

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL DEILY and NORMAN CRANDALL

Appeal No. 97-0082
Application No. 07/993,718¹

ON BRIEF

Before McCANDLISH, Senior Administrative Patent Judge, and
COHEN and MEISTER, Administrative Patent Judges.

MEISTER, Administrative Patent Judge.

DECISION ON APPEAL

Michael Deily and Norman Crandall (the appellants) appeal from the final rejection of claims 1-15 and 18-23.² Claims 16 and 17, the only other claims present in the application, stand withdrawn from further consideration by the

¹ Application for patent filed December 16, 1992.

² Independent claim 1 has been amended subsequent to final rejection.

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examiner under the provisions of 37 CFR § 1.142(b) as being directed to a nonelected invention. We affirm-in-part and, pursuant to our authority under the provisions of 37 CFR § 1.196(b), enter a new rejection of claims 6, 7 and 23.

The appellants' invention pertains to (1) a neck flange, (2) the combination of a tracheostomy tube and neck flange, and (3) a method of using the tracheostomy tube in conjunction with the neck flange. Independent claims 1, 18 and 19 are further illustrative of the appealed subject matter and copies thereof, as they appear in the appendix to the appellants' brief, are appended to this decision.³

The references relied on by the examiner are:

Randford et al.	4,235,229	Nov. 25, 1980
Kalt	5,000,741	Mar. 19, 1991
Bales	5,054,482	Oct. 8, 1991

The answer states that the following rejections are applicable in the claims on appeal.⁴

³ The copy of claim 1 appearing in the appellants' brief is incorrect in that (as amended subsequent to final rejection) in the penultimate line "interconnection of a material" should be --interconnection formed of a material--.

⁴ The rejections based on prior art were set forth as new grounds of rejection in the answer. In view of the lack of mention of the rejection of claims 1-4 under 35 U.S.C. § 102(b) as being anticipated by Ranford and claims 5-15 and 18-23 under
(continued...)

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Claim 23 stands rejected under 35 U.S.C. § 112, first paragraph.

Claims 1-4 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ranford in view of Bales.

Claims 5-15 and 18-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ranford in view of Bales and Kalt.

The examiner's rejections are explained on pages 5-10 of the answer. Rather than reiterate the arguments of the appellants and examiner in support of their respective positions, reference is made to the brief, amended reply brief, answer and supplemental answer for the full exposition thereof.

OPINION

As a preliminary matter we note that the appellants have presented arguments concerning the propriety of (1) the examiner entering new grounds of rejection in the answer and (2) of the group director "conditionally" granting the appellants' petition filed on April 7, 1995. Under 35 U.S.C. § 134 and 37 CFR

⁴(...continued)
35 U.S.C. § 103 as being unpatentable over Ranford in the answer, we presume the examiner has withdrawn the final rejection of the appealed claims on these grounds. **See Ex parte Emm**, 118 USPQ 180, 181 (Bd. App. 1957).

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§ 1.191, appeals to the Board of Patent Appeals and Interferences are taken from the decision of the primary examiner to reject claims. We exercise no general supervisory power over the examining corps and the decisions of primary examiners to enter new grounds of rejection in the answer and of group directors to "conditionally" grant petitions are not subject to our review. See MPEP §§ 1002.02(c) and 1201; *Cf. In re Mindick*, 371 F.2d 892, 894, 152 USPQ 566, 568 (CCPA 1967) and *In re Deters*, 515 F.2d 1152, 1156, 185 USPQ 644, 648 (CCPA 1975). Thus, the relief sought by the appellants would have properly been presented by a petition to the Commissioner under 37 CFR § 1.181.

We have carefully reviewed the appellants' invention as described in the specification, the appealed claims, the prior art applied by the examiner and the respective positions advanced by the appellants in the brief and amended reply brief and by the examiner in the answer and supplemental answer. As a consequence of this review, we will sustain the examiner's rejections of claim 23 under 35 U.S.C. § 112, first paragraph, and claims 1, 4, 5, 8 and 18 under 35 U.S.C. § 103. We will not, however, sustain the examiner's rejections of 6, 7, 9-15 and 19-23 under 35 U.S.C. § 103. Additionally, pursuant to our authority under the

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provisions of 37 CFR § 1.196(b), we will enter a new rejection of claims 6, 7 and 23 under 35 U.S.C. § 103.

