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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL J. BUSCEMI

Appeal 2011-003429
Application 11/426,133
Technology Center 3700

Before DONALD E. ADAMS, ERIC GRIMES, and
ERICA A. FRANKLIN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claim 1 (App. Br. 11; Ans. 2; Reply Br. 2). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claim 1 is directed to a method for treating obstructive sleep apnea and is reproduced in the Claims Appendix of Appellant's Brief.

Claim 1 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Conrad.¹ We reverse.

¹ Conrad et al., US 2005/0092334 A1, published May 5, 2005.

ISSUE

Does the preponderance of evidence on this record support a conclusion that Conrad suggests an implant comprising a fibrosis-inducing agent and an anchor, wherein the fibrosis-inducing agent is anchored to the hyoid bone by the anchor, as required by Appellant's claimed invention?

FACTUAL FINDINGS (FF)

FF 1. Appellant's Figures 1 and 4 are reproduced below:

FIG.1

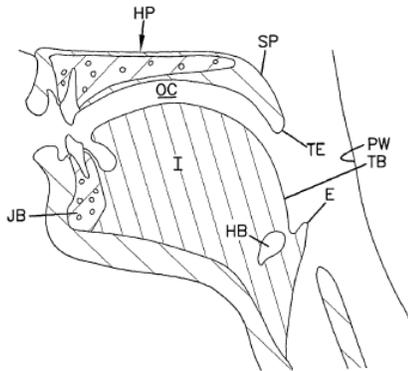


FIG.4

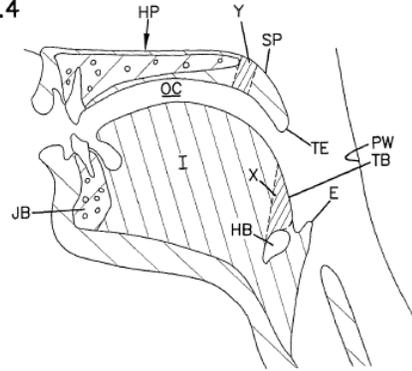


Fig. 1 is a schematic representation of an upper airway of a patient. Fig. 1 shows the tongue T with a tongue base TB opposing a pharyngeal wall PW. The hard palate HP and soft palate SP reside over the top of tongue T with the soft palate SP extending rearward to a trailing end TE between the tongue base TB and the pharyngeal wall PW. A hyoid bone HB resides near the bottom of the tongue near an epiglottis E. A mandible or jaw bone JB is at the front of the tongue T.

(Spec. 4: 25-30.)

“Fig. 4 is the view of Fig. 1 showing a region of the tongue to be stiffened according to ... [Appellant's] invention” (*id.* at 3: 22-23).

Specifically, Appellant's

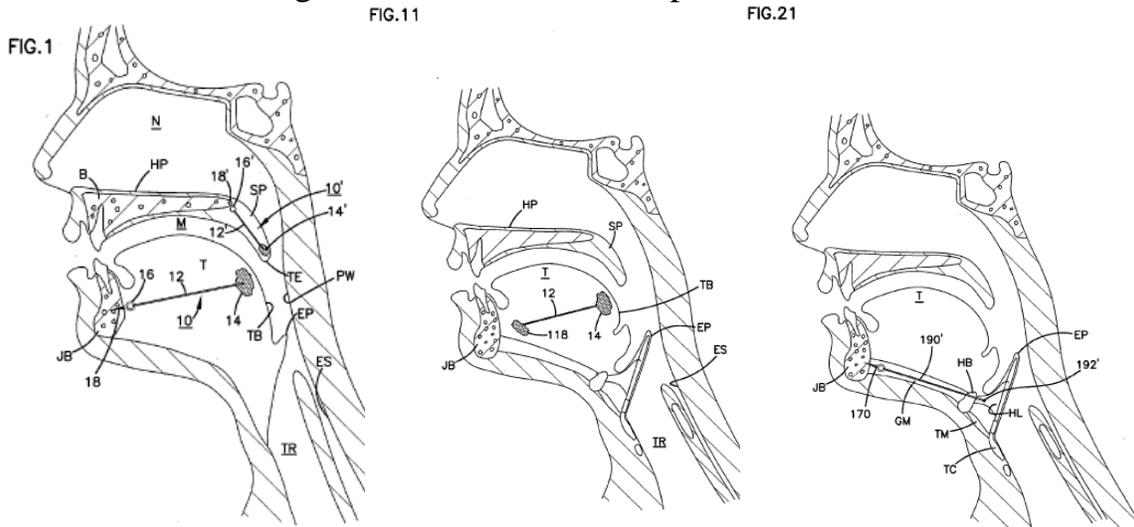
[I]nvention stiffens the tongue base in a manner to create a stiffened area which is anchored to the hyoid bone HB. This is schematically illustrated in Fig. 4 where an area to be stiffened is indicated by X. The area X extends substantially from the

hyoid bone rearward towards a back surface of the tongue and upwardly along a back wall of the tongue toward a free end of the soft palate. This region extends laterally superior to the hyoid bone and preferably includes an area including the genioglossus muscle in the region of the hyoid bone.

(Spec. 5: 11-17.)

FF 2. Conrad suggests “a method for treating obstructive sleep apnea comprising: identifying a patient with sleep apnea ... attributable at least in part to movement of a base of a tongue of said patient toward a pharyngeal wall of said patient[and] placing an implant ... within said tongue” (Ans. 4).

FF 3. Conrad’s Figures 1, 11, and 21 are reproduced below:



“**FIG. 1** is a side elevation, schematic view of a patient illustrating structure defining an upper airway of the patient and showing[, *inter alia*,] an implant [10] according to an embodiment of ... [Conrad’s] invention positioned ... in the tongue and secured to the bony structure of the jaw” (Conrad 1: ¶ [0013]; 2: ¶ [0039]).

[I]mplant **10** includes an elongated member **12** having a tissue in-growth end **14** and a static end **16**. The tissue in-growth end **14** may be any tissue growth inducing material (e.g., felt or PET) to induce growth of tissue into the end **14** to secure the

end **14** to surrounding tissue following implantation. The elongated member **12** may be suture material one end secured to the felt **14** and with the static end **16** being a free end of the suture material **12**.

An anchor **18** (shown in the form of a treaded [sic] eye-bolt although other fastening mechanisms could be used) is secured to the jawbone JB.... The end **16** is secured to the anchor **18**.

The end **14** is placed in the tongue near the tongue base TB. A surgeon adjusts a tension of the suture **12**. This causes the tongue base TB to be urged toward the jawbone JB thereby placing the tissue of the tongue in compression.

(Conrad 2: ¶¶ [0040]-[0042].)

“**FIG. 11** is a view similar to that of **FIG. 1** ... showing an alternative embodiment” (*id.* at 2: ¶ [0023]).

Elements in common with those of **FIG. 1** ... are numbered identically. The tissue in-growth end **14** is embedded in the tongue T near the tongue base TB. In stead [sic] of an anchor **18** in the jaw bone JB as described with reference to **FIG. 1**, the embodiment of **FIG. 11** employs an[] additional tissue in-growth material **118** embedded in the tongue T near the jaw bone JB.

(*id.* at 3: ¶ [0054]; Ans. 4 (Conrad suggests that “in lieu of a jawbone anchor ..., a tissue embedded anchor[] (such as anchor 118) could be used”).)

FIG. 21 is a view of **FIG. 11** showing an alternative embodiment of Conrad’s invention, wherein a lever, illustrated as a cable secured to an epiglottis cartilage, is positioned to advance a hyoid bone of a patient (*id.* at ¶¶ [0023]; [0031]; [0033]; and [0034]). “The cable **190**’ may pass through (as shown) or over the hyoid bone HB. The cable **190**’ further passes

through the geniohyoid muscle GM and terminates at a second end **194'** at the jawbone JB where it is secured to an anchor **170'** (*id.* at 4: ¶ [0063]).
FF 4. “Conrad fails to explicitly disclose where said implant is located entirely within a region laterally superior of the hyoid bone” (Ans. 4).

ANALYSIS

The method of Appellant’s claim 1 comprises, *inter alia*, the placement of an implant in a region of the tongue of a patient (Appellant’s Claim 1). Appellant’s claim 1: (a) defines the region as extending laterally superior to a hyoid bone, substantially from the hyoid bone rearward toward a back surface of the tongue; and (b) requires that the implant is located entirely within the foregoing region of the tongue (*id.*; Reply Br. 4). In addition, Appellant’s claim 1 requires the implant to include a fibrosis-inducing agent and an anchor, *wherein the fibrosis-inducing agent is anchored to the hyoid bone by the anchor (id.)*.

Based on Conrad, Examiner concludes that, at the time of Appellant’s claimed invention, it would have prima facie obvious to a person of ordinary skill in this art

to combine the portion of the anchor that passes over the hyoid with the fibrosis inducing agent such as anchor 14 since Conrad provides motivation for the combination ... to achieve an implant located entirely within a region laterally superior of the hyoid bone in order to enhance manipulation of the hyoid bone for airway patency.

(Ans. 4-5; *id.* at 6). In support of this conclusion, Examiner characterizes Conrad’s cable 190’ as an anchor and reasons that since Conrad suggests fibrosis inducing agents as anchors, “[t]he primary fibrosis inducing agent 14 could ... be relied on as the fibrosis agent that is attached to the portion

of the anchor (190') that passes over the hyoid bone" (*Id.* at 4; *see also id.* at 5).

Notwithstanding Examiner's assertion to the contrary, Conrad's element 190' is a cable not an anchor (FF 3; *see* Reply Br. 5 (Examiner's rejection relies on an unsupported modification of "the material of [Conrad's] cable 190' so as to provide anchoring characteristics"); App. Br. 9 (Conrad's "cable 190' is not anchored to the hyoid bone"); *Cf.* Ans. 4-6). Accordingly, Examiner failed to establish an evidentiary basis on this record to support a conclusion that Conrad suggests an implant comprising a fibrosis-inducing agent and an anchor, *wherein the fibrosis-inducing agent is anchored to the hyoid bone by the anchor*, as required by Appellant's claimed invention.

CONCLUSION OF LAW

The preponderance of evidence on this record fails to support a conclusion that Conrad suggests an implant comprising a fibrosis-inducing agent and an anchor, wherein the fibrosis-inducing agent is anchored to the hyoid bone by the anchor, as required by Appellant's claimed invention. The rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Conrad is reversed.

REVERSED

cdc