

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

CDX DIAGNOSTICS, INC. and
SHARED MEDICAL RESOURCES, LLC,
Patent Owner.

Case IPR2014-00642
Patent 6,258,044 B1

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

KAMHOLZ, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

U.S. Endoscopy Group, Inc. (“Petitioner”) filed a Corrected Petition (Paper 4, “Pet.”), requesting institution of an *inter partes* review of claims 1-39 of U.S. Patent No. 6,258,044 B1 (“the ’044 patent”). Patent Owners CDx Diagnostics, Inc. and Shared Medical Resources, LLC (collectively “Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314.

We institute *inter partes* review because we determine that the information presented in the Petition and in the Preliminary Response shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. *See* 35 U.S.C. § 314(a). In particular, we institute *inter partes* review with respect to claims 1-17, 19, 20, 23-28, 32, and 35-39, but not as to claims 18, 21, 22, 29-31, 33, and 34.

B. The ’044 Patent

The ’044 patent relates to an 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 may 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.

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

1. Apparatus to obtain cells in epithelial tissue of the body comprising:

transepithelial non-lacerational sampling apparatus to collect cells from at least two layers of said epithelial tissue, said transepithelial non-lacerational sampling apparatus comprising a brush, said brush comprising bristles having sufficient stiffness to penetrate at least said two layers of said epithelial tissue.

12. A transepithelial non-lacerational sampling apparatus to harvest cells in an oral cavity from the epithelial tissue, said epithelial tissue comprising superficial, intermediate and basal layers, and a basement membrane located between the basal layer and the submucosa, said non-lacerational sampling apparatus comprising means to traverse said superficial, intermediate and basal layers and to collect cells from said three layers.

26. A method to collect cells in epithelial tissue of the body comprising:

passing a transipithelial¹ non-lacerational sampling means through the epithelial tissue to collect cells from at least two layers of said epithelial tissue.

¹ For purposes of this decision, we interpret the term “transipithelial” as “transepithelial.” The error appears to have been introduced by the Office. *Compare* Ex. 1002, 76 *with id.* at 42.

C. Prior Art Relied Upon in the Petition

Petitioner relies upon the following references, as well as the declaration of Michael Kahaleh, M.D. (Ex. 1011):

Parasher	U.S. Pat. No. 5,535,756	July 16, 1996	Ex. 1003
Markus	U.S. Pat. No. 5,407,807	Apr. 18, 1995	Ex. 1005
SpiraBrush	Specimen of Use filed in U.S. Trademark Appl. Ser. No. 74/370,500	Mar. 22, 1993	Ex. 1006
Stormby	U.S. Pat. No. 4,759,376	July 26, 1988	Ex. 1007
Boon	Boon et al., "Exploiting the 'Toothpick Effect' of the CytoBrush by Plastic Embedding of Cervical Samples." <i>Acta Cytologica</i> , 35(1): 57-63	Jan.-Feb. 1991	Ex. 1008
Nomiya	U.S. Pat. No. 2,675,572	Apr. 20, 1954	Ex. 1009

D. The Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable based on the following grounds:

Reference(s)	Basis	Claims Challenged
Parasher	§ 102	1-8, 11-17, 23-28, and 31-39
Parasher and Markus	§ 103	9, 10, 19, and 20
Parasher and SpiraBrush	§ 103	18, 21, and 22
Parasher and Nomiya	§ 103	18, 21, and 22
Stormby, Boon, and Parasher	§ 103	1-8, 11-18, and 21-39
Stormby, Boon, Parasher, and Markus	§ 103	9, 10, 19, and 20

Reference(s)	Basis	Claims Challenged
Stormby, Boon, Parasher, and SpiraBrush	§ 103	18, 21, and 22
SpiraBrush and Parasher	§ 103	1-8, 11-18, and 21-39
SpiraBrush, Parasher, and Markus	§ 103	9, 10, 19, and 20

II. DISCUSSION

A. Claim Construction

Petitioner proposes a construction of the terms “transepithelial” (occurring in all claims), “non-lacerational” (occurring in all claims), “abrasive surface” (in claims 4 and 24), and “tip stiffness” (in claims 9 and 19). Pet. 7. Patent Owner does not comment on these proposed constructions in the Preliminary Response.

We have considered Petitioner’s proposed constructions, but determine that no express constructions of these or other terms are necessary for purposes of this decision.

B. Anticipation by Parasher

Petitioner argues that claims 1-8, 11-17, 23-28, and 31-39 are anticipated by Parasher. Pet. 7-21.

1. Claims 1-11, 14-17, and 37-39

With regard to claim 1, 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. 8-10 (citing, *inter alia*, Ex. 1003, 2:12-40, 4:46-59, 5:46-57, Figs. 4a-4c).

Petitioner asserts, citing Dr. Kahaleh’s declaration for support, that a person

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