Considering first the rejection of claim 23 under 35 U.S.C. § 112, first paragraph, it is the examiner's position that:

the disclosure is not enabling for the recitation found in the last three lines of claim 23. Appellants have failed to set forth the specific support for this new language, and such is not readily apparent to the Examiner. [Answer, page 5; citation omitted.]

In support of this position the answer states that:

The Appellants' refusal to specifically point out support in the written disclosure and specific reference numerals in the drawings to give credence to the arguments to the new matter rejection,⁵ lead[s] the examiner to believe that they are incapable of doing so, i.e.[,] that no such support exists. [Page 10; footnote added.]

We observe that the description requirement found in the first paragraph of § 112 is separate from the enablement requirement of that provision. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64, 19 USPQ2d 1111, 1114-17 (Fed. Cir. 1991) and *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977), *cert. denied, sub. nom, Barker v. Parker*, 434 U.S. 1238

⁵ The proper basis for a new matter rejection is under § 112, first paragraph, and the analysis is whether the original disclosure provides descriptive support for the invention now being claimed. *See In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981).

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(1978). As explained by the court in *Vas-Cath*, 935 F.2d at 1563-64, 19 USPQ2d at 1117:

35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

. . . drawings alone *may* be sufficient to provide the "written description of the invention" required by § 112, first paragraph.

When viewed in this context it is readily apparent from the examiner's comments that, although the examiner states that "the disclosure is not enabling for . . .," the rejection is in reality based upon failure to comply with the description requirement of the first paragraph of § 112 (i.e., that the appellants were not in possession of the claimed subject matter at the time of filing of the application) rather than failure to comply with the enablement requirement of that provision (i.e., that the appellants' disclosure failed to adequately teach how to "make and use" the claimed invention).

Apparently recognizing that the rejection is based upon a lack of descriptive support, the appellants argue that they

have repeatedly noted that the amendment was fully supported "as will be readily apparent upon review of the description and drawings (especially Figs. 1 and 3) of the disclosure." The appellants fail to understand what further support is necessary. It seems unfortunate that the appellants must teach the Examiner that the drawings are considered to be a part of the disclosure and as such can provide support for claims and amendments. A simple review of Figs. 1 and 3 by the Examiner will reveal the support for the last three lines of claim 23, e.g. the neck engaging portion and interconnection formed in (substantially) the same plane. [Amended reply brief, page 21.]

We are unpersuaded by the appellants' arguments. The last two lines of claim 23⁶ expressly require that the neck engaging portion and the interconnection be "formed in the same plane." Noting that a "plane" has no width, we are of the opinion that this limitation would require the center lines of the neck engaging portion and the interconnection to be coextensive. As the examiner has noted, there is no express statement in the specification that the neck engaging portion and the interconnection are formed in the same plane. Viewing Fig. 3 of the drawings, it is readily apparent that the center lines of the flange 11 and the interconnection 26 fall in spaced apart or parallel planes. This being the case, we agree with the examiner

⁶ Reference to specific lines in the claims in this decision is with respect to the lines of the claims as they appear in the appendix to the appellants' brief.

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that there is no descriptive support in the appellants' original disclosure for the recitation that the neck engaging portion and the interconnection "are formed in the same plane" and, accordingly, we will sustain the rejection of claim 23 under 35 U.S.C. § 112, first paragraph.

