

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TAKASHI MATSUMOTO, HAJIME TSUJIKAWA, HAYASHI SHUNICHI, SATORU
KONDO, ATSUSHI UTSUMI and TAMOTSU KAIDE

Appeal No. 96-3717
Application 08/229,115¹

HEARD: February 9, 1999

Before FRANKFORT, WEIFFENBACH and WARREN, *Administrative Patent Judges*.

WEIFFENBACH, *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 12-30. Claim 31, the only other claim remaining in the application, stands allowable. We affirm-in-part and enter new grounds of rejection of claims 12-31 pursuant to 37 CFR § 1.196(b) and remand this

¹ Application for patent filed April 18, 1994. According to appellants, the application is a continuation of Application 07/845,598 filed March 4, 1992, now abandoned.

application to the examiner for further consideration.

The Claimed Subject Matter

The claimed subjected matter is directed to a medical tube. Claims 12 and 16 are representative of the claims on appeal and read as follows:²

12. A medical tube for insertion into a mammal made of a hydrophobic non-halogenated polyurethane comprising a tube of an isocyanate component, a chain extender and a non-halogenated polyol component, having a water absorption at body temperature of said mammal of not more than 5 wt%; a mechanical loss tangent of at least 0.5 at said body temperature; a modulus of transverse elasticity of 1-1000 MPa at said body temperature; and a modulus of transverse elasticity at a temperature of 10EC lower than said body temperature which is at least twice said modulus of transverse elasticity at said body temperature.

16. The medical tube of Claim 12, wherein the molar ratio of isocyanate component, chain extender and non-halogenated polyol component in said hydrophobic non-halogenated polyurethane is 1.5-3:0.5-2:1.

²In our opinion, claims 12-20 and claims 21-29 are identical in scope. The only difference between claim 12 and claim 21 is the addition of the language "said medical tube" in line 3 of claim 21 after --polyol component, --. At oral hearing, counsel for appellants stated that claims 12 and 21 were distinguishable in that claim 21 attempts to distinguish a single layered tube from a multi-layered tube. We fail to see this distinction between the claims. Claim 12 defines a medical tube as being made of a hydrophobic non-halogenated polyurethane and a tube having the properties set forth in the claim, while claim 21 defines the medical tube as being made of a hydrophobic non-halogenated polyurethane and having the same properties as set forth in claim 12. We find that the "medical tube" and the "tube" as set forth in the claims are the same. The specification does not disclose that the "medical tube" and "tube" are structurally different or separate and distinct elements. On page 3 specification, the "medical tube" is defined as being "in the form of a tube." On pages 6-9 of the specification, the "tube" is disclosed as being non-halogenated polyurethane having an isocyanate component, a chain extender and a non-halogenated polyol component. Based on these facts, we must conclude that "a tube" recited in both claims 12 and 21 means a "medical tube" as set forth in the preamble of each claim. Upon return of this application to the jurisdiction of the examiner, the examiner should address this matter in accordance with Section 706.03(k) of the *Manual of Patent Examining Procedure*, 7th Edition, July 1998.

References of Record

The following references of record are relied upon by the examiner in support of the rejection of the claims:

Solomon et al. (Solomon)	4,999,210	Mar. 12, 1991
Lambert et al. (Lambert)	5,102,401	Apr. 7, 1992 (filed Aug. 22, 1990)

The Rejections

Claims 12-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants regard as their invention.

Claims 12, 13, 16-22 and 25-30 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Solomon or Lambert.³

Opinion

We have carefully considered the respective positions advanced by appellants and the examiner. For the reasons set forth below, we will affirm the rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as anticipated by Solomon and the rejection of the same claims under 35 U.S.C. § 103

³We note that the sole ground of rejection over prior art in the final Office action was the rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as being anticipated by Solomon or Lambert. We further note that in the first Office action on the merits, that the examiner rejected the claims as now stated in the answer. See paper no. 18, p. 3. We do not know whether the examiner's failure to carry over the rejection under 35 U.S.C. § 103 to the final Office action was an inadvertent omission or intentional. Be it as it may, appellants did respond to the obviousness rejection; so we have the benefit of appellants' arguments traversing the rejection.

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over Solomon or Lambert, but we will reverse the examiner's rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as anticipated by Lambert and the examiner's rejection of claims 12-29 under 35 U.S.C. § 112. We also enter a new ground of rejection of claims 12-31 and remand the application for the examiner to consider the patentability of the claims pending in this application over a reference supplied to this merits panel by the attorney of record during oral hearing.

REJECTION UNDER 35 U.S.C. § 112

The examiner rejected claims 12-29 under 35 U.S.C. § 112, second paragraph, because it is “unclear what temperature is the body temperature of a mammal” (answer: p. 3). The legal standard for indefiniteness under the second paragraph of 35 U.S.C. § 112 is whether a claim reasonably apprises those of skill in the art of its scope. *See Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir.), *cert. denied sub nom., Genetics Inst., Inc. v. Amgen, Inc.*, 112 S.Ct. 169 (1991). The definiteness of the language employed must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and the application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *See In re Angstadt*, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976).

The examiner argues that all of the properties set forth in the claims are dependent on “body temperature” and that since the temperature range is not disclosed in the specification, the properties are “unascertainable.” According to appellants, the claimed medical tube “is applicable to mammals including humans [sic, “non-humans] (e.g. cow, rabbit, horse, sheep, monkey, dog, cat, etc.)” and that “the body

temperature ... varies depending on the animal species” (specification: pp. 4-5). We find that this disclosure would be sufficient for a person having ordinary skill in the biological sciences to ascertain a temperature range. The body temperatures for humans as well as for non-human mammals can be readily obtained by those skilled in the art from standard reference texts in the biology, zoology and animal sciences. On the record before us, the examiner has not presented a analysis based on scientific and technical reasoning as to why a person having ordinary skill in the art could not have ascertained the scope of the claimed subject matter based on appellants’ disclosure. For these reasons, the rejection of claims 12-29 under 35 U.S.C. § 112, second paragraph, is reversed.

REJECTION UNDER 35 U.S.C. § 102/103

The examiner rejected claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over either Solomon or Lambert. Both references disclose a medical tube comprising polyurethane. In particular, Solomon discloses a catheter made of a polyurethane 80 A or polyurethane 55 D (col. 4, lines 14-34). Solomon does not disclose the components which make up polyurethane 80 A and 55 D, but the examiner made a finding that “[i]t is well known that polyurethane is the product of three main parts: an isocyanate component, a chain extender and a polyol component” (answer: p. 5). Appellants’ have not challenged this factual finding. Therefore, we accept it as fact. *In re Fox*, 471 F.2d 1405, 1406-1407, 176 USPQ 340, 341 (CCPA 1973); *In re Boon*, 439 F.2d 724, 727-728, 169 USPQ 231, 234 (CCPA 1971); *In re Ahlert*, 424 F.2d 1088, 1091-1092, 165 USPQ 418, 421-422 (CCPA 1970).

The claims on appeal require that the polyurethane composition exhibit a water absorption at body temperature of 5 wt% or less. Solomon discloses that the water absorption for polyurethane 80 A and polyurethane 55 D are 1.85% and 1.66% , respectively (col. 4, lines 31-34). This water absorption is clearly within the water absorption defined by appellants' claims. Appellants' claims also require the claimed medical tube as having certain modulus of transverse elasticity properties and a mechanical loss tangent of at least 0.5, both of which are a function of body temperature. The examiner asserts that the transverse elasticity and mechanical loss of tangent properties are inherent in the polyurethanes disclosed by Solomon. Appellants argue that the properties are not inherent and that Solomon does not teach or suggest the claimed molar amounts of isocyanate, chain extender or polyol components of the polyurethane.

It is well settled that when a claimed product appears to be substantially identical to a product disclosed by the prior art, the burden is on the applicant to prove that the product of the prior art does not necessarily or inherently possess characteristics or properties attributed to the claimed product. *In re Spada*, 911 F.2d 705, 708-09, 15 USPQ2d 1655, 1657-58 (Fed. Cir. 1990). The reason for this is that the Patent and Trademark Office is not able to manufacture and compare products. *In re Best*, 562 F.2d 1252, 1255-56, 195 USPQ 430, 433-34 (CCPA 1977). Under such circumstances, a rejection may be properly made under 35 U.S.C. § 102 or § 103. *In re