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Paper 27
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

U.S. ENDOSCOPY GROUP, INC.,
Petitioner,

v.

CDX DIAGNOSTICS, INC.,
Patent Owner.

Case IPR2014-00639
Patent 6,676,609 B1

Before PHILLIP J. KAUFFMAN, SCOTT A. DANIELS, and BARRY L. GROSSMAN, *Administrative Patent Judges.*

KAUFFMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

A. Procedural History

Petitioner, U.S. Endoscopy Group, Inc., filed a Petition (Paper 1, "Pet.") seeking *inter partes* review of claims 1–4 of U.S. Patent No. 6,676,609 B1 (Ex. 1001, "the '609 patent").[1] Patent Owner, CDx Diagnostics, Inc., filed a preliminary response. Paper 7 ("Prelim. Resp.").

In the Decision to Institute (Paper 8, "Inst. Dec."), we instituted trial on claims 1–4 based on the following grounds:

1) claims 1–4 based under 35 U.S.C. § 102(b) by Parasher[2]; and

2) claims 3 and 4 under 35 U.S.C. § 103(a) over Parasher and Eisen[3].

Subsequently, Patent Owner filed a Patent Owner's Response[4] (Paper 17, "PO Resp."), and Petitioner filed a Reply (Paper 18, "Pet. Reply").

Patent Owner did not file a motion to amend. Neither party filed a motion to exclude evidence.

At the request of both parties, oral hearing was held on Thursday May 21, 2015. Papers 20, 22, 23. A transcript of the oral hearing is included in the record. Paper 26 ("Tr.").[5]

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[1] Subsequently, Petitioner filed an Exhibit List that was absent from the original Petition. *See* Paper 5.

[2] U.S. 5,535,756, issued July 16, 1996 (Ex. 1003).

[3] U.S. 6,297,044 B1, filed April 23, 1999, issued October 2, 2001 (Ex. 1005).

[4] Patent Owner filed a response and subsequently filed a corrected response. Papers 15, 17, respectively.

[5] A single transcript was created for the oral hearing for IPR2014-00639, IPR2014-00641, and IPR2015-00642. *See infra*, Section I.B. ("*Related Proceedings"*).

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4 of the '609 patent are unpatentable.

B. Related Proceedings

Patent Owner asserted the '609 patent in *CDx Diagnostics, Inc. v. U.S. Endoscopy Grp., Inc.,* Case No. 1:13-cv-5669-NSR (S.D.N.Y.). Pet. 3; Paper 6, 1.

Related U.S. Patent No. 7,004,913 B1 ("the '913 patent") is involved in an *inter partes* review designated IPR2014-00641. The '913 patent is a continuation of application No. 10/321,010, now the '609 patent.

II. THE '609 PATENT

The '609 patent was filed on December 17, 2002, and is a continuation in part of application No. 09/849,085 filed on May 4, 2001 (now U.S. 6,494,845 B2). Ex. 1001, 1. It is undisputed that claims 1 and 2 are entitled to a May 4, 2001, priority date, and claims 3 and 4 are entitled to a December 17, 2002, priority date. *See* Pet. 5, 25.[6] Petitioner contends that Eisen is prior art as to claims 3 and 4, but not as to claims 1 and 2. *Id.*

To understand this case, it is helpful to understand that the term "biopsy" can be used to refer to either (1) the procedure for removing tissue for examination, or (2) the specimen obtained by that procedure. *See* Ex. 2003, 4; Ex. 2004, 5.[7]

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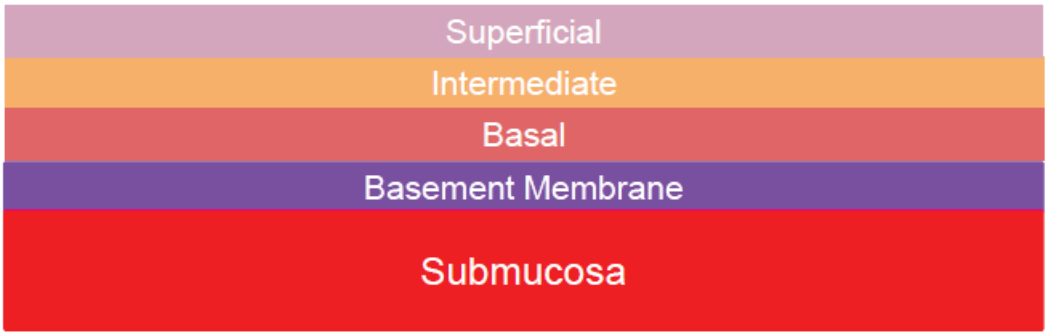
[6] Patent owner does not contest these priority dates, and consistent with this interpretation, Patent Owner states that the "earliest priority date of the '609 patent is May 2001." *See* PO Resp. 19.

[7] The pages of Exhibits 2003 and 2004 are not numbered. *See* 37 C.F.R. § 42.63(d)(2)(i). For Exhibit 2003 we refer to page 200 of the portion of the dictionary provided, and for Exhibit 2004 we refer to page 100 of the portion of the dictionary provided.

The '609 patent is titled, "Retractable Brush for Use with Endoscope for Brush Biopsy," and is directed to a method and apparatus for obtaining trans-epithelial specimens of body surfaces using a non-lacerating technique with retractable tools, such as a brush used with endoscopes. Ex. 1001, 1:10–15. Epithelial tissue can be comprised of a superficial, intermediate, and basal layer, these three layers resting on the basement membrane which rests in turn on the submucosa. The figure on slide 4 of Patent Owner's Demonstrative illustrates this tissue structure:



This figure depicts the layers of epithelial tissue adjacent to the basement membrane and submucosa. *See* Ex. 2006, 4[8] (Patent Owner's Demonstratives); Ex. 1014, 2 (Petitioner's Demonstratives).[9]

[8] Citing Ex. 1001 at 4:34–37, 11:56–65 of related case IPR2014-00642.

[9] Pursuant to our Order (Paper 23), these demonstratives have not been entered, but this Decision directs the parties to do so. This information appears uncontested in that the parties each depict the layers in the same manner. We discern no evidence in the case that contradicts this depiction.

