

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 IPR2014-00641
Patent 7,004,913 B1

Before PHILLIP J. KAUFFMAN, SCOTT E. KAMHOLZ, and
BARRY L. GROSSMAN, *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, U.S. Endoscopy Group, Inc., seeks review of claims 1–3 of U.S. Patent No. 7,004,913 B1 (issued Feb. 28, 2006) (Ex. 1001, “the ’913 patent”).¹ *See* Paper 1 (“Pet.”). Patent Owner, CDx Diagnostics, Inc., contends that Petitioner’s request should be denied. *See* Paper 6 (“Prelim. Resp.”). Based upon our review of the record to this point in the proceedings, Petitioner has established a reasonable likelihood of prevailing on the claims challenged in the Petition. Therefore, we institute an *inter partes* review of claims 1–3 of the ’913 patent. *See* 35 U.S.C. § 314.

A. *Related Proceedings*

Related U.S. Patent No. 6,676,609 B1 (“the ’609 patent”) is involved in an *inter partes* review designated IPR2014-00639. The ’913 patent is a continuation of the ’609 patent. Ex. 1001, 1.

Petitioner states that Patent Owner has asserted infringement of the ’913 patent against the Petitioner in co-pending district court case: *CDx Diagnostics, Inc., et al. v. U.S. Endoscopy Group, Inc.*, Case No. 1:13-cv-5669-NSR (S.D.N.Y.). Pet. 3.

¹ Petitioner also filed a corrected petition (Paper 4) to provide an Exhibit List that was absent from the original Petition.

B. The Prior Art

Petitioner relies on the following prior art references:

1003	Parasher	US 5,535,756	July 16, 1996
1004	Parasher Article	“Endoscopic Retrograde Wire-Guided Cytology of Malignant Biliary Structures Using a Novel Scraping Brush,” <i>Gastrointestinal Endoscopy</i> , Vol. 48, No. 3	1998
1005	Eisen	US 6,297,044 B1	Oct. 2, 2001
1006	Stormby	US 4,759,376	July 26, 1988
1007	Olympus	<i>1992 Endo-Therapy System Catalog: Gastrointestinal Devices</i>	Dec. 31, 1992
1008	Boon	<i>Exploiting the “Toothpick Effect” of the Cytobrush by Plastic Embedding of Cervical Samples, ACTA CYTOLOGICA</i>	Jan-Feb 1991
1009	Falk	<i>Surveillance of Patient’s with Barrett’s Esophagus for Dysplasia and Cancer with Balloon Cytology, Gastroenterology Vol. 112, No. 6</i>	1997

C. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

Reference[s]	Basis	Claim(s)
Parasher	§ 102	1–3
Parasher and Eisen	§ 103	3
Olympus and Eisen	§ 103	1–3
Olympus, Stormby, and Boon	§ 103	1–3
Olympus and Falk	§ 103	1–3

D. The '913 Patent

The '913 patent discloses that cancers of the oral cavity and pharynx are a major cause of death in the United States, due in part to delay in diagnosis caused by limited diagnostic tools. Ex. 1001, 1:42–2:28. According to the '913 patent, Lacerational biopsies (histological sections to remove tissue taken by scalpel or laser) were the only reliable means for determining if a suspect lesion was cancerous or precancerous; however, this approach was often inconvenient, painful, and expensive. *Id.* at 2:29–38, 6:25–28. Cytology, an alternative to lacerational biopsies, was performed using a brush designed of various soft materials (with or without bristles) to remove gently surface material (exfoliated or sloughed cells) from the surface of the epithelium with minimum abrasion to the epithelium. *Id.* at 3:31–33, 3:67–4:3. Cytology suffered from a high false negative rate because in many oral cavity lesions the abnormal cells are blocked in the keratin layer and never reach the surface. *Id.* at 5:8–14. The '913 patent discloses a brush biopsy device intended to be used with endoscopes to sample tissue without the pain and injury of lacerational biopsies. *Id.* at 5:50–52.