Turning to the rejections under 35 U.S.C. § 103 of (1) claims 1 and 4 as being unpatentable over Ranford in view of Bales and (2) claim 5 as being unpatentable over Ranford in view of Bales and Kalt, it is the appellants' position that there is no suggestion to combine the teachings of Ranford and Bales. In support of this position the amended reply brief states

Ranford et al does not in any manner suggest that different materials could be used to modify the makeup of the flange. Rather, Ranford et al states that variation of the configuration of the flange portions modifies the flexibility of the collar. The collar is further defined as being both the flange portions 30 and the tubular sleeve portion 29 (note column 3, lines 5-9 of Ranford et al). Therefore, if any modifications are to be made, Ranford et al necessarily requires that the entire collar; flange portions and tubular sleeve portion, be so modified, and thus using different materials for the different portions is not contemplated or suggested by Ranford et al.

Because Ranford et al so clearly teaches away from the present invention, Bales can not be combined with Ranford et al to arrive at the present invention. Obviousness can not be found by using a secondary reference (Bales) to directly override the stated objectives and purposes of a primary reference (Ranford et al). [Page 12].

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We are not persuaded by the appellants' arguments. While there must be some teaching, reason, suggestion, or motivation to combine existing elements to produce the claimed device (**see ACS-Hospital Systems, Inc. v. Montefiore Hospital**, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)), it not necessary that the cited references or prior art specifically suggest making the combination (**B.F. Goodrich Co. V. Aircraft Braking Systems Corp.**, 72 F.3d 1577, 1583, 37 USPQ2d 1314, 1319 (Fed. Cir. 1996) and **In re Nilssen**, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988)). Rather the test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. **In re Young**, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and **In re Keller**, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

Here, as the examiner has noted, Ranford teaches a neck flange for positioning a tracheostomy tube 11 comprising a flexible (column 3, line 5) neck engaging portion 30 and an interconnection 20 having a ring shaped body with an opening 35 for surrounding the tracheostomy tube, with both the neck engaging portion 30 and the interconnection 20 being molded from a polymer (column 4, line 23). Thus, Ranford teaches all the

subject matter set forth in independent claim 1 with the exception of the interconnection being formed of a material less flexible than the neck engaging portion. Bales discloses a neck flange for positioning a tracheostomy tube 12 comprising a neck engaging portion 22 and an interconnection 19 having a ring shaped body with an opening for surrounding the tracheostomy tube, wherein both the neck engaging portion 22 and the interconnection 19 are molded from different polymers, namely, polycarbonate for the interconnection and polyurethane for the neck engaging portion.⁷ Bales states that the purpose of utilizing two different materials is to prevent fracturing of the neck engaging portion (i.e., flange member 22; see column 4, lines 14-16). This stated advantage would have provided more than ample motivation to the artisan to combine the teachings of Ranford and Bales in the manner proposed by the examiner. That is, one of ordinary skill in this art would have found it obvious to modify the neck flange of Ranford by making the neck engaging portion 30 of polyurethane and the interconnection 29 of polycarbonate in order to achieve Bales' expressly stated

⁷ The appellants likewise use these very same materials, i.e., polycarbonate for the interconnection and polyurethane for the neck engaging portion (see specification, page 5, line 32, and page 6, line 24).

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advantage of preventing fracture. As to the appellants' criticisms of the references individually, nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. ***See In re Merck & Co. Inc.***, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986).

As to the rejection of claim 5 based on the combined disclosures of Ranford, Bales and Kalt, the examiner has only relied upon Kalt for a teaching of making the neck flange transparent. There is, however, no limitation in claim 5 which requires transparency. Claim 5 does require the polymer from which the interconnection is molded to be of a durometer greater than that of the polymer utilized in the neck engaging portion. While Bales makes no mention of the respective durometers of the polymers utilized, inasmuch as Bales does in fact disclose the very same polymers as used by the appellants, there is a reasonable basis to conclude that the durometer of polycarbonate is greater than that of polyurethane.

In view of the foregoing, we will sustain the rejections under 35 U.S.C. § 103 of claims 1 and 4 based on the combined disclosures of Ranford and Bales and of claim 5 based on the combined disclosures of Ranford, Bales and Kalt.