Figure 3 of the ’609 patent depicting the retractable brush is reproduced below:

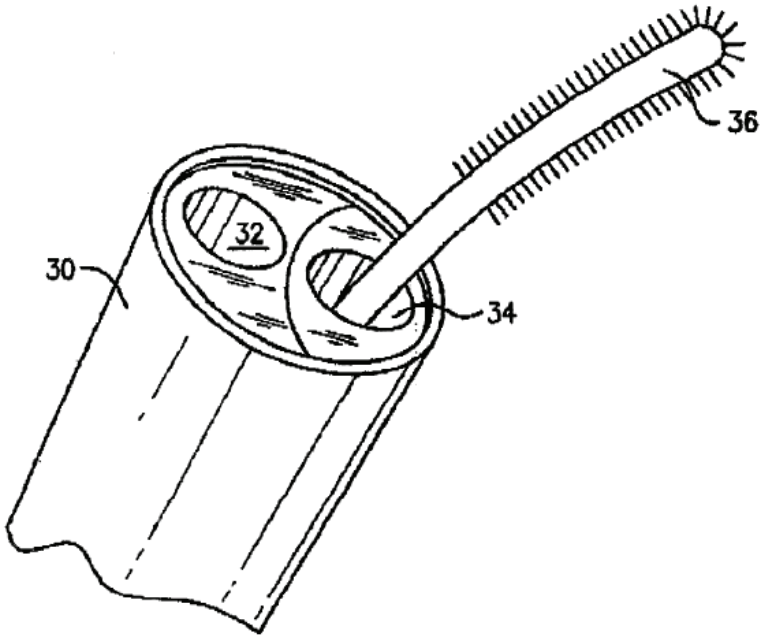


FIG. 3

Figure 3 of the ’609 patent is a preferred embodiment shown in partial perspective and sectional view. Ex. 1001, 7:44–46.

The ’609 patent describes the claimed apparatus through a contrast to cytology. Cytology uses a soft brush to gently remove (sweep) previously freed cells (exfoliated or sloughed off) from the surface of the epithelium in non-invasive manner that avoids or minimizes abrasion of the epithelium and is intended to be painless. *Id.* at 3:24–31, 46–67; 4:67–5:3. A brush biopsy uses a stiffer brush and rubs harder than cytology so that the surface of the epithelium is penetrated. *Id*. at 5:64–67; 6:44–46. In other words, a brush biopsy penetrates the

surface of the epithelium by dislodging cells (as opposed to sweeping up previously freed cells) and picks up those cells.

III. THE CHALLENGED CLAIMS

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275–79 (Fed. Cir. 2015) ("Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA,"[10] and "the standard was properly adopted by PTO regulation."). We expressly interpret below only those claim terms that require analysis to resolve arguments related to the patentability of the contested claims. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms which are in controversy need to be construed and only to the extent necessary to resolve the controversy). All claim terms not explicitly construed below are given the plain and ordinary meaning that the term would have had to a person of ordinary skill in the art, without further elaboration. *See* 37 C.F.R. § 42.100(b).

The '609 patent includes claims 1–4. Independent claim 1, the sole independent claim, follows:

> 1. An apparatus to be used in conjunction with an endoscope to examine tissue cells located within epithelium tissue having a surface, said apparatus comprising a channel extending the length of the endoscope; said apparatus comprising a rod passing through said

[10] The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA").

> channel having a distal and a proximal end; a retractable non-lacerational brush attached to the distal end of the rod, said brush being movable to bear against the tissue being examined and being controlled by said rod to remove tissue from a tissue area being examined, said brushing apparatus comprising bristles which exert sufficient pressure to conduct a biopsy to dislodge cells and pick up a specimen of the tissue area located below the surface of said epithelium tissue.

A. Institution Decision

We construed the following terms in the Institution Decision.

1. "said apparatus comprising a channel extending the length of the endoscope"

Petitioner contended that claim 1 is potentially ambiguous because it may be interpreted in two ways: one, that the endoscope comprises a channel, or two, that the apparatus comprises a channel. Pet. 10–11, 18–19. We interpreted that claim 1 unambiguously requires the apparatus to include a channel. Inst. Dec. 7.

2. "said brushing apparatus"

In the Institution Decision we noted that Claim 1 recites "said brushing apparatus comprising bristles which exert sufficient pressure to conduct a biopsy to dislodge cells and pick up a specimen of the tissue area located below the surface of said epithelium tissue," and the phrase "said brushing apparatus" technically lacks an antecedent basis. *See* Inst. Dec. 8; Pet. 13, 21. We determined that this oversight does not render claim 1 indefinite.

3. "bristles which exert sufficient pressure to conduct a biopsy to dislodge cells and pick up a specimen of the tissue area located below the surface of said epithelium tissue"

Petitioner contended that the broadest reasonable interpretation of this limitation is: "bristles having penetrating edges of a sufficient stiffness to obtain a

biopsy sample including cells located below the surface layer of the epithelium where the epithelium is glandular epithelial tissue having a surface layer and a basement membrane." Pet. 13.

We corrected two aspects of this interpretation. Inst. Dec. 9–10. First, we clarified that claim 1 recites "'epithelium tissue having a surface,' not glandular epithelial tissue." *Id.* at 9. Second, we interpreted that claim 1 "is not limited to a brush that includes bristles having penetrating edges of sufficient stiffness." Rather, "this limitation requires that the brushing apparatus include bristles capable of exerting sufficient pressure to obtain a biopsy that dislodges cells and picks up a specimen of tissue located below the surface layer of the epithelium." *Id*. at 10.

B. Current Interpretation

Petitioner asks, "[t]o the extent the Board did not adopt Petitioner's proposed claim constructions, Petitioner respectfully requests reconsideration." Pet. Reply 10. This request is not in the form of a timely request for reconsideration under 37 C.F.R. § 42.71(d). More importantly, this request, without a cogent explanation of how our claim construction is in error, is unpersuasive.

We adopt our interpretations from the Institution Decision with one exception. We preliminarily interpreted that the brushing apparatus of claim 1 requires bristles capable of exerting sufficient pressure to obtain a biopsy that dislodges cells and picks up a specimen of tissue located "below the *surface layer* of the epithelium." Inst. Dec. 10 (emphasis added). However, as explained below, claim 1 requires the specimen to include cells taken from tissue located below the surface (verses the surface layer) of the epithelium.

C. Claim 1 - "bristles which exert sufficient pressure to conduct a biopsy to dislodge cells and pick up a specimen of the tissue area located below the surface of said epithelium tissue"

In the Patent Owner's Response, Patent Owner argues that Parasher's reference is silent regarding obtaining tissue from the area "located below the *surface of the epithelium*." PO Resp. 4 (emphasis added). Then later in the Response, Patent Owner argues that Petitioner has not shown that Parasher's device collects cells from at least two layers of the epithelium. PO Resp. 13. Although not explicit, this argument implies that Patent Owner interprets claim 1 to require that the uppermost layer of the epithelium is penetrated so that cells from the second layer are obtained.[11]

Patent Owner's interpretation is inconsistent with the plain language of claim 1 in that claim 1 recites "below the surface of said epithelium tissue," not "below the surface *layer* of said epithelium tissue" (emphasis added).[12] Likewise, "the surface" has antecedent basis in the preamble which recites "epithelium tissue having a surface," not "epithelium tissue having a surface layer."

