

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN GRAEME HOUSTON,
PETER ARNO STONERBRIDGE, JOHN BRUCE CAMERON DICK,
ROBERT GORDON HOOD, ALLANA JOHNSTONE,
CHRISTOPHE EMMANUEL SARRAN, and CRAIG MCLEOD DUFF

Appeal 2008-0106
Application 10/300,298
Technology Center 3700

Decided: February 27, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the
Examiner's final rejection of claims 21 and 23-31. We have jurisdiction

under 35 U.S.C. § 6(b). Claims 21, 25, and 26 are representative of the claims on appeal, and read as follows:

21. A tube for a human or animal body, the tube comprising a flexible tubular material, a side wall of the tube being deformed to form a helical formation in an internal surface of the side wall of the tube, and a corresponding helical indentation in an external surface of the side wall, there being a coating applied to the indentation, the coating ensuring that the helical formation maintains its shape.

25. A tube according to claim 21, wherein the coating comprises a polymeric material.

26. A tube according to claim 25, wherein the polymeric material comprises polyurethane.

The Examiner relies on the following references:

Houston	WO 00/38591 A2	6 July 2000
Burkoth	WO 98/23228 A1	4 June 1998

We affirm.

DISCUSSION

Claims 21 and 23-31 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Houston and Burkoth. As Appellants do not argue the claims separately, claims 23-31 stand or fall with claim 21, and we thus focus our analysis on claim 21. 37 CFR § 41.37(c)(1)(vii).

According to the Examiner, Houston discloses “the invention as claimed except for particularly disclosing coating the external helical indentation with a [polymeric material containing a] therapeutic substance.” (Ans. 3.)

The Examiner cites Burkoth as evidence that such coating methods are well known in the art (*id.*). Burkoth is cited for teaching a tube-type stent comprising a helical groove on the external surface of the stent. In particular, the Examiner notes:

With regards to newly added functional language “the coating ensuring that the helical formation maintains its shape”, it should be noted that [the] polymeric coating . . . , when cured, creates a solid layer that will inherently ensure/help [the] groove . . . maintain its shape (i.e., prevents collapsing of the groove during expansion of the stent and/or when the stent is pressed against the blood vessel). It is noted that the Applicants claim polyurethane (see dependent claim 26) as the polymeric material comprising the coating. Since Burkoth et al.’s coating may comprise polyurethane, and since polyurethane is the same coating material as Applicants’, therefore it will inherently provide some level/degree of structural stability. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of coating an external helical indentation with a therapeutic substance, with the tube of Houston et al., as taught by Burkoth et al., in order to prevent restenosis, thrombosis, inflammation, to encourage healing, and/or to provide numerous other treatments/advantages such as ensuring/helping the helical groove to maintain its shape.

(Ans. 3-4.)

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the

differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 1739. Moreover, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

Appellants argue that there is no motivation to combine Burkoth and Houston (App. Br. 5). Appellants assert that Houston does not suggest that the stents disclosed may require additional support to maintain the helical formation, and Burkoth does not suggest that the active agent serves any structural role (*id.*). Thus, Appellants argue that it “appears that the Examiner is employing impermissible hindsight to combine these references, as the only suggestion for their combination comes from the present disclosure.” (*Id.*)

Appellants’ arguments are not convincing. Houston teaches a tube “comprising a flexible tubular material, a side wall of the tube being deformed to form a helical formation in an internal surface of the side wall of the tube, and a corresponding helical indentation in an external surface of the side wall,” as required by claim 21 (*see Ans. 3*). As noted by the Examiner (Ans. 5), Houston teaches a numerous therapeutic uses for the

tubing, such as for an implant in various locations in the cardiovascular system, and as a stent (Houston, p. 5). Burkoth teaches that it is known to the ordinary artisan that external indentations in therapeutic implants, such as stents, may be filled with a therapeutic substance that can be delivered through the use of a biocompatible polymer, such as a polyurethane (Burkoth, pp. 2-5, 13). Thus, it would have been obvious to the ordinary artisan to fill the external indentations of the tube of Houston with a therapeutic agent delivered through the use of the biocompatible polymer polyurethane, in order to achieve site-selective delivery of the therapeutic. As polyurethane is one of the claimed coatings (claim 26) that may be used to ensure that the helical formation maintains its shape, the tube taught by the combination is the same as the tube of claim 21.

As noted by the United States Supreme Court,

If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

KSR, 127 S. Ct. at 1740.

Appellants assert that the combination is improper as “the Burkoth patent does not teach or disclose a coating having any structural support capabilities.” (App. Br. 4.) According to Appellants, the active agent disclosed in the Burkoth patent is an anti-inflammatory agent, and thus would likely dissolve and disappear as the drugs are delivered to the site, leaving only the groove, and thus a weakened area of the stent (*id.* at 5).

Appeal 2008-0106
Application 10/300,298

Burkoth teaches that the therapeutic compound, such as the anti-inflammatory, can be delivered through a biocompatible delivery matrix, such as a biocompatible polymeric matrix (Burkoth, p. 13, ll. 3-6). Burkoth specifically teaches that the biocompatible polymeric matrix may be a polyurethane (*id.* at ll. 6-10). Thus, as Burkoth teaches adding the same material to the external grooves, *i.e.*, polyurethane, it would inherently have the property of providing support to the helical formation. Thus, the preponderance of the evidence of record supports the Examiner's position, and the rejection is affirmed. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

No time period for taking any subsequent action in connection with this appeal may be extender under 37 C.F.R. § 1.136(a)

AFFIRMED

Renner, Kenner, Greive, Bobak, Taylor & Weber
Fourth Floor
First National Tower
Akron OH 44308-1456

lp