Turning to the rejections under 35 U.S.C. § 103 of claims 2 and 3 as being unpatentable over Ranford in view of Bales and claims 11-15⁸ and 19-22 as being unpatentable over Ranford in view of Bales and Kalt, each of these claims expressly require a pair of opposed pivot pins. It is apparently the examiner's position that the lugs 46 of Ranford may be considered to be pivot pins and in support of this position the examiner makes reference in Ranford to the paragraph bridging columns 3 and 4 (see supplemental answer, pages 7 and 8). However, we find nothing in Ranford which supports the examiner's position. In Ranford the lugs 46 are disposed in circumferential grooves 44 that are located between ribs 43 in such a manner that the lugs hold tube extension 13 in axial position by interacting with the adjacent ribs (see column 3, lines 44-49). In the paragraph bridging columns 3 and 4 it is further stated that the engagement of the lugs in the grooves permits the tube extension 13 to rotate with respect to the collar or neck flange and that the tube extension may further be moved upwardly and downwardly in the elongated opening 35 in the sleeve portion 29 (i.e., the

⁸ In line 3 of claim 11 "the pair of opposed pivot pins" should apparently be --a pair of opposed pivot pins-- inasmuch as there is no antecedent basis for "the pair. . . ."

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interconnection). Thus, while Ranford teaches that the lugs function to allow for rotational adjustment about the axis of the tube extension 13, as well as upwardly and downwardly of adjustment of the tube extension, there is absolutely nothing to suggest that these lugs function as pivot pins as asserted by the examiner. As the examiner apparently recognizes, there is nothing in either Bales or Kalt which would overcome this deficiency. This being the case, we will not sustain the rejections under 35 U.S.C. § 103 of claims 2 and 3 as being unpatentable over Ranford in view of Bales and claims 11-15 and 19-22 as being unpatentable over Ranford in view of Bales and Kalt.

Considering next the rejection of claims 6 and 7 under 35 U.S.C. § 103 as being unpatentable over Ranford in view of Bales and Kalt, both of these claims require that the neck engaging portion be "molded about" the interconnection. In the primary reference to Ranford, however, the neck engaging portion 30 is apparently molded at the same time as the interconnection 29 so as to form a homogeneous, one-piece construction and the examiner has not provided any persuasive line of reasoning as to why one of ordinary skill in this art would have found it obvious to modify Ranford such that the neck engaging portion 30 is

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"molded about" the interconnection 30 in view of the teachings of the secondary references to Bales and Kalt. Therefore, we will not sustain the rejection of claims 7 and 8 under 35 U.S.C. § 103 based on the combined teachings of Ranford, Bales and Kalt.

Treating now the rejection of claims 8 and 18 under 35 U.S.C. § 103 as being unpatentable over Ranford in view of Bales and Kalt, the examiner is of the opinion that it would have been obvious to make the neck flange of Ranford, as modified by Bales, of transparent polymers in view of the teachings of Kalt. On the other hand, the appellants contend:

Ranford et al notes in column 3, lines 18-21 that "The openings 31 traverse the junction between the flange portions 30 and the sleeve portion 29 to permit better visual inspection of the stoma site." In other words, Ranford et al leaves bigger gaps in the neck flange so that visual inspection of the stoma site can be accomplished. If the neck flange were transparent, such measures would not be necessary. Therefore, it is clear that Ranford et al did not consider, or suggest, and actually teaches away from the use of transparent materials for the neck flange. [See the paragraph bridging pages 18 and 19 of the amended reply brief.]

Such contentions are not persuasive. The mere fact that Ranford alone does not suggest transparent materials is not dispositive inasmuch as the test for obviousness is what the **combined** teachings of the references would have suggested to one of ordinary skill in the art. **See In re Young, supra,** and **In re**

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Keller, supra. Although the appellants are correct in noting that Ranford provides openings 31 in the neck flange in order to view the stoma site, there is, nevertheless, a recognition by Ranford of the need to view this site. Kalt in the embodiments of Figs. 5a, 5b, 6a and 6b teaches that tracheostomy tube holders should be constructed at least in part of transparent materials in order that the area of the stoma site can be observed without removal of the tracheostomy tube holders (note column 1, lines 17-34; column 7, lines 4-7). In our view, a combined consideration of Ranford and Kalt would have fairly suggested to the artisan to make the neck flange of Ranford, as modified by Bales, of a transparent material in view of the teachings of Kalt in order to further enhance the ability to view the stoma site. Accordingly, we will sustain the examiner's rejection of claims 8 and 18 under 35 U.S.C. § 103 based on the combined teachings of Ranford, Bales and Kalt.