The '609 patent does not contain a lexicographical definition of the claim term "surface," and an ordinary meaning of this term is "the exterior boundary of a solid object."[13] Ex. 3001, 6.[14] Consistent with the ordinary meaning of "surface,"

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[11] At oral argument, Patent Owner was presented with, and responded to, our interpretation that "surface" as claimed means the boundary of the epithelium. Tr. 56–63. Those arguments are addressed below.

[12] Claim 1 does not describe the specimen collected as a "biopsy." Rather, only the procedure performed is described as a "biopsy."

[13] We depart from the ordinary meaning of a term only for a lexicographical definition or clear disavowal of claim scope, neither of which is present here. *See* e.g., *Hill-Rom Srvs., Inc., v. Stryker Corp*., 755 F.3d 1367, 1371 (Fed. Cir. 2014).

the ’609 patent describes that exfoliated cells may be present “on the superficial epithelial surface.” *See, e.g.*, Ex. 1001, 3:58–61. This disclosure also illustrates how Patent Owner’s interpretation is inconsistent with the Specification. Specifically, if “surface” as claimed, means the uppermost layer of the epithelium, then it would be redundant to refer to the “superficial epithelial surface.”

Patent Owner contends that the purpose of the ’609 patent is to detect pre-cancerous cells before cancer spreads which requires the specimen to include cells from beneath the uppermost layer of the epithelium. Tr. 60. The ’609 patent describes that it is “important” to determining whether a patient has a precancerous or cancerous condition to reach through the superficial layer to the basement membrane. Ex. 1001, 7:9–14. The ’609 patent does not describe that the basement membrane must be reached in every case. *Id.* Likewise, the ’609 patent does not state that abnormal cells never penetrate the uppermost layer of the epithelium; rather, it states that in many oral cavity lesions abnormal cells never reach the *surface*. *Id.* at 5:4–8. Further, although the ’609 patent refers to specimens obtained by the claimed device as “transepithelia” specimens (*see, e.g., id.* at 1:10–11), the claimed device samples cells from “all levels,” including the basal, intermediate, and superficial layers *(id*. at 5:64–67, 6:49–52). That is, the claimed device may penetrate one, two, or all three layers of the epithelium. Consistent with this interpretation, the ’609 patent describes that the claimed device removes tissue by being rotated and moved against the tissue. *Id.* at 6:35–37; *see also* Ex. 2005, 28 (describing repeating brushing to obtain a deeper sample). Thus, greater rotation and movement produces a deeper sample and vice versa. The variability

[14] “Surface,” TABER’S CYCLOPEDIC MEDICAL DICTIONARY, (12th ed. 1973), Ex. 3001, 6.

of the extent of the specimen is also reflected in claims 1 and 4 (below the surface verus to the submucosa, respectively).

Consequently, claim 1 does not require penetrating the superficial layer so that the specimen includes cells from the intermediate layer of the epithelium. Instead, claim 1 requires the specimen to include cells taken from tissue located below the exterior boundary (surface) of the epithelium.

D. Claims 2–4

Claim 2 depends from claim 1 and adds that the "brush bristles are at least 1000 microns in length." Claim 3 depends from claim 1 and adds that the "epithelium tissue comprises metaplastic glandular epithelium tissue." Claim 4 depends from claim 3 and adds, "wherein said specimen of the tissue area comprises a disaggregated specimen of the whole tissue, said whole tissue being defined of at least glandular cells, plus basement membrane fragments, plus elements of the submucosa in the area being examined."

IV. EVIDENTIARY ISSUES[15]

A. Parasher Article (Ex. 1004)

As evidence that the device disclosed in Parasher[16] ("the Parasher brush") is inherently capable of collecting a tissue sample as claimed, Petitioner contends that the Parasher Article[17] describes using the Parasher brush to obtain a biopsy sample of tissue located below the surface of the epithelium. Pet. 22. It is critical to this

[15] This analysis is applicable to both grounds of unpatentability.

[16] Ex. 1003.

[17] Parasher, et al., ENDOSCOPIC RETROGRADE WIRE-GUIDED CYTOLOGY OF MALIGNANT BILIARY STRUCTURES USING A NOVEL SCRAPING BRUSH, Gastrointestinal Endoscopy, Vol. 48, No. 3, 1998, (Ex. 1004).

assertion that the brush used in the experiments described in the Parasher Article is the Parasher brush.

Although the Parasher device and the Parasher Article are each attributed to Vinod K. Parasher, that does not demonstrate convincingly the brush used in the experiments described in the Parasher Article is the Parasher brush. *See* Ex. 1003, 1; Ex. 1004, 1. Petitioner asserts that the Parasher Article "describes patient trials of the device disclosed in the patent [the Parasher brush]." Pet. 22. This attorney argument is not supported by citation to evidence. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) (attorney's arguments do not take the place of evidence). Petitioner does not identify, nor do we discern, an explicit disclosure that the brush used for the experiments described in the Parasher Article was the Parasher brush. *See* Pet. 22; Ex. 1004, 1–3.

Petitioner asserts that the Parasher Article utilized a brush having semi-rigid and rough bristles made from a Velcro® pad. *Id.* (citing Ex. 1004, 290–91). Although the Parasher Article discloses this information (Ex. 1004, 290),[18] Petitioner does not explain how this information demonstrates that the brush used in the experiments described in the Parasher Article is the Parasher brush. For example, Petitioner does not explain the relevance of this information by pointing out that the Parasher brush includes a Velcro® pad, nor does Petitioner cite to such disclosure in Parasher. We recognize that a preferred embodiment of the Parasher brush includes bristles comprised of a Velcro® pad. *See, e.g.* Ex. 1003, Abstract, 1:15. We also recognize that there are other similarities between the Parasher brush and the brush described in the Parasher Article. For example, both brushes

[18] Exhibit 1004 does not contain a page 291. It appears that the Exhibit is not missing a page because page 290 of the Parasher Article is numbered as page 3 of the Exhibit.

are described as having mushroom-shaped bristles. *See* Ex. 1003, 2:51–57; Ex. 1004, 1. However, it is Petitioner's burden to set forth the relevance of evidence to the challenge raised, including identifying specific portions of the evidence that support the challenge, and the Board may give no weight where a petitioner has failed to do so. 37 C.F.R. § 42.104(b)(5). Petitioner does not explain based on persuasive evidence, nor identify specific portions of the evidence to demonstrate persuasively that the brush described in the Parasher Article is the Parasher brush.

Patent Owner pointed out that Petitioner did not establish adequately that the Parasher Article describes use of the Parasher brush. PO Resp. 10–11. Petitioner responds with the contention that Patent Owner's inherency arguments are not relevant, and that the Board did not reply upon inherency in the Institution Decision. *See* Pet. Reply. 12. These contentions are inapposite to Patent Owner's argument. Petitioner had, and failed to use, a second opportunity to establish adequately that the experiments of the Parasher Article utilized the Parasher brush.

Accordingly, we give no weight to the Parasher Article in our analysis.

B. Dr. Michel Kahaleh

Dr. Michel Kahaleh, Petitioner's witness, provided a Declaration (Ex. 1010) and was deposed by Patent Owner (Ex. 2005). Dr. Kahaleh is a medical doctor and professor. Ex. 1010 ¶ 5.

1. Capabilities of Parasher's Brush

In support of the contention that Parasher's brush is capable of collecting a specimen that includes cells from tissue located below the surface of the epithelium, Petitioner stated, "[o]ne of ordinary skill in the art would understand that a biopsy sample necessarily includes fragments of the epithelial tissue, as well as portions of the basement membrane and submucosa below the epithelium." Pet.

17, 22 (citing Exhibit 1010 ¶ 10). That is, Petitioner asserts that if a specimen is a "biopsy," it necessarily includes cells from epithelial tissue, the basement membrane, and submucosa.

We are not persuaded by this evidence for several reasons. First, at deposition, Dr. Kahaleh consistently referred to a sample taken using a brush as a "brushing," and a sample taken using a biopsy forceps as a "biopsy." *See, e.g.*, Ex. 2005, 15–17.[19] This suggests that the definition of a biopsy specimen in paragraph 10 of Dr. Kahaleh's Declaration was not referring to a specimen collected with a brush. Indeed, Dr. Kahaleh confirmed during his deposition that paragraph 10 of his Declaration was referring to a biopsy specimen obtained via a forceps biopsy procedure. PO Resp. 5–6; Ex. 2005, 16; *see also* Ex. 1010 ¶ 6 (Parasher not listed as a document reviewed in preparation for the Declaration). For these reasons, paragraph 10 of Dr. Kahaleh's Declaration adds nothing to Petitioner's contention that Parasher's brush is capable of collecting a specimen that includes cells from tissue located below the surface of the epithelium.

Petitioner asserts that paragraph 16 of Dr. Kahaleh's Declaration supports the contention that a brush biopsy specimen includes "tissue located below the top surface of the epithelium including basement membrane and submucosa" as required by claim 1. Pet. Reply 4–5 (quoting Ex. 1010 ¶ 16). As explained above, Dr. Kahaleh did not review Parasher before making this statement. *See* PO Resp. 9–10; Ex. 2005, 6:18–7:6.[20] Therefore, at most, Dr. Kahaleh's statement conveys that some unspecified brush is capable of obtaining such a specimen. The question

[19] When asked "so that when you use the brush you're really not doing a biopsy, is that your opinion?," Dr. Kahaleh responded, "right." Ex. 2005, 17:8–10.

[20] Further supporting this conclusion, Petitioner objected to Patent Owner's question as beyond the scope of direct, suggesting that Dr. Kahaleh's Declaration did not address the Parasher reference. *See* Ex. 2005, 6:25–7:3.

before us is not whether some brush has the claimed capability; the question is whether Parasher's brush has such capability. The proffered evidence sheds little or no light on the capabilities of Parasher's brush.

Petitioner contends that Dr. Kahaleh testified that "brushing" (use of a brush to obtain a specimen for examination) can obtain a specimen as claimed. Pet. Reply. 5 (citing Ex. 2005, 17–18, 27–28). In the cited portions, Dr. Kahaleh testified with regard to the capabilities of the U.S. Endoscopy brush ("biliary brush") and not with regard to Parasher's brush. Therefore, this evidence sheds little or no light on the capabilities of Parasher's brush.

For these reasons, we determine that paragraphs 10 and 16 of Dr. Kahaleh's Declaration (Ex. 1010) and the portions of Dr. Kahaleh's testimony relied upon as detailed above, to be unpersuasive regarding the capability of Parasher's brush to gather a specimen as claimed.

Because we do not rely on Dr. Kahaleh's definition of biopsy, we need not address Patent Owner's arguments why Dr. Kahaleh's definition of biopsy is incorrect and why relying upon such evidence would be improper gap filling. *See* PO Resp. 5–10, 14–16.

2. Dr. Kahaleh's Qualifications

Petitioner relies upon Dr. Kahaleh for other evidentiary issues, including for example, to provide evidence that Parasher's brush can examine glandular epithelium and as to the depth of the submucosa. *See* Pet. 23, 25 (citing Ex. 1010 ¶¶ 11, 12). Before considering this evidence below, we address Patent Owner's arguments regarding Dr. Kahaleh's qualifications.

Patent Owner makes two arguments why we should give the testimony of Dr. Kahaleh little or no weight. PO Resp. 16–20. First, Patent Owner contends that Dr. Kahaleh is not an expert qualified to testify as to what constitutes a biopsy,

analyzing biopsy specimens, diagnosing disease based on review of biopsy specimens, and or to make determinations as to the sufficiency and/or adequacy of biopsy specimens. *Id.* at 16–17 (citing Ex. 2005, 30). According to Patent Owner, the relevant expert would be a pathologist or someone with similar knowledge of biopsies. PO Resp. 16–18.

As an initial matter, we note that Patent Owner is not seeking to exclude Dr. Kahaleh's testimony, and therefore the proper inquiry is not whether Dr. Kalaleh is qualified under the Federal Rules of Evidence ("Fed. R. Evid."). *See* 37 C.F.R. §§ 42.62, 42.64; Fed. R. Evid. 702, 703. In other words, contrary to what Patent Owner's argument suggests, it is not necessary that Dr. Kahaleh qualify as an expert under for the Federal Rules of Evidence for us to consider evidence from him. We consider Dr. Kahaleh's qualifications to determine what weight should be accorded to the evidence he provided.

We disagree with Patent Owner's assertion that the relevant expert is limited to a pathologist.[21] The field of the '609 patent relates to *obtaining* transepithelial specimens with an endoscope, not the study of the specimens so obtained. *See* Ex. 1001, 1:10–12. Indeed, all of the claims of the '609 patent deal with obtaining a specimen with an endoscope, and none of the claims deal with examination of that specimen. Therefore, expertise in the obtaining of specimens with an endoscope has relevance to the claimed subject matter.

Dr. Kahaleh has expertise in obtaining specimens with an endoscope. Dr. Michel Kahaleh has a medical science degree (cum Laude) as well as a doctor of medicine. Ex. 1010 ¶ 8. He completed an internship in surgery, two

[21] "Pathologist: [a] specialist in diagnosing the morbid changes in tissues removed at operations and postmortem examinations," TABER'S CYCLOPEDIC MEDICAL DICTIONARY, (12th ed. 1973), Ex. 3001, 3.

fellowships in gastroenterology,[22] and an internship and residency in internal medicine. *Id.* at 8–9. He is skilled in the art and use of endoscopic tools, including brushes for use in gastroenterology. *Id*. ¶ 4. For example, he has served as a Chief of Endoscopy and a Chief of Advanced Endoscopy, is board certified in internal medicine and gastroenterology, and has performed between 3,000 and 5,000 brush biopsies. *Id*. at 9; Ex. 2005, 27:7–11. From this and other information provided regarding Dr. Kahaleh, we determine that Dr. Kahaleh has experience relevant to the field of the invention, and Patent Owner's argument that we should give such testimony little or no weight is not persuasive.

Second, Patent Owner contends that we should give Dr. Kahaleh's testimony little or no weight because, "Dr. Kahaleh did not 'have the skill and experience of an ordinary worker in the field,' and he did not 'have knowledge of all pertinent prior art' . . . in May of 2001." PO Resp. 18–20 (citing *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.,* 807 F.2d 955, 962–63 (Fed. Cir. 1986), and *Schott Gemtron Corp. v. SSW Holding Co., Inc.,* Case IPR2013-00358, slip op. at 18 (PTAB Aug 20, 2014) (Paper 106)).

The cited portion of *Custom Accessories* explains that when analyzing the level of skill in the art in a *Graham* analysis, the critical question is whether the claimed invention would have been obvious at the time to a person of ordinary skill in the art, who is a hypothetical person presumed to be aware of all the pertinent prior art. *Custom Accessories*, 807 F.2d at 962 (referring to *Graham v. John Deere Co.*, 383 U.S. 1 (1966)). *Custom Accessories* does not address

[22] "Gastroenterology: [t]he branch of medical science concerned with study of physiology and pathology of the stomach, intestines, and related structures such as the esophagus, liver, gallbladder, and pancreas." *Id.* at 4.

whether an expert must have been qualified as of the critical date of the patent being discussed. *Id.*

Schott, a non-precedential Board decision, does not stand for the proposition that an expert witness must have been a person of ordinary skill in the art at the time of the claimed invention of the patent challenged. The Board did not cite to any legal authority with regard to being a person of ordinary skill as of the critical date. Rather, in context, the Board determined that Petitioner's witness was not a person of ordinary skill in the art at any time, to include at the time of the invention of the challenged patent. *Schott* at 17–18. A witness must provide testimony about the level of skill in the art as of the critical date; however, the witness need not have acquired that knowledge as of the critical date. We note that in *Schott*, where the witness was not a person of ordinary skill in the art, the Board reduced the weight given that testimony and did not elect to give the testimony no weight.

Accordingly, Patent Owner's second argument that we should give Dr. Kahaleh's testimony little or no weight is not persuasive.

V. ANTICIPATION BY PARASHER

"Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). Accordingly, an anticipatory reference must show all of the limitations of the claims "arranged or combined in the same way as recited in the claims." *Id.* at 1370; *see Finisar Corp. v The DirecTV Grp.,*

Inc., 523 F.3d 1323, 1334–37 (Fed. Cir. 2008); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1366–68 (Fed. Cir. 2000).

To prevail in its challenges to the patentability of claims, Petitioner must establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

> The burden of showing something by a preponderance of the evidence ... simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.

Metro. Stevedore Co. v. Rambo, 521 U.S. 121, 137 n.9 (1997) (alteration in original) (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622 (1993)).

Petitioner contends that claims 1–4 are unpatentable as anticipated by Parasher. Pet. 14–25. We have considered the arguments and evidence presented by both parties, and we determine Petitioner has shown by a preponderance of the evidence that claims 1–4 are unpatentable as anticipated by Parasher.

A. Uncontested Aspects

Parasher discloses an apparatus (device 1) to be used in conjunction with an endoscope to examine tissue cells located within epithelium tissue. Pet. 14–17, 19; Ex. 1003, 1:10–11, 54–67; 2:20–40; 3:6–32; 5:58–6:20; *see also* Ex. 1001, 1:16–19 (noting that the upper esophagus is lined with epithelium).

Figure 3 of Parasher follows:

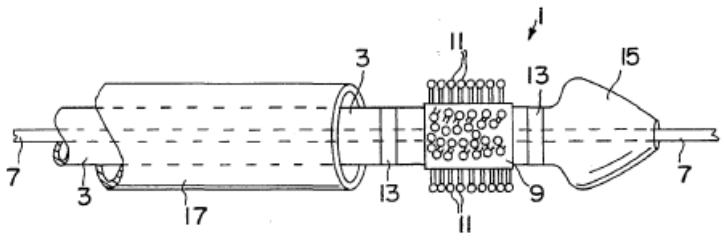

FIG.3

Figure 3 is a partial elevation view of a third embodiment of Parasher's device. Ex. 1003, 4:12–13.

Parasher's device includes a channel extending the length of the endoscope (formed by sheath of sleeve 17), a rod (catheter 3) passing through that channel, and a retractable non-lacerational[23] brush (brush 9) attached to the distal end of that rod.[24] Pet. 17–20; Ex. 1003, 3:7–32; 4:46–48; 5:33–45, 5:58–6:20; Figs. 1–3.

Parasher's brush is movable to bear against the tissue being examined and is controlled by the rod to remove tissue from a tissue area being examined. Specifically, Parasher's brush is pushed and pulled back and forth over the inner wall of the duct to collect scrapings of tissue and brushings of cells. Pet. 21; Ex. 1003, 3:21–28; 6:6–10. This process is also described as a "scrape biopsy." Pet. 15; Ex. 1003, 1:10–11; *see also* Ex. 1003, 1:14–17 (describing abrading against the duct walls); *cf.* Ex. 1001, 6:35–37, 44–47 (describing the brush as moved or rubbed against the tissue to collect a specimen).

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[23] Parasher's brush reduces the risk of perforating the duct, suggesting the brush is non-lacerational. *See* Pet. 16, Ex. 1003, 2:16–19; *see also* Pet. 16–17; Ex. 1003, 3:60–67 (Parasher's brushing procedure is safer than surgical extraction); Ex. 1012, 101 (Patent Owner's witness, Dr. Fromowitz, acknowledging that Parasher's brush is non-lacerational).

[24] Parenthetical nomenclature is to Parasher's nomenclature.

Parasher's brush 9 is comprised of bristles 11 that are stiff or semi-rigid. Pet. 21; Ex. 1003, 4:46–58. The tips of bristles 11 have features that facilitate collection of cell and tissue, such as hook ends, ball-tips, mushroom tips, loops, or the like. Pet. 21–22; Ex. 1003, 4:46–58; Figs 4a–4c; *cf.* Ex. 1001, 7:15–20 (like the brush of the claim 1, the stiffness and shape of the bristle tips of Parasher contribute to the effectiveness of retrieving a specimen).

