

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 IPR2014-00642
Patent 6,258,044 B1

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

DANIELS, *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 4, “Pet.”) seeking *inter partes* review of claims 1–39 of U.S. Patent No. 6, 258,044 B1 (Ex. 1001, “the ’044 patent”).¹ Patent Owner, CDx Diagnostics, Inc., filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

In the Decision to Institute (Paper 7, “Inst. Dec.”), we instituted trial on claims 1–17, 19–20, 23–28, 32, and 35–39 based on the following grounds:

1) claims 1–8, 11–17, 23–28, 32, and 35–39 based under 35 U.S.C. § 102(b) by Parasher²; and

2) claims 9, 10, 19, and 20 under 35 U.S.C. § 103(a) over Parasher and Markus.³

Subsequently, Patent Owner filed a Patent Owner Response⁴ (Paper 14, “PO Resp.”), and Petitioner filed a Reply (Paper 16, “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 18, 20, and 21. A transcript of the oral hearing is included in the record. Paper 24 (“Tr.”).⁵

¹ We refer to the Corrected Petition, filed April 28, 2014.

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

³ U.S. 5,407,807, issued April 18, 1995 (Ex. 1005).

⁴ We refer to Patent Owner’s Corrected Patent Owner’s Response, filed February 9, 2015.

⁵ A single Transcript was created for the oral hearing for IPR2014-00639, IPR2014-00641, and IPR2015-00642. *See the Related Proceedings* section below.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–17, 19, 20, 23–28, 32, and 35–39 of the '044 patent are unpatentable.

B. Related Proceedings

Petitioner asserted the '044 patent in *CDx Diagnostics, Inc. v. U.S. Endoscopy Group, Inc.*, Case No. 1:13-cv-5669-NSR (S.D.N.Y.). Pet. 2.

The parties are also involved in IPR2014-00639, a challenge to U.S. 6,676,609 B1 (the "'609 patent") and IPR2014-00641 challenging U.S. Patent No. 7,004,913 B1 (the "'913 patent"). The '609 patent, the '913 patent, and the '044 patent all relate to similar subject matter of a brush for obtaining a patient biopsy. The '044 patent is, however, not related to the '609 patent or the '913 patent.

II. THE '044 PATENT

The '044 patent relates to a method and apparatus for obtaining cells from multiple layers of epithelium by abrasion and without laceration. Ex. 1001, 4:55–5:8; 5:25–28. In a preferred embodiment, the apparatus includes a brush having bristles of sufficient stiffness to allow them to dislodge and sweep up cells from superficial, intermediate, and basal layers of epithelium, and to penetrate the basement membrane underlying the epithelium to reach the submucosa, without having to resort to the dangers of incisional-based biopsy. *Id.* at 4:63–5:8; 5:24–40; 9:19–20. The brush is mounted on the distal end of a handle. *Id.* at 7:8–9. The bristles extend from wires that emanate from the distal end of the handle. The wires may form a toroid or spiral shape that is oriented substantially perpendicular to the axis of the handle. *Id.* at 7:23–28; Fig. 4. Figure 4 of the '044 patent is reproduced below:

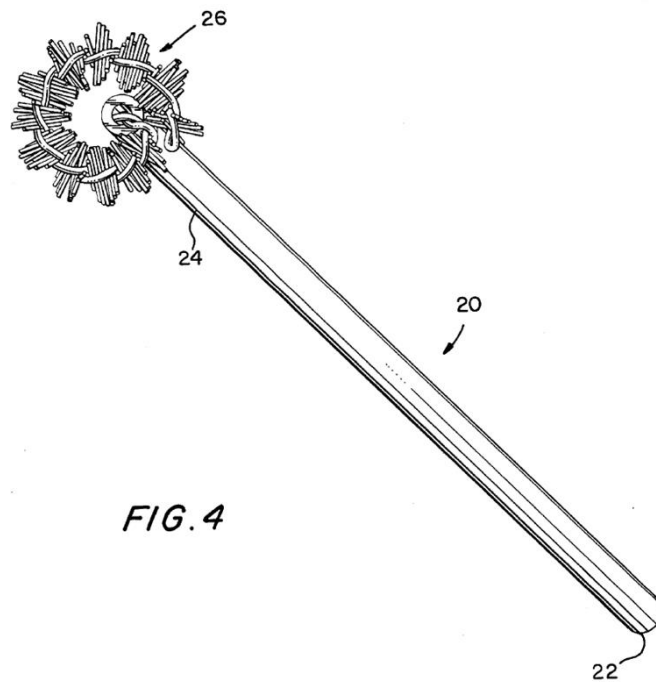
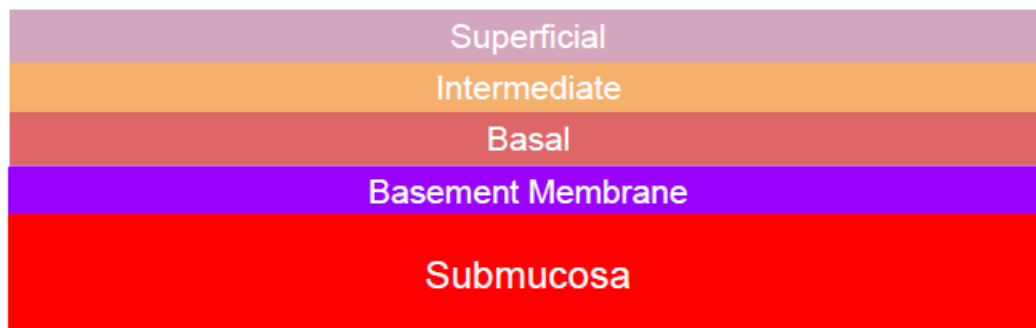


FIG. 4

Figure 4 of the '044 patent illustrates a preferred embodiment shown in perspective view. *Id.* at 7:44–46.

Also helpful to our Decision, below, is an illustration of the layers of epithelial tissue. 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 follows:



This figure depicts the layers of epithelial tissue adjacent to the basement membrane and submucosa. *See* Ex. 3002, 4⁶ (Patent Owner's demonstratives); Ex. 3003, 2 (Petitioner's demonstratives).⁷

The '044 patent describes its claimed apparatus through a contrast to cytology as well as lacerating biopsy. Cytology uses a soft brush to gently remove (sweep) previously freed cells (exfoliated or sloughed off) from the surface of the epithelium in a non-invasive manner that avoids or minimizes abrasion of the epithelium and is intended to be painless. Ex. 1001 at 2:26–4:24. On the other hand, a lacerating biopsy uses a cutting instrument such as a scalpel or a laser to remove tissue for evaluation. *Id.* at 1:65–2:3. The described brush uses a stiffer brush and rubs harder than cytology so that the surface of the epithelium is penetrated. *Id.* at 4:63–5:2. In other words, the stiff brush penetrates the surface of the epithelium by dislodging cells (as opposed to sweeping up previously freed cells) and picks up those cells without the invasive effects and discomfort of lacerating biopsy. *Id.*

III. THE CHALLENGED CLAIMS

Independent claims 1, 12, and 26 are illustrative of the claimed subject matter and are reproduced below.

⁶ Citing Ex. 1001 at 4:34–37, 11:56–65.

⁷ We exercise our discretion and enter the parties' demonstratives, which we earlier ordered to be served and not filed. *See* Paper 21, 2–3. This information appears uncontested in that the parties each depict the layers in the same manner. *Compare* Ex. 3002, 4, *with* Ex. 3003, 2. We discern no evidence in the case that contradicts this depiction.

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