Treating now the rejection of claims 9 and 10 under 35 U.S.C. § 103 as being unpatentable over Ranford in view of Bales and Kalt, obviousness under § 103 is a legal conclusion based on **factual evidence** (*In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988)) and "[a] rejection based on section 103 must rest on a factual basis, and these facts must be

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interpreted without hindsight reconstruction of the invention from the prior art," (*In re GPAC Inc*, 57 F.3d 1573, 1582, 35 USPQ2d 1116, 1123 (Fed. Cir. 1995) quoting with approval from *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968)). There is nothing in Kalt to indicate that his transparent device will "remain substantially transparent after a sterilization process" (claim 9) or "remain imperceptibly less transparent after radiation sterilization process of up to approximately 3.5 rads" (claim 10). Since the examiner has not provided a factual basis for establishing the obviousness of the subject matter defined by claims 9 and 10, we are constrained to reverse the examiner's rejection of these claims under 35 U.S.C. § 103 based on the combined disclosures of Ranford, Bales and Kalt.

We turn last to the rejection of claim 23 under 35 U.S.C. § 103 as being unpatentable over Ranford in view of Bales and Kalt. While we agree with the examiner that it would have been obvious to have made the interconnection of Ranford of a material less flexible than the neck engaging portion in view of the teachings of Bales,⁹ we must point out that this claim expressly

⁹ Bales has been relied on only for a teaching of making the
(continued...)

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requires that the neck engaging portion and the interconnection be "formed in the same plane." In Ranford, however, the interconnection 29 is in a plane which is perpendicular to the plane of the neck engaging portion 30. Accordingly, we will not sustain the rejection of claim 23 under 35 U.S.C. § 103 based on the combined teachings of Ranford, Bales and Kalt.

Under the provisions of 37 CFR § 1.196(b) we make the following new rejection.

Claims 6, 7 and 23 are rejected under 35 U.S.C. § 103 as being unpatentable over Bales. Initially, we note that the issue of obviousness is not only determined by what the references expressly state but also is determined by what they would fairly suggest to those of ordinary skill in the art. **See, e.g., In re Delisle**, 406 F.2d 1386, 1389, 160 USPQ 806, 808-09 (CCPA 1969) and **In re Bozek**, 416 F.2d 1385, 1390, 163 USPQ 545, 549-50 (CCPA 1969). Moreover, in evaluating such references it is proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art

⁹(...continued)
interconnection of a material less flexible than the neck engaging portion while Kalt has apparently been relied on by the examiner only for a teaching of transparency (a limitation which we observe is not found in claim 23).

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would reasonably be expected to draw therefrom. **See In re Preda**, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Here, Bales discloses a neck flange for positioning and supporting a tracheostomy tube having a neck engaging portion 22 and an interconnection 19 formed of a material less flexible than the neck engaging portion (see column 4, lines 9-14). Bales in column 4, line 5, further states that the neck engaging portion or flange member 22 is "formed about" the interconnection 19. Bearing in mind that Bales forms his neck flange from plastic (i.e., polymers), it is our conclusion that this statement in conjunction with the illustrations in Figs. 1, 3 and 6 would have fairly suggested to the artisan to construct Bales' neck flange by molding the neck flange about the interconnection.

With respect to claim 23, we initially observe that artisans must be presumed to know something about the art apart from what the references disclose (**see In re Jacoby**, 309 F.2d 513, 516, 135 USPQ 317, 319 (CCPA 1962)) and the conclusion of obviousness may be made from "common knowledge and common sense" of the person of ordinary skill in the art (**see In re Bozek**, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969)). Moreover, skill is presumed on the part of those practicing in the art. **See In re Sovish**, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

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Therefore, while it is unclear whether the interconnection 19 of Bales is in exactly the same plane as the neck engaging portion 22, one of ordinary skill in this art would have found it obvious to form the interconnection and the neck engaging portion in the same plane if, for no other reason, than to provide a more secure connection therebetween.

In summary:

The examiner's rejection of claim 23 under 35 U.S.C. § 112, first paragraph, is affirmed.

The examiner's rejections of claims 1, 4, 5, 8 and 18 under 35 U.S.C. § 103 are affirmed.

The examiner's rejections of claims 2, 3, 6, 7, 9-15 and 19-23 under 35 U.S.C. § 103 are reversed.

A new rejection of claims 6, 7 and 23 under 35 U.S.C. § 103 has been made.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date hereof (37 CFR § 1.197).

With respect to the new rejection under 37 CFR § 1.196(b), should appellants elect the alternate option under that rule to prosecute further before the Primary Examiner by way of amendment

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or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision. In the event appellants elect this alternate option, in order to preserve the right to seek review under 35 U.S.C. § 141 or 145 with respect to the affirmed rejections, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejections are overcome.

If the appellants elect prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to us for final action on the affirmed rejection, including any timely request for reconsideration thereof.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART
37 CFR § 1.196(b)

HARRISON E. McCANDLISH, Senior)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
IRWIN CHARLES COHEN)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
)	
)	
JAMES M. MEISTER)	
Administrative Patent Judge)	

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APPENDIX

1. A neck flange for tracheostomy tube to position and support the tube when inserted into the neck of a human comprising a neck engaging portion having a sheet shape with a pair of generally parallel major surfaces defined by an edge, the neck engaging portion fashioned of a flexible material, and an interconnection positioned centrally within the neck engaging portion and carried thereby as part thereof, the interconnection having a ring shaped body with an opening therethrough, the ring shaped body for surrounding and movably connecting to the tracheostomy tube passing therethrough for permitting limited relative movement therebetween, the interconnection of a material less flexible than the neck engaging portion.

18. A method for using a neck flange for a tracheostomy tube with a neck engaging portion of a flexible transparent material and an interconnection of a less flexible transparent material by the following steps:
 - (i) placing the tracheostomy tube into an entry in the patient's neck;
 - (ii) swiveling the neck engaging portion relative to the tracheostomy tube so as to conform the neck engaging portion to the patient's neck;
 - (iii) flexing the neck engaging portion to conform to the curvature around the entry into the patient's neck, and (iv) observing the condition of the entry into the neck under the transparent interconnection or the transparent engaging portion.

19. A neck flange for a tracheostomy tube to position and support the tube when inserted into the neck of a human comprising: a neck engaging portion having a thin flexible flat sheet with a pair of generally parallel major surfaces defined by an edge therearound and a generally central aperture therethrough, the neck engaging portion molded of a flexible, transparent polymer material; an interconnection positioned centrally within the neck engaging portion and carried thereby, the interconnection having a ring shaped body with an opening and a pair of opposed pivot pins extending into the opening for carrying the tracheostomy tube passing therethrough, the pair of opposed pins movably

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held in respective recesses in the tracheostomy tube for permitting limited swivel movement thereof and substantially within a plane generally normal to one major surface of the neck engaging portion, the interconnection molded of a transparent polymer material less flexible than the neck engaging portion, the interconnection having a stepped cross section with the pair of opposed pivot pins raised relative to the ring shaped body.

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APJ MEISTER

APJ COHEN

Senior APJ McCANDLISH

DECISION: AFFIRMED-IN-PART
37 CFR § 1.196(b)

Typed By: Jenine Gillis

DRAFT TYPED: 02 Jul 97
Revision: 07 Jul 97

FINAL TYPED: