends on the ability of the analyser system to direct the gas sample from the patient, through the tube of a sampling line to the gas sensor, without distorting the gas sample flow.” *Id.* at 1:33–37; *see also, id.* at 1:42–45 (“Distortion of the gas sample flow, regardless of cause, can degrade rise time of the measured waveform making accurate analysis, especially at higher breath rates, difficult or impossible.”).

After discussing the problem of sample distortion and the problem of removing moisture from exhaled respiratory gas, the specification identifies a need for *both* removing moisture and avoiding distortion of the gas to be analyzed. It states: “there is a need for improvement of prior art solutions for respiratory gas analysis in respect of, e.g., low distortion, long lasting moisture and/or water removal or low cost.” Ex. 1001, 2:13–16; *see also, id.* at 1:52–54 (stating that means for separating moisture were known and describing “[t]he challenge” as being “to design such a water trap or moisture separation means that achieves sufficient efficiency and capacity without distorting the gas sample flow”).

Finally, after discussing the problems presented in the prior art, the ’298 patent describes the objects of the invention as including both avoiding distortion and removing water. It states:

An object of the present invention is to provide means for sampling of respiratory gases from a patient while protecting a gas monitor from moisture and/or water as well as providing a

reading of high accuracy of gas components, including air gases, such as CO<sub>2</sub>, N<sub>2</sub>O and anesthetic agents. Thus, it is an object of the invention to allow for a signal having a **low distortion**, particularly in a low flow gas sample and/or a gas sample from a patient having a high breath rate.

\* \* \*

A further object of the present invention is to provide means of low material and production cost fulfilling the mentioned aspects of moisture and/or water removal as well as **accurate gas component reading**.

*Id.* at 2:20–39 (emphasis added).

Petitioner contends, however, that the testimony of Patent Owner’s expert, Mr. Czuba supports that the problem solved by the ’298 patent was simply removing moisture from respiratory gas. Citing paragraph 36 of Mr. Czuba’s declaration, Petitioner argues:

Patent Owner’s own expert, [Mr.] Czuba, characterizes the problem to which the invention claimed in the ’298 patent is directed as follows:

Liquid water that has condensed in a gas sampling line can result in inaccurate readings from the gas monitor and can also cause damage to the gas monitor . . . for this reason, moisture must be removed from the patient’s exhaled breath before it reaches the gas monitor. (Ex. 2002, ¶ 36).

Reply 4. Petitioner also argues that “[w]hen asked at deposition ‘what problem in your opinion did the ’298 patent solve,’ Mr. Czuba reconfirmed that the ’298 patent provided ‘a way to remove moisture from an airstream that could be used both economically [with high functionality] and efficien[cy].’” *Id.* (bracketed text added to correct errors and omissions in Petitioner’s quotation of Mr. Czuba’s testimony (*see* Ex. 1027, 59:12–18 (Mr. Czuba’s actual testimony))).

Although Petitioner is correct that paragraph 36 of Mr. Czuba's declaration discusses the need to remove moisture from a patient's breath, Petitioner omits to mention that paragraph 37, the very next paragraph of Mr. Czuba's declaration, discusses the importance of not distorting the gas sample while extracting moisture. It states that "to ensure accurate readings from the gas monitor, the gas sampling line must not distort the sample flow" and explains that in view of this, there was a "need at the time of the invention for an improved gas sampling line that would remove the moisture from the gas sample and would not distort the gas sample." Ex. 2002 ¶ 37.

Petitioner similarly omits to discuss Mr. Czuba's unequivocal testimony that "the challenge addressed by the '298 Patent was to design a gas sampling line to remove as much water vapor as possible from the gas sample without distorting any of the gases to be analyzed." *Id.* ¶ 69. Particularly when considered together with this testimony, Mr. Czuba's deposition testimony that the '298 patent provides a way to remove moisture "economically with high functionality and efficiency" (Ex. 1027, 59:12–18) does not support broadening the problem faced by the inventors of the '298 patent to just removing moisture from a gas stream. Indeed, viewed in the context of Mr. Czuba's full testimony, we understand his reference to "high functionality" to refer to the need not to distort the gas sample so as to allow an accurate measurement. *See*, Ex. 1027, 95:17–96:3.

In sum, the evidence of record, including both the '298 patent and Mr. Czuba's testimony regarding the '298 patent, supports that the problem faced by the inventors was not just removing moisture from a stream of gas, as argued by Petitioner, but instead was removing moisture from exhaled respiratory gas without distorting the gas to be analyzed.

2. Determination of whether Sijbesma would “logically have commended itself to an inventor’s attention”

“A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d at 659.

Petitioner contends that the Sijbesma would have commended itself to an inventor’s attention because: 1) it relates to polymer membranes that were used across a variety of industries to separate gases; 2) it addresses the same problem as faced by the inventors of the ’298 patent; 3) Mr. Czuba testified that PEBAX 1074 was known to be used to manufacture tubing for similar purposes; and 4) Mr. Czuba testified that he would have consulted general information available regarding the properties of various polymers.

Patent Owner contends that Petitioner has not carried its burden to establish that Sijbesma is reasonably pertinent. In addition, Patent Owner points to the testimony of Mr. Czuba that POSAs generally do not consult materials outside the field of medical devices for information about polymers. Patent Owner also identifies a number of differences between the problems faced in Sijbesma, and those faced by the inventors of the ’298 patent that, Patent Owner contends, would have discouraged an inventor from considering Sijbesma in trying to solve the problem faced by the inventors.

Having considered the arguments presented and the evidence of record, we find that the preponderance of the evidence of record supports

that the subject matter with which Sijbesma deals would not logically commend Sijbesma to the inventors' attention in considering their problem.

*a. Evidence identified by Petitioner*

Petitioner presents four arguments as to why Sijbesma is analogous art. Reply 3–13. We address each argument in turn.

First, Petitioner argues that “the prior art explicitly recognized that ‘[p]olymeric membranes are used widely for both gas and liquid phase separations in industries ranging from the chemical and petrochemical sectors to the food processing, water purification, and medical fields’ (Ex. 1021, 2) and thus, a POSITA would have known to look to other fields outside of respiratory sampling when looking to select a polymeric material for drying a gas stream.” Pet. 13.

We agree that the known use of membranes in a wide range of applications provides reason for a POSA considering using a membrane to separate gas for respiratory sampling to look outside the respiratory gas analysis field. Accordingly, we give this evidence weight in our evaluation of whether Sijbesma is analogous art. The weight we give this evidence, however, is somewhat diminished by the absence of evidence specific to whether a POSA would consider Sijbesma. In particular, Petitioner does not direct us to persuasive evidence that the “other fields” a POSA would have looked to when selecting a polymeric material include the field of dehydrating flue gas in coal-fired power plants.

Petitioner's second argument is that Sijbesma is analogous art because it is “directed to the exact same problem” as the '298 patent – drying a gas stream. Reply 4; *see also*, Pet. 13 (arguing that “[b]oth Sijbesma and Norlien are directed to the problem of drying a gas stream”) (emphasis omitted). Petitioner further argues that Sijbesma “teaches a solution to this

problem” – the use of membrane technology to selectively remove water vapor from gas streams. Reply 5. We do not find this argument persuasive because it is premised on limiting the “problem” to just drying gas. For the reasons discussed above, we find that the problem faced by the inventors was not just removing moisture from exhaled respiratory gas, but doing so without distorting the gas to be analyzed.

We recognize that flue gas dehydration arguably relates to one aspect of the problem to be solved – drying a gas stream. However, the evidence of record supports that this aspect of the problem had already been solved and that the aspect of the problem not implicated by flue gas dehydration – i.e. avoiding gas distortion – was the crux of the problem faced by the inventors. For example, the ’298 patent teaches that “water trap[s]” and “moisture separation means” were known, but “[t]he challenge . . . is to design . . . a water trap or moisture separation means that achieves sufficient efficiency and capacity without distorting the gas sample flow.” Ex. 1001, 1:49–54. And Mr. Czuba identifies Sijbesma’s indifference to gas distortion and the absence of a need to analyze the gas stream as one of “numerous differences” that are “so significant that a skilled artisan would not have believed the reference would be helpful for solving the problems faced by the ’298 Patent’s inventors.” Ex. 2002 ¶ 72. Accordingly, while we recognize that Sijbesma might arguably relate to one aspect of the problem faced by the inventors, we give relatively little weight to Petitioner’s incorrect assertion that Sijbesma is “directed to the exact same problem” as the ’298 patent. *In re Clay*, 966 F.2d at 658–59 (explaining that a reference is analogous if it is “reasonably pertinent to the *particular problem* with which the inventor is involved”) (emphasis added); *Circuit Check Inc.*, 795

F.3d 1331 at 1335 (rejecting notion that reference is analogous art because it is “within the common knowledge of humankind” and explaining that “the question is whether an inventor would look to this *particular* art to solve the *particular* problem at hand”) (emphasis added).

Petitioner’s third argument relies on a combination of Mr. Czuba’s declaration and deposition testimony to support the conclusion that PEBAX 1074 was “the perfect material to use in Norlien’s application – removing moisture from a gas stream without removing significant CO<sub>2</sub>.” Reply 5–6. Specifically, in his declaration Mr. Czuba testified that “[o]ne of skill in the art designing a respiratory sampling line such as the respiratory sampling line disclosed in the ’298 Patent would have had...a general knowledge regarding materials used to manufacture tubing used for similar purposes.” Ex. 2002 ¶ 61. And in his deposition, Mr. Czuba testified that the “materials . . . used for similar purposes” include PEBAX 1074. Ex. 1027, 51:15–52:21. We do not find this argument persuasive.

As an initial matter, Petitioner does not present a ground that the challenged claims would have been obvious over the combination of Norlien and a general knowledge in the art that PEBAX 1074 was used to manufacture tubing used for similar purposes. Rather, Petitioner argues that the challenged claims would have been obvious over the combination of Norlien and Sijbesma. Petitioner does not articulate how Mr. Czuba’s cited testimony relates to its argument that Sijbesma is analogous art. *See* Reply 6. More particularly, Petitioner does not provide persuasive argument or evidence explaining how the existing “general knowledge” of the use of PEBAX 1074 “to manufacture tubing used for similar purposes” makes a reference discussing PEBAX 1074 – i.e., Sijbesma – reasonably pertinent to

the particular problem with which the inventors were involved. Absent such explanatory argument or evidence, it is not clear how the cited testimony establishes that Sijbesma is analogous art.

The problem presented by the absence of explanatory argument or evidence is highlighted when one specifically considers what the “general knowledge” of PEBAX 1074 “to manufacture tubing used for similar purposes” comprises. The evidence of record, other than Sijbesma, reflects one known use of PEBAX 1074 in “tubing used for similar purposes” – as one component of tubes for catheters. *See* Ex. 1005 ¶¶ 3, 81, Table 1; Ex. 1006, 4:16–45. The question raised by Mr. Czuba’s testimony is thus: would the general knowledge that PEBAX 1074 had been used in catheter tubing commend Sijbesma to an inventor’s attention in considering the problem of drying respiratory gas without distortion? Although catheter tubing is in the field of medical devices, its purpose seems remote from both respiratory sampling and flue gas dehydration. The purpose of a catheter tube is to convey liquid from one point to another (*see* Ex. 1005 ¶ 1 (“The present invention relates to a conduit device for conducting fluid from a fluid source to a recipient.”)), while the purpose of a respiratory sampling tube is to extract water from exhaled breath without distorting the gases in the breath. Petitioner does not provide persuasive argument or direct us to persuasive evidence explaining how or why use of PEBAX 1074 as a catheter tube would commend a reference relating to flue gas that mentions PEBAX 1074 to an inventor’s attention.

The evidence of record also includes a brochure reflecting that PEBAX 1074 was known to be used as a film that provides “waterproof barrier protection” in applications such as surgical gowns and gloves,

mattress covers, medical adhesives, and baby diapers. Ex. 1011.

Considering Mr. Czuba's testimony in context, it appears he may have been referring to these uses when he called out PEBAX 1074 as one of the materials he was referring to in paragraph 61 of his declaration. Ex. 1027, 51:15–52:21. Immediately after testifying in paragraph 61 of his declaration that the POSA would have had “knowledge of prior art respirator sampling designs and a general knowledge regarding materials used to manufacture tubing used for similar purposes,” Mr. Czuba explained, in paragraph 62, what he meant by “general knowledge regarding materials.” Ex. 2002 ¶¶ 61, 62). Mr. Czuba testified:

The general knowledge regarding materials possessed by one of skill in the art would have included knowledge of similar medical devices, and information available from suppliers of materials and/or components used in medical devices. An example of such literature from a supplier would be the PEBAX® brochure, which is Exhibit 1011 of the Petition.

*Id.* ¶ 62. The example reflecting the “general knowledge” that Mr. Czuba provides is the brochure discussed above, reflecting the use of PEBAX 1074 as a film that provides “waterproof barrier protection.” *See* Ex. 1011.

If the knowledge in this brochure is the “general knowledge” Mr. Czuba was referring to, it is no more helpful to Petitioner's analogous art argument than the knowledge that PEBAX 1074 had been used in catheters. As with the use of PEBAX 1074 in catheter tubes, there is no evidence that the use of PEBAX 1074 in surgical gowns and gloves, mattress covers, medical adhesives, and baby diapers (Ex. 1011) would commend a reference involving flue gas dehydration that mentions PEBAX 1074 to an inventor's attention.

Petitioner does not argue, and the record does not support, that Mr. Czuba's testimony regarding "general knowledge" of PEBAX 1074 "to manufacture tubing used for similar purposes" includes knowledge beyond the use of PEBAX 1074 in catheters or as a film that provides "waterproof barrier protection." *See*, Reply 5–6 (citing references showing use of PEBAX 1074 in catheters as evidence that "the use of PEBAX 1074 in medical tubing was well known," and then arguing that Mr. Czuba's testimony on the "general knowledge" of PEBAX 1074 "to manufacture tubing used for similar purposes" "firmly supported" this); *id.* at 7 (summarizing Petitioner's analogous art argument, as it relates to Mr. Czuba's testimony, by arguing that Sijbesma is analogous art because PEBAX 1074 was "widely known as a polymer suitable for medical use according to numerous prior art references and the Patent Owner's own expert"). As the record does not include persuasive evidence or argument connecting the POSA's "general knowledge" of PEBAX 1074 "to manufacture tubing used for similar purposes" to a reason an inventor would have consulted a reference relating to flue gas dehydration that mentions PEBAX 1074, we give relatively little weight to Petitioner's argument and evidence that the cited portion of Mr. Czuba's testimony establishes that Sijbesma is analogous art.

Petitioner's fourth and final argument is that Sijbesma is analogous art because Mr. Czuba testified that the POSA would have "consulted general information available regarding the properties of various polymers and their uses . . . involving medical devices" and later testified that PEBAX 1074 was among the polymers the POSA would have investigated. Reply 6. (citing Ex. 2002 ¶¶ 61, 63). Petitioner points out that Mr. Czuba further

testified that a POSA would quickly eliminate unsuitable polymers leaving polymers like Nafion, PEBAX 1074, and SPEEK as candidate polymers. *Id.* (citing Ex. 1027, 55:18–57:19). Finally, Petitioner points to Mr. Czuba’s testimony that once the POSA identified PEBAX 1074 as a candidate polymer, they “would simply have tested the material to determine whether it fit the requirement.” *Id.* (citing Ex. 2002 ¶ 90). We do not find this argument persuasive.

Although Mr. Czuba did testify that the POSA would have “consulted general information available regarding the properties of various polymers” (Ex. 2002 ¶ 63), Petitioner does not identify, and we do not find, anything in the record to support that this general information would have included Sijbesma. To the contrary, Mr. Czuba expressly testified that the general information a POSA would have consulted would not include Sijbesma. *Id.* ¶ 61 (“The skilled artisan . . . would not have considered an article like Sijbesma.”), *id.* ¶ 64 (“In my opinion, a skilled artisan would not have done an exhaustive search through the literature—especially literature in remote fields—in an attempt to identify the relevant properties of any plausible polymer that could be useful.”), *id.* ¶ 65 (“In my opinion, a skilled artisan would be expected to look towards references in the medical device field, but would not look to references such as Sijbesma to understand properties of potential materials.”); *see also, id.* ¶¶ 67–81 (identifying specific differences that Czuba considered “so significant that a skilled artisan would not have believed the reference would be helpful for solving the problems faced by the ’298 patent’s inventors”).

Similarly, Mr. Czuba did testify the POSA would have looked at the universe of polymers that were available and “quickly eliminate[d] virtually

95% of all polymers out there,” leaving behind a universe of polymers, including PEBAX 1074, that “have high permeability to moisture or water, [and] high diffusivity.” Ex. 1027, 57:7–19. However, absent evidence that the POSA would have consulted Sijbesma, or a reference like Sijbesma, to narrow the universe of polymers, this testimony does little to establish that Sijbesma is analogous art. Simply put, the relevant question is whether Sijbesma logically would have commended itself to an inventor’s attention. In considering this question, we find little relevance in evidence regarding how quickly the POSA would have narrowed the universe of polymers or what the POSA would have done once that universe was narrowed.

Having considered the evidence offered by Petitioner, we turn now to the evidence and arguments provided by Patent Owner as to why Sijbesma is not reasonably pertinent to the particular problem with which the inventors were involved.

*b. Evidence identified by Patent Owner*

Patent Owner argues that generally speaking, a POSA would not have looked outside the field of medical devices for information on polymers. PO Resp. 29. As support, Patent Owner relies on the testimony of Mr. Czuba, who testifies that the POSA would have consulted “general information available regarding the properties of various polymers and their uses in the medical device industry” but, “given the vast number of polymers that could be used in the medical device industry,” it would have been an “enormous task even for someone with large resources” to “track[] down the relevant properties of each and every potential compound.” Ex. 2002 ¶¶ 63, 64. Mr. Czuba further testifies that the “vast majority of people who work in the medical device industry – including those with more than 3–5 years of

experience – typically are not familiar with the state of the art regarding polymers used in the industry and are not comfortable making decisions based on information gleaned from uses in different fields.” *Id.* ¶ 65.

Mr. Czuba thus concludes that “a skilled artisan would be expected to look towards references in the medical device field, but would not look to references such as Sijbesma to understand properties of potential materials.” *Id.*

Although Mr. Czuba’s testimony on this point is largely unsupported by citation to corroborating sources, it is reasonable, within the scope of his unchallenged expertise, and unrebutted. Accordingly we give Mr. Czuba’s testimony on this point some weight, albeit modest, in our determination of whether Sijbesma constitutes analogous art.

Patent Owner also supports its argument that Sijbesma is not reasonably pertinent with testimony specific to Sijbesma’s disclosure. PO Resp. at 29–35. In particular, Patent Owner argues that “numerous key differences [between the ’298 patent and Sijbesma] would have precluded a skilled artisan from having any interest in reviewing the teachings of a flue gas reference like Sijbesma.” *Id.* Petitioner does not dispute the facts described by Patent Owner as to how Sijbesma’s flue gas dehydration differs from the respiratory gas analysis taught in the ’298 patent. Nor does Petitioner present testimony rebutting the conclusions Mr. Czuba draws from these facts. Instead, Petitioner presents arguments that the differences between Sijbesma and the ’298 patent do not affect the obviousness analysis. We address each of the four differences identified by Patent Owner, and Petitioner’s arguments regarding these differences, in turn.

The first “key difference” Patent Owner identifies is that “unlike the ’298 Patent, Sijbesma does not involve the monitoring, measurement, or analysis of gas streams generally.” *Id.* at 30. In Sijbesma, “the gases that remain in Sijbesma’s stack . . . are released to the environment” without analysis. *Id.* at 31. Patent Owner cites the testimony of Mr. Czuba to explain why this is important. Mr. Czuba explains that “because there is no ‘analysis’ there is also no concern expressed in Sijbesma for avoiding distortion of the gas sample.” Ex. 2002 ¶ 73. According to Mr. Czuba, not only is Sijbesma unconcerned with avoiding distortion, “it determines that the partial removal of CO<sub>2</sub> could be beneficial.” *Id.* (citing Ex. 1004, 263).

Petitioner argues that the fact that Sijbesma does not involve analyzing gas steams is of no moment because “[t]hose elements are all already in Norlien.” Reply 8. We do not find this persuasive because it does not address the issue of whether Sijbesma is analogous art. Put another way, we must first determine that Sijbesma is analogous art before we consider whether the combined teachings of Norlien and Sijbesma render the challenged claims obvious. *Circuit Check*, 795 F.3d at 1335 (“To be considered within the prior art for purposes of the obviousness analysis, a reference must be analogous.”). As discussed above in connection with identifying the problem to be solved, avoiding gas distortion is fundamental to the ’298 patent. Accordingly, as the record lacks persuasive evidence or argument to the contrary, we find the difference from the ’298 patent that Sijbesma does not analyze the gas stream it dries to be significant and give it substantial weight in our determination of whether Sijbesma constitutes analogous art.

The second “key difference” identified by Patent Owner is that the dehydration that occurs in flue gas is different than that required in respiratory sampling. Thus, according to Patent Owner, “the inventors of the ’298 Patent were faced with the problem of taking exhaled air with approximately 6% water and removing as much of the water as possible,” while the authors of Sijbesma “set a goal of removing only 18%” of the water vapor from a flue gas stream containing 11.2% water. PO Resp. 31. Patent Owner concludes that “[t]he partial dehydration of flue gas [in Sijbesma] would still yield a gas stream that has 50% greater percentage of water vapor present than the exhaled air the inventors of the ’298 Patent sought to effectively completely dehydrate.” *Id.* at 32. Patent Owner supports this argument with citations to Sijbesma, the ’298 patent, and the testimony of Mr. Czuba. PO Resp. 31–32 (citing Ex. 1001, 2:20–24; Ex. 1004, 264, 265 (Table 2); Ex. 2002 ¶¶ 74–75, 78).

Petitioner argues that the POSA would “clearly have known that the specific amount of moisture removed in any particular application would have to be determined based upon parameters such as the length and thickness . . . of the tube, temperature, etc.” Reply 10 (citing Ex. 1007, 902–903). We recognize that the POSA could likely have varied the amount of moisture removed from exhaled air by varying the length or thickness of the tube,<sup>6</sup> and that this supports that the POSA would not have excluded from consideration a reference in which the amount of water removed differs from that required for respiratory sampling. Nonetheless, the considerable difference in requirements for removing moisture from flue gas as compared

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<sup>6</sup> It is not clear how the Petitioner proposes the POSA would have varied the temperature, as air is typically exhaled from patients at 98.6° F (*see* Ex. 2002 ¶ 75) and Petitioner does not discuss heating or cooling exhaled air.

to removing moisture to analyze respiratory gas lends some support to Patent Owner's argument that an inventor would not have considered Sijbesma "reasonably pertinent" to the problem faced by the inventors.

The third "key difference" identified by Patent Owner is that "the type of membrane used in Sijbesma is significantly different than the type of tubing a skilled artisan would have considered for a gas sampling line." PO Resp. 32. Patent Owner cites the testimony of Mr. Czuba, who explains that while Sijbesma uses composite hollow fibers coated with a 2–5  $\mu\text{m}$  polymer membrane, the '298 patent employs a simple tube that is 0.75 mm thick to convey and dry a gas sample. Ex. 2002 ¶ 81. Mr. Czuba opines that "[a] skilled artisan considering appropriate tubing for use in a gas sampling line (with a thickness of 0.75 mm) would not have believed the properties of a 2–5  $\mu\text{m}$  thick coating would be relevant." *Id.* In addition, in Sijbesma, each fiber is coated with membrane material and a vacuum system draws moisture through the membrane. *Id.* ¶ 80, 81. Mr. Czuba points to the teaching in the '298 patent that "[a]ny physical obstacles in the gas sample line, such as valves or even material seams, can distort the gas flow, which may cause the gas monitor's readings to be inaccurate." *Id.* ¶ 80 (citing Ex. 1001, 1:40–45). Mr. Czuba then explains that "the membrane system described in Sijbesma is itself a physical obstacle" that would "distort the gas stream." *Id.*

Petitioner argues that "the obviousness issue does not depend upon whether Sijbesma's hollow tubes can be physically installed into Norlien." Reply 11. According to Petitioner, "the question is whether the teaching of Sijbesma to use PEBAX® 1074 to remove moisture from a gas stream would render it obvious to make Norlien's tubing from PEBAX® 1074 instead of

from Nafion.” *Id.* We do not find this argument persuasive because it presupposes that Sijbesma is analogous art and thus available to be used in combination with Norlien in analyzing whether the challenged claims would have been obvious. As discussed above, we must first determine that Sijbesma is analogous art before we consider whether the combined teachings of Norlien and Sijbesma render the challenged claims obvious. *Circuit Check*, 795 F.3d at 1335 (“To be considered within the prior art for purposes of the obviousness analysis, a reference must be analogous.”). As the record lacks persuasive evidence or argument to the contrary, we find the difference in the type of membrane used supports that Sijbesma is not reasonably pertinent and is entitled to some weight in our determination of whether Sijbesma constitutes analogous art.

The fourth and final “key difference” identified by Patent Owner is that the “operating conditions are completely different.” PO Resp. 33. Patent Owner summarizes that, as compared to respiratory sampling, Sijbesma’s flue gas line: “(1) operates at a significantly higher volume; (2) operates at a significantly higher temperature; (3) includes the presence of ‘aggressive compounds’; and (4) includes the presence of ‘fly ash dust and/or gypsum crystals.’” *Id.* at 33–34. Patent Owner’s argument on this point is supported by citation to Sijbesma and to the testimony of Mr. Czuba, who testifies that the “aggressive compounds” include “compounds that can corrode the power plant’s stack such as hydrochloric and hydrofluoric acid.” Ex. 2002 ¶ 76. Indeed, Patent Owner points out that “the tested conditions were so harsh in Sijbesma that ‘the ventilator to supply the flue gas was broken several times during the field test due to the aggressive environment.’” PO Resp. 34 (citing Ex. 1004, 272; Ex. 2002

¶ 76). Finally, Patent Owner cites Mr. Czuba’s testimony that the flue gas system disclosed in Sijbesma was intended to be a long-term solution and so membranes were tested for “up to 5300 hours” while “respiratory sampling lines are designed to be disposable products” such that an “experimental gas sampling tube that was effective for over 24 hours was an outstanding result.” Ex. 2002 ¶ 77 (cited at PO Resp. 34).

Petitioner concedes that the conditions in Sijbesma are “very different from those in which the ’298 device would be used” (Reply 12; *see also*, Pet. 22 n. 4 (admitting that “[n]either the foregoing condition [relating to a water vapor removal rate], nor membranes only microns thick, nor the relative humidity or pressures in the gas stream, or flow rates, etc. are analogous to the conditions surrounding a respiratory tube”)), but argues that a POSA would have known to adapt the material and structure used “based upon the particular application.” Reply 12. Petitioner further argues that a POSA “would have simply tested the material to determine whether it fit the requirement.” *Id.* We do not find these arguments persuasive because, again, they presuppose that Sijbesma is available, analogous art. Petitioner’s arguments do not address the underlying question of whether the differences between Sijbesma and the problem addressed in the ’298 patent were so great that Sijbesma would not logically have commended itself to an inventor seeking to solve that problem. We find the conditions under which Sijbesma operates to be quite different from the conditions in respiratory analysis. As the record lacks persuasive evidence or argument to the contrary, we give substantial weight to the disparate conditions under which water is extracted in flue gas dehydration as compared to respiratory analysis in our determination of whether Sijbesma constitutes analogous art.

Considering all of the differences between Sijbesma and the '298 patent together, Mr. Czuba opines that the differences are “so significant that a skilled artisan would not have believed the reference would be helpful for solving the problems faced by the '298 Patent’s inventors.” Ex. 2002 ¶ 72. As noted above, Petitioner does not dispute the facts described by Patent Owner as to how Sijbesma’s flue gas dehydration differs from the respiratory gas analysis taught in the '298 patent. Nor does Petitioner present testimony rebutting the conclusions Mr. Czuba draws from these facts. Absent evidence to the contrary, we credit the evidence set forth by Patent Owner and the testimony provided by Mr. Czuba regarding the differences between Sijbesma’s flue gas dehydration and the respiratory gas analysis taught in the '298 patent. We find that these differences and Mr. Czuba’s testimony are supported by the evidence of record and provide considerable support for Patent Owner’s position that an inventor would not have considered Sijbesma reasonably pertinent to the problem solved by the inventors.

*c. Conclusions on whether Sijbesma would “logically have commended itself to an inventor’s attention”*

Having considered the parties’ arguments, and the evidence identified by the parties, we find that the current record does not support that Sijbesma would “logically have commended itself to an inventor’s attention.” *In re Clay*, 966 F.2d at 659. We summarize our weighing of the evidence below.

Petitioner has identified evidence that an inventor would look outside the field of respiratory sampling for information on polymers because polymeric membranes were known to be used in a wide range of applications. We give this testimony some weight in our analysis, but that

weight is diminished by the absence of evidence that an inventor would look to a reference relating to flue gas for information on polymers and by the testimony of Mr. Czuba that, generally speaking, a POSA would not look to information outside the field of medical devices for information on polymers. Petitioner has also identified evidence that Sijbesma discloses drying a gas stream which arguably relates to one aspect of the problem faced by the inventors. We give this testimony some weight in our analysis, however that weight is diminished by the fact that flue gas dehydration is indifferent to avoiding gas distortion, which was the crux of the particular problem faced by the inventors. For the reasons discussed above, we give little weight to Petitioner's arguments based on Mr. Czuba's testimony that the POSA would have a "general knowledge" of PEBAX 1074 "to manufacture tubing used for similar purposes" and that the POSA would have "consulted general information available regarding the properties of various polymers."

Patent Owner has identified evidence, in the form of Mr. Czuba's testimony, that the POSA would not have looked outside the field of medical devices for information on polymers. This testimony is reasonable, within the scope of Mr. Czuba's unchallenged expertise, and unrebutted, although not supported by corroborating evidence. Accordingly, we give Mr. Czuba's testimony on this point some weight, albeit modest, in our determination of whether Sijbesma constitutes analogous art. Patent Owner has also identified evidence of specific differences between Sijbesma's flue gas dehydration and the problem faced by the inventors. Petitioner does not challenge the fact of these differences, and Mr. Czuba's testimony regarding the importance of these differences to an inventor faced with the problem

solved by the inventors is un rebutted. Collectively, we give substantial weight to the differences identified by the Patent Owner. We find the difference in the need to analyze gases and in the conditions under which moisture is removed from gases particularly persuasive in considering whether Sijbesma would logically commend itself to an inventor's attention. We also give weight to Mr. Czuba's opinion that these differences were "so significant that a skilled artisan would not have believed the reference would be helpful for solving the problems faced by the '298 Patent's inventors." Mr. Czuba's opinion is supported by citation to evidence, reasonable in view of that evidence, and un rebutted.

Considering all of the arguments and evidence presented by the parties, we find that Petitioner's evidence that Sijbesma is analogous art is relatively weak and the evidence presented by Patent Owner that Sijbesma would not commend itself to the attention of an inventor is persuasive. Accordingly, we conclude the current record does not support that Sijbesma is reasonably pertinent to the problem faced by the inventors.

*E. Conclusion with Respect to Analogous Art*

For the reasons discussed above, we determine that Petitioner has not established, by a preponderance of the evidence, that Sijbesma is in same field of endeavor as the '298 patent or that Sijbesma is reasonably pertinent to the particular problem with which the inventors were involved. Accordingly, we conclude that Petitioner has not established that Sijbesma is analogous art. Because Petitioner's obviousness challenge is based, in part, on Sijbesma, our determination that Sijbesma is not analogous art is dispositive.

III. CONCLUSION

<b>Claims</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Claims Shown Unpatentable</b>	<b>Claims Not Shown Unpatentable</b>
1, 2, 8– 13	103(a)	Norlien, Sijbesma		1, 2, 8–13

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not proved by a preponderance of the evidence that claims 1, 2, and 8–13 are unpatentable;

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

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Patent 9,861,298 B2

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