The '913 patent is titled “Retractable Brush for Use with an Endoscope for Brush Biopsy,” and is directed to a method and apparatus for obtaining transepithelial specimens of body surfaces using a non-lacerating technique with retractable tools, such as a brush used with endoscopes. Ex. 1001, 1:16–20. The reason for obtaining transepithelial specimens is that suspect cells originate at the basal layer within the tissue. *Id.* at 7:6–8. Figure 3 of the '913 patent is reproduced below:

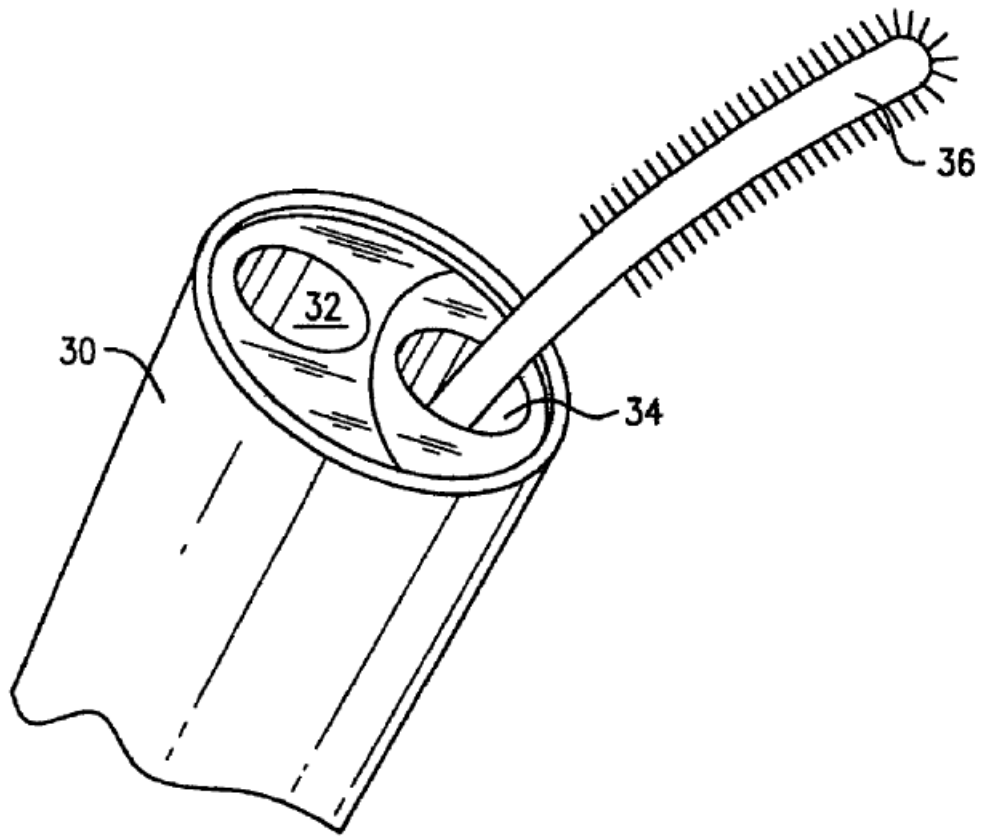


FIG. 3

Figure 3 of the '913 patent is a preferred embodiment shown in partial perspective and sectional view. *Id.* at 7:48–50.

The '913 patent includes claims 1–3. Claim 1 is independent and is directed to an apparatus to be used in conjunction with an endoscope, specifically:

1. An apparatus to be used in conjunction with an endoscope to examine tissue cells located within glandular epithelium, said glandular epithelium comprising tissue at the outermost surface thereof and tissue area below said outermost surface, said apparatus comprising a channel extending the length of the endoscope; said apparatus comprising a rod passing through said 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 dislodge cells and to pick up a specimen from said uppermost surface and said tissue area therebelow.

Claim 2 depends from claim 1 and adds that the “bristles are at least 1000 microns in length.” Claim 3 depends from claim 1 and adds that the “specimen picked up comprises a disaggregated specimen.”

II. CLAIM CONSTRUCTION

A. *“said apparatus comprising a channel extending the length of the endoscope”*

Claim 1 recites, “said apparatus comprising a channel extending the length of the endoscope.” Ex. 1001, 10:38–39. Petitioner contends 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. 9, 18–19. For the reasons that follow, the quoted language has but one reasonable meaning in light of the Specification, namely, an apparatus that includes a channel for use with an endoscope.

Claim 1 recites “said apparatus comprising a channel extending the length of the endoscope.” These terms unambiguously require that the

apparatus include a channel. With this claim language in mind, we turn to the Specification.

The Specification states that the objects of the '913 patent “are accomplished by providing a channel in the longitude interior of an endoscope through which a retractable brush may pass.” Ex. 1001, 6:34–36. The Specification also describes endoscope 24 that includes channel 22. Ex. 1001, 8:13–14, Fig. 1. Thus, the Specification describes that the endoscope may include a channel. Such disclosure is not inconsistent with our interpretation that claim 1 requires that the apparatus include a channel, because both the endoscope and the claimed apparatus may include a channel. We discern nothing in the Specification inconsistent with our interpretation that claim 1 requires the apparatus to include a channel.

B. “said brushing apparatus”

Claim 1 recites “said brushing apparatus comprising bristles.” Although we agree with Petitioner that the phrase “said brushing apparatus” technically lacks an antecedent basis (*see* Pet. 12, 20), such error does not render claim 1 indefinite if the scope of the claim would be reasonably ascertainable by those skilled in the art. *See Energizer Holdings Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 1370–71 (Fed. Cir. 2006). Claim 1 requires that the apparatus include a retractable non-lacerational brush attached to the distal end of the rod, with the brush being movable to bear against and remove tissue from the tissue area being examined. Claim 1 also requires that the “brushing apparatus” includes bristles that exert sufficient pressure to conduct a biopsy to dislodge cells and pick up a specimen of tissue. In parity with the claim language, the Specification describes that the brush

removes suspect tissue for examination. Ex. 1001, 6:39–42. Specifically, the Specification describes that rod 21 permits pressure by the bristles 20 of brush 10 against the tissue being examined. *Id.* at 8:11–13, 42–48, Fig. 1. In light of this, a person of ordinary skill in the art would reasonably ascertain that the claimed “brushing apparatus” that includes bristles refers to the “retractable non-lacerational brush attached to the distal end of the rod,” recited earlier in the claim.

C. *“bristles which exert sufficient pressure to dislodge cells and to pick up a specimen from said uppermost surface and said tissue area therebelow.”*

Petitioner contends 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. 12. Patent Owner does not contest directly this interpretation.

We agree with Petitioner’s claim construction except that claim 1 is not limited to a brush that includes bristles having penetrating edges of sufficient stiffness. Rather, claim 1 defines the bristles of the brush functionally in terms of capability, a point acknowledged by Petitioner. *See* Pet. 2, 6. Therefore, claim 1 encompasses any brush bristles capable of dislodging cells and picking up a specimen of tissue from the uppermost surface of the glandular epithelium and the tissue therebelow.

III. ANALYSIS

A. *Alleged Anticipation by Parasher - Claims 1-3*

Petitioner contends that claims 1–3 are unpatentable as anticipated by Parasher. Pet. 13–23. Significantly, for this ground of unpatentability, Petitioner contends that Parasher’s apparatus comprises a channel (sleeve 17). Pet. 18.

Patent Owner contends that Parasher is “essentially a cytological brush,” and does not teach or suggest a brush that penetrates an epithelial layer and picks up tissue located below the surface of the epithelial tissue as claimed. Prelim. Resp. 4–5. In support of this contention, Patent Owner emphasizes that Petitioner misquoted Parasher as stating that “a biopsy sample is a gross tissue sample that includes the mucous lining of the duct, the tissue of the duct, and even adjacent *connective* tissues (*e.g. the submucosa*),” when Parasher actually discloses just “tissue,” not “connective tissue,” and does not give the example of submucosa. Prelim Resp. 4–5 (quoting Pet. 15) (emphasis added).

To the extent that Patent Owner’s argument can be seen as an assertion that Petitioner literally incorrectly quoted Parasher, we do not agree. Petitioner did not quote Parasher; rather, Petitioner summarized what is disclosed by Parasher. *See* Pet. 15 (citing Ex. 1003, 1:54–67). We, however, agree with Patent Owner that the portion of Parasher cited by Petitioner refers to “adjacent tissues,” not “adjacent connective tissues,” and does not provide the example of submucosa as adjacent tissue. *See* Prelim. Resp. 4–5; Ex. 1003, 1:54–67. For that reason, Petitioner overstates what the reference discloses. Yet, this does not end our inquiry because the Petition provides other support for the contention that Parasher’s brush is

capable of dislodging cells and picking up a specimen of tissue below the surface of the epithelium tissue. In particular, Petitioner asserts that Parasher's device 1 includes brush 9 having semi-rigid bristles 11 that permit collection, without laceration, of a tissue sample sufficient to qualify as a biopsy. Pet. 13–17, 20–22 (citing, *inter alia*, Ex. 1003, 2:12–40, 4:46–59, 5:46–57, Figs 4a–4c). Petitioner asserts, citing for support the Declaration of Michel Kahaleh, M.D., that a person of ordinary skill in the art would have understood a biopsy sample to include fragments of tissue all the way down to the submucosa, as well as fragments of the basement membrane. Pet. 16, 21–23 (citing Ex. 1010 ¶ 10). The portions of Parasher cited by Petitioner and the supporting evidence in the declaration adequately support Petitioner's assertion that Parasher's brush 9 includes bristles that penetrate an epithelial layer and picks up tissue located below the surface of the epithelial tissue as required by claim 1. *See* Pet. 22.

Regarding the remaining limitations of claim 1 and the limitations of claims 2 and 3, Petitioner specifically alleges where each element of the claim is found in the prior art with citations by exhibit number to the specific portion of the evidence that supports the challenge. Pet. 13–23. Petitioner also provides a supporting declaration that is cited and explained as applicable. *See, e.g.*, Pet. 16 (citing Ex. 1010 ¶ 10). Having considered the Petition and Patent Owner's Preliminary Response, we determine that Petitioner has established a reasonable likelihood of prevailing in establishing that claims 1–3 are anticipated by Parasher.

B. Parasher and Eisen - Claim 3²

Petitioner contends that claim 3 is unpatentable over Parasher and Eisen. Pet. 23–26. 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 claim 3. Pet. 24–25.

Patent Owner presents three arguments against this ground of unpatentability. Prelim. Resp. 5–7. First, Patent Owner reasserts the argument against Parasher discussed in section III.A. above. Prelim. Resp. 5. Patent Owner’s argument that Parasher’s brush is not capable of dislodging cells and picking up a specimen as claimed is inapposite because Petitioner’s arguments supporting this ground of unpatentability rely upon Eisen’s brush, not Parasher’s. *See* Pet. 25.

Second, Patent Owner asserts that Eisen “was considered by the Examiner during prosecution of the ’913 patent.” Prelim. Resp. 6 (citing an Office Action dated 1/12/2004). The Director may take into account and reject a petition where the same or substantially the same prior art or arguments previously were presented to the Office. 35 U.S.C. § 325(d). Patent Owner states that Eisen was considered in an Office Action dated January 12, 2004; however, the ’913 patent was filed on this date so it is highly unlikely an Office Action was issued on that date. *See* Ex. 1001, 1.

² At one point Petitioner states this ground applies to claims 1–3 (Pet. 23); however, elsewhere Petitioner consistently refers to this ground as applying to claim 3 (*see, e.g.*, Pet. 5, 23). Further, only claim 3, not claims 1 and 2, has a sub-heading in section V.C. of the Petition. Consequently, this ground of unpatentability applies only to claim 3.

Indeed, the prosecution history of the '913 patent does not include a rejection based upon Eisen. Ex. 1002. Perhaps more importantly, Patent Owner's assertion relates to Eisen alone, and the ground of unpatentability at issue here is Parasher and Eisen. For these reasons, the Office has not considered previously the same art and arguments at issue here, and we decline to reject the petition based upon our discretion under 35 U.S.C. § 325(d).

Third, Patent Owner attacks Petitioner's asserted rationale for combining Parasher and Eisen. Prelim. Resp. 6–7. Specifically, Patent Owner asserts that Petitioner has relied upon improper hindsight analysis, and that the combination would not have been obvious to try. *Id.* at 6. Further, Patent Owner asserts, without supporting evidence, that diagnosing cancer of the aero-digestive tract necessitates obtaining tissue architecture, but Eisen's brush destroys tissue architecture in the process of obtaining cells, so that the combination of Parasher and Eisen would have been counter-intuitive. *Id.* at 6-7.

Petitioner's rationale is that it would have been obvious to combine Parasher and Eisen as a simple substitution of one brush for another with predictable results. Pet. 25–26. Owner asserts that Petitioner's rationale is based upon improper hindsight; however, Patent Owner has not provided sufficient evidence to suggest that Petitioner is relying on improper hindsight. Further, Petitioner does not rely upon an obvious to try rationale. Regarding Patent Owner's assertion that the combination would have been counter intuitive, we note that claim 3 does not require that the sample taken is suitable for diagnosing cancer of the aero-digestive tract. Further, for purposes of this decision, we credit Petitioner's argument and evidence that

Eisen's and Parasher's brushes have the same purpose and perform the same function, so that the proposed modification creates a device that is still suitable for Parasher's purpose. *See* Pet. 21 (citing Ex. 1003, 1:54-67; 2:17-19, 35-40; Ex. 1010 ¶ 10), 23-26 (citing, *inter alia*, Ex. 1005, 2:20-32; 5:59-67; 4:24-30). Consequently, Patent Owner's attacks on the rationale provided by Petitioner are unpersuasive.

Petitioner specifically alleges where each element of claim 3 is found in the prior art with citations by exhibit number to the specific portion of the evidence that supports the challenge. Pet. 23–26. Petitioner also provides a supporting declaration that is cited and explained as applicable. *See* Pet. 26 (citing Ex. 1010 ¶ 6). Having considered the Petition and Patent Owner's Preliminary Response, we determine that Petitioner has established a reasonable likelihood of prevailing in establishing that claims 3 and 4 are unpatentable over Parasher and Eisen.

C. Remaining Grounds Based in Part on Olympus

Each of the Petitioner's remaining grounds of unpatentability relies upon Olympus as disclosing an endoscope having a channel. Pet 26–48. Petitioner's assertion is based upon Petitioner's proposed interpretation of claim 1 as requiring calls for an endoscope comprising a channel, rather than the claimed apparatus comprising a channel. As explained above, claim 1 requires the claimed apparatus to comprise a channel. Because Petitioner's argument are based on an incorrect claim construction, Petitioner fails to make a cogent assertion that Olympus discloses an apparatus that comprises a channel or that it would have been obvious to modify Olympus's apparatus

to include such a channel. Consequently, Petitioner has failed to establish a reasonable likelihood of prevailing on these grounds of unpatentability.

IV. CONCLUSION

For the foregoing reasons, we are persuaded that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail with respect to claims 1–3.

The Board has not made a final determination on the patentability of any challenged claims.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–3 of the '913 patent for the following grounds:

A. Claims 1–3 under 35 U.S.C. § 102 by Parasher; and

B. Claim 3 under 35 U.S.C. § 103 over Parasher and Eisen.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial is commencing on the entry date of this decision; and

FURTHER ORDERED that the trial is limited to the grounds identified above and no other grounds are authorized.

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