These contentions are not contested by Patent Owner. *See* 37 C.F.R. § 42.23(a) (any material fact not specifically denied may be considered admitted).

B. Contested Aspect[25]

Patent Owner contends that not all of the claimed elements are found within the four corners of Parasher, as is required for anticipation, because Parasher is silent regarding obtaining a specimen that includes tissue from below the surface of the epithelium. PO Resp. 3–4, 11–12. This contention is premised on the claim construction that claim 1 requires penetrating at least two layers of epithelium. *Id.* at 13. Patent Owner puts forth several reasons why Dr. Kahaleh's definition of biopsy proffered by Petitioner does not cure this deficiency. *Id*. at 5–10.

Patent Owner's arguments are unpersuasive for two reasons. First, Patent Owner's argument is not based upon proper claim construction. Second, Patent Owner mischaracterizes what is required for anticipation and does not address persuasively the merits of Petitioner's contentions regarding Parasher.

[25] Our analysis does not address new arguments by Patent Owner because those arguments were not in the record prior to oral hearing. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012); Paper 25 (Petitioner's Objections to Patent Owner's Demonstratives). Later in this opinion we address one such new argument in greater detail.

1. Claim Construction

Patent Owner contends that claim 1 requires penetrating as least two layers of the epithelium. To the contrary, as explained above, claim 1 requires the specimen to include cells from below the exterior boundary of the epithelium. Consequently, all that is required is that the exterior boundary (surface) of the epithelium is penetrated so that cells are dislodged and picked up. Therefore, patent Owner's arguments are not commensurate in scope with claim 1.

With the properly construed claim in mind we turn to the reference. *See Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003) (citations omitted) ("Both anticipation under § 102 and obviousness under § 103 are two-step inquiries. The first step in both analyses is a proper construction of the claims. . . . The second step in the analyses requires a comparison of the properly construed claim to the prior art.").

2. Parasher

Patent Owner contends that Parasher is silent regarding the ability of the brush to pick up tissue from the area below the surface of the epithelium. PO Resp. 4, 12, 14. We disagree both with the implication that Parasher must disclose such capability in the words of the '609 patent and with Patent Owner's characterization of the reference.

Parasher need not explicitly state that the device picks up tissue from below the surface of the epithelium. *See generally In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990) ("These elements must be arranged as in the claim under review, but this is not an '*ipsissimis verbis* test'") (citation omitted); *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (Although a reference must disclose each and every limitation in a claim to anticipate the claim, the reference need not satisfy an *ipsissimis verbis* test.).

The proper inquiry is what a person of ordinary skill in the art would understand as the capability of Parasher's brush. Further, contrary to Patent Owner's characterization, Parasher is not silent regarding the capabilities of the brush. Instead, as detailed below, Petitioner identifies and explains numerous disclosures regarding the extent of the specimen that is collected by Parasher's brush.

As detailed above, Parasher's device includes a brush having stiff or semi-rigid bristles with tips that facilitate the collection of cell and tissue. Further, Parasher's device obtains a specimen by bearing against the tissue being examined.

Regarding the composition or extent of the specimen collected, Parasher's brush is capable both of collecting cells (cytology) and of collecting a larger (greater) sample of tissue (biopsy). Pet. 15, 20; Pet. Reply 9; Ex. 1003, 1:8–11, 2:20–40, 3:26–28; *see also* Ex. 1003, Title ("Catheter with Simultaneous Brush Cytology and Scrape Biopsy Capability); 3:60–67 (describing the sample collected as "more substantial" than that collected with conventional cytology).[26] Parasher describes that the device enables collection of a "gross tissue sample or biopsy." Pet. 16, Pet. Reply 9; Ex. 1003, 1:56–58; 2:20–25. Parasher also describes the brush as capable of collecting "scrapings of tissue." Pet. 21; Pet. Reply 10; Ex. 1003, 3:24–28.

A person of ordinary skill in the art would have considered these disclosures in the context that "tissue" is an aggregation of similarly specialized cells and that

[26] Petitioner identifies numerous other examples of Parasher referring to the sample collected as a tissue sample. *See, e.g.,* Pet. 14, 16, 21–22; Ex. 1003, 2:12–20.

"gross" means large enough to be visible to the naked eye. *See* Ex. 2003, 4; Ex. 2004, 6; Ex. 3001,[27] 5.

In sum, Parasher's brush, like the claimed device, includes bristles that are stiff and have a shape that contributes to collecting a specimen. Parasher's brush, like the claimed device, obtains a specimen by bearing against the tissue being examined. The specimen obtained by Parasher's brush is an aggregation of cells large enough to be visible to the naked eye. Considering the evidence to this point, Petitioner has shown by a preponderance of the evidence that Parasher's brush obtains such a specimen by dislodging cells from below the exterior boundary of the epithelium.

C. Dr. Fromowitz

Dr. Frank Fromowitz, Patent Owner's expert witness, provided a Declaration (Ex. 2001) and was deposed by Petitioner (Ex. 1012). Dr. Fromowitz is a licensed physician with 35 years of experience as a pathologist. Ex. 2001 ¶¶ 3, 4, 7. Each party relies upon the testimony of Dr. Fromowitz, and it is uncontested that Dr. Fromowitz is qualified to provide expert testimony. *See e.g.*, PO Resp. 21; Pet. Reply 1–2, 7–8.

1. Patent Owner

Patent Owner relies upon the testimony and Declaration of Dr. Fromowitz to attempt to counter Dr. Kahaleh's evidence regarding the composition of a biopsy specimen. PO Resp. 12. Because we are not considering Dr. Kahaleh's evidence regarding the composition of a biopsy specimen, Patent Owner's arguments are not relevant.

[27] "Gross," TABER'S CYCLOPEDIC MEDICAL DICTIONARY, 12th ed. (1973), Ex. 3001, 5

Patent Owner does not rely upon evidence from Dr. Fromowitz to attempt to counter Petitioner's analysis of Parasher. PO Resp. *passim*.

2. Petitioner's Use of Dr. Fromowitz's Testimony

Petitioner contends that Dr. Fromowitz testified that the "brush of Parasher collects a specimen of tissue located below the surface of the epithelium as required by the claims of the '609 Patent." Pet. Reply 7–8 (citing Ex. 1012, 94–101).[28] Our interpretation of this portion of Dr. Fromowitz's testimony follows.

As background, Parasher discloses that "[t]o diagnose a malignancy associated with a stricture, for example, it may be appropriate to examine the mucous lining of the duct, the tissue of the duct wall and *even adjacent tissues*." Ex. 1003, 1:61–64 (emphasis added). Petitioner asked Dr. Fromowitz if "adjacent tissue" in this context included submucosa. Ex. 1012, 94:8–95:12. Dr. Fromowitz stated that it could refer to a different organ, such as the liver or duodenum, but subsequently added that it "would have to include the submucosa." *Id.*

Petitioner subsequently directed Dr. Fromowitz's attention to the disclosure that Parasher's device can obtain a larger tissue than may be obtained with cytology so that the sample obtained is a gross tissue sample or biopsy. *Id.* at 95:13–22 (referring to Ex. 1003, 2:20–25). Dr. Fromowitz interpreted this disclosure to state that a brush can be used to get more tissue than may be obtained by cytology, and that the sample obtained would be a biopsy. *Id.* at 94:8–96:12. Dr. Fromowitz disagrees with the reference in that obtaining more cells does not mean the constituents of a biopsy have been obtained. *Id.* at 96:5–12. This observation must be interpreted in the light that Dr. Fromowitz considers a biopsy

[28] Petitioner's argument is previewed at pages 1–2 of the Reply and provided in detail at pages 7–8. Our analysis focuses on pages 7–8.

specimen to be "a segment of intact tissue," as may be obtained by cutting, pulling, excising or the like (methods other than brushing). *Id.* at 21:18–19. Therefore, Dr. Fromowitz is stating that he thinks a brush cannot obtain a segment of intact tissue. None of the challenged claims require the specimen to be a segment of intact tissue. Nor do the claims recite that the specimen obtained is a "biopsy;" rather, the claims specify the composition of the specimen obtained. *See, e.g.,* Ex. 1001, claim 1 (requiring the specimen to include cells from tissue located below the surface of the epithelium). Consequently, this particular portion of Dr. Fromowitz's testimony sheds little or no light on whether Parasher's brush can obtain a specimen as claimed.

Petitioner contends that Dr. Fromowitz stated that the sample collected by Parasher is similar to a specimen as claimed. Pet. Reply 7 (citing Ex. 1012, 96:13–18). Dr. Fromowitz did not explicitly state that the sample collected by Parasher is similar to a specimen as claimed. Ex. 1012, 96:13–18. Rather, in context, Dr. Fromowitz testified that a "gross tissue sample," as used in Parasher, means a sample of tissue that you can actually see. Ex. 1012, 95:16–96:18 (referring to Ex. 1003, 2:20–25).

Subsequently, Petitioner pointed out that Parasher's device is capable of obtaining "scrapings of tissue," and asked, if Parasher's device were to be used to obtain a specimen from tissue such as shown in Figure 5 of the '609 patent, would the specimen obtained include cells from the submucosa. Ex. 1012, 97:15–98:24 (referring to Ex. 1003, 3:26–28). Dr. Fromowitz initially did not understand the question, and asked Petitioner to start again. *Id.* at 98:25–99:4. Petitioner then asked if scraping as disclosed by Parasher would obtain a specimen that included cells from the submucosa. *Id.* at 99:5–10. Dr. Fromowitz replied, "not

necessarily," and then added that Parasher's device could obtain such a specimen, but not reliably so. *Id.* at 99:11–16.

Petitioner referred again to the disclosure that Parasher's device can obtain a specimen that qualifies as a gross tissue sample or biopsy, and asked whether a person of ordinary skill in the art would understand this disclosure to mean that the specimen obtained includes portions of the submucosa. *Id.* at 99:20–100:4 (referring to Ex. 1003, 2:24–25). Dr. Fromowitz stated that in some instances it could. *Id.*

In light of this, we determine Dr. Fromowitz testified that Parasher's device can obtain a gross tissue sample, meaning a sample that is visible to the naked eye, and this sample would include more cells than would be obtained by cytology. *See* Ex. 1012, 95:16–96:18 (referring to Ex. 1003, 2:20–25), 94:8–96:12 (referring to Ex. 1003, 2:20–25). The size of the specimen collected (more cells than cytology and visible to the naked eye) supports Petitioner's contention that Parasher's device dislodges cells from below the exterior boundary of the epithelium. This information is consistent with our analysis of Parasher above.

Further, Dr. Fromowitz testified three times that Parasher's could obtain a specimen that included portions of the submucosa. *Id.* at 94:8–95:12 (referring to Ex. 1013, 1:61–64 and stating that a specimen "would have to also include the submucosa"), 99:12–16 (referring to Ex. 1003, 3:26–28 and stating that Parasher's device could obtain a specimen that included submucosa, but not reliably so), 99:20–100:4 (referring to Ex. 1003, 2:24–25 and stating that in some instances Parasher's device could obtain such a specimen). This evidence is consistent with our analysis of Parasher above. This evidence suggests that Parasher's brush not only is capable of dislodging cells from below the surface of the epithelium, but can also penetrate to the submucosa.

D. Conclusions by Claim

1. Claim 1

Petitioner identifies and explains how Parasher discloses each element of claim 1, with the only contested aspect being whether Parasher's brush is capable of dislodging and collecting cells from the tissue below the surface of the epithelium. Patent Owner challenges Dr. Kahaleh's evidence regarding the composition of a biopsy; however, this challenge is not persuasive because our analysis of Petitioner's case does not rely on this evidence. With regard to Petitioner's analysis of Parasher, Patent Owner simply contends that Parasher is silent regarding the capabilities of the brush. To the contrary, Parasher is not silent, and Petitioner's analysis of Parasher demonstrates that it is more likely than not that Parasher's brush obtains such a specimen by dislodging cells from below the exterior boundary of the epithelium. Dr. Fromowitz's testimony is consistent with, and further supports Petitioner's case.

We conclude that Petitioner has shown by a preponderance of the evidence that claim 1 is anticipated by Parasher.

2. Claim 2

Claim 2 depends from claim 1 and adds that the "brush bristles are at least 1000 microns in length." Parasher discloses that bristles 11 of brush 9 may extend 1 to 3 millimeters. Pet. 23; Ex. 1003, 4:59–64. Patent Owner repeats the arguments for claim 1, and these arguments are not persuasive for the reasons given above. PO Resp. 13. Further, these arguments do not address persuasively the additional limitation of claim 2. *See* 37 C.F.R. § 42.23(a).

We conclude that Petitioner has shown by a preponderance of the evidence that claim 2 is anticipated by Parasher.

3. Claim 3

Claim 3 depends from claim 1 and adds that the "epithelium tissue comprises metaplastic glandular epithelium tissue." Petitioner explains that Parasher's device is capable of obtaining samples from metaplastic glandular epithelium tissue.[29] Pet. 23–24; Ex. 1010 ¶ 12. Patent Owner repeats the arguments for claim 1. These arguments are unpersuasive for the reasons given above. Further, these arguments do not address persuasively the additional limitation of claim 3. *See* 37 C.F.R. § 42.23(a).

We conclude that Petitioner has shown by a preponderance of the evidence that claim 3 is unpatentable as anticipated by Parasher.

4. Claim 4

Claim 4 depends from claim 3 and adds, "wherein said specimen of the tissue area comprises a disaggregated specimen of the whole tissue, said whole tissue being defined of at least glandular cells, plus basement membrane fragments, plus elements of the submucosa in the area being examined." Petitioner contends that Parasher's brush is capable of obtaining a specimen as required by claim 4. Pet. 24–25.

The '609 patent describes that by rubbing harder than normal cytological sampling with a stiff device which penetrates epithelium, the basement membrane can be reached. Ex. 1001, 6:42–50. As explained above Parasher's device includes stiff or semi-rigid bristles and operates in a similar manner.

[29] Metaplastic glandular epithelium tissue can be present in the esophagus and Parasher's device may be used in the esophagus. Ex. 1001, 9:30–33; Ex. 1003, 1:27–30.

Parasher's brush 9 has bristles that are 1 to 3 millimeters in length, which Petitioner contends is long enough to reach the submucosa and is not contested by Patent Owner. *See* Pet. 25; Ex. 1010 ¶ 11; Ex. 1003, 4:59–64.

Beyond this similarity in structure and method of obtaining a sample, Petitioner contends that Parasher's brush obtains a specimen from adjacent tissue, which includes the submucosa. Pet. 25 (citing Ex. 1003, 1:54–67). As explained above, Dr. Fromowitz testified that Parasher's brush could obtain a specimen that included portions of the submucosa. *See* Pet. Reply 7–8. In fact, as detailed above, Dr. Fromowitz was asked in three different ways if Parasher's brush was capable of obtaining a specimen from the submucosa, and each time testified that it could.

We conclude that Petitioner has shown by a preponderance of the evidence that claim 4 is unpatentable as anticipated by Parasher.

VI. OBVIOUSNESS OVER PARASHER AND EISEN

Petitioner contends that claims 3 and 4 are unpatentable over Parasher (Ex. 1003) and Eisen (Ex. 1005). Pet. 25–29; Pet. Reply 12. Specifically, Petitioner contends that Eisen discloses a brush that obtains samples that are the functional equivalent of tissue samples taken by laceration, and it would have been obvious to substitute Eisen's brush for Parasher's brush to reach the subject matter of claims 3 and 4. Pet. 25–29. Regarding claim 3, Petitioner contends that Eisen's brush 126 is capable of obtaining a biopsy sample of metaplastic glandular epithelium tissue. Pet. 27–28; Pet. Reply. 12. Regarding claim 4, Eisen's brush is capable of penetrating all layers of the epithelia so that the brush is capable of obtaining disaggregated specimen of glandular cells, basement membrane fragments, and

elements of the submucosa. Pet. 28; Ex. 1005, 12:30–45, 13:48–14:7. As explained below, these findings are adequately supported.

Eisen discloses brush 126 for performing a brush biopsy of epithelial tissue to obtain a cellular sample for diagnosis of cancer. Pet. 25; Ex. 1005, 2:20–32, 5:59–67. Bristles 140 of brush 126 have an upper limit on stiffness to avoid bleeding, trauma, discomfort, and scarring (non-lacerational). Pet. 26–27; Ex. 1005, 12:30–45, 13:2–6. Bristles 140 are stiff or semi-rigid, and are capable of exerting sufficient pressure to conduct a brush biopsy that dislodges cells from all epidermal layers. Pet. 26–27; Ex. 1005, 12:30–45, 13:2–6. The sample obtained is the functional equivalent of samples taken by lacerating biopsy procedures. Pet. 26; Ex. 1005, 3:56–4:12. The brush may be used in various areas of the body, to include the esophagus. Pet. 26; Ex. 1005, 4:25–30.

Petitioner's reasoning that modifying Parasher's device to utilize Eisen's brush is a simple substitution with predictable results is supported by the factual underpinning that Eisen's and Parasher's brushes have the same purpose and perform the same function. *See* Pet. 22 (citing Ex. 1003, 1:54–67; 2:17–19, 35–40), 25–27 (citing at least Ex. 1005, 2:20–32; 5:59–67; 4:24–30).

In the Preliminary Response, Patent Owner argued that Petitioner relies upon improper hindsight analysis, the combination would not have been obvious to try, and the combination would have been counter-intuitive. Prelim. Resp. 6–7. In the Institution Decision we stated that these arguments were unpersuasive without supporting evidence. Inst. Dec. 13–14. Patent Owner does not repeat these arguments in the Response, or provide supporting evidence. Consequently our analysis has not changed.

In the Response, Patent Owner repeats the argument that Parasher's brush is not capable of dislodging cells and picking up a specimen as claimed. PO Resp.

14–15. Such argument is not responsive because Petitioner's arguments supporting this ground of unpatentability rely upon Eisen's brush, not Parasher's. *See* Pet. 25–29.

At the oral hearing, Patent Owner argued that Eisen's brush cannot be substituted into Parasher's endoscope. *See* Ex. 2006, 49–51, Tr. 72–75. Petitioner correctly objects that this is a new argument. Paper 25, 3[30]; Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012).[31] Therefore, we do not consider this argument.

In light of this, Patent Owner has not challenged effectively any material fact in Petitioner's ground of unpatentability. *See* 37 C.F.R. § 42. 23(a).

Petitioner has demonstrated by a preponderance of the evidence that claims 3 and 4 are unpatentable over Parasher and Eisen.

VII. CONCLUSION

Petitioner has met its burden of proof by a preponderance of the evidence that (1) claims 1–4 are anticipated by Parasher and (2) claims 3 and 4 would have been obvious over Parasher and Eisen.

[30] The pages of this exhibit are not numbered.

[31] *See also* Paper 23, 3 (directing the parties to *St. Jude Med., Cardiology Div., Inc. v. Bd. of Regents of the Univ. of Mich.*, IPR2013-00041 (PTAB January 27, 2014) (Paper 65), for guidance regarding the appropriate content of demonstrative exhibits).

VIII. ORDER

Accordingly, it is

ORDERED that claims 1–4 of U.S. Patent 6,676,609 B1 are determined by a preponderance of the evidence to be unpatentable;

ORDERED that no later than five business days from the entry of this decision, that Petitioner's Demonstratives be filed as Exhibit 1014 and Patent Owner's Demonstratives be filed as Exhibit 2006; and

FURTHER ORDERED that because this is a final written decision of the Board under 35 U.S.C. § 318(a), parties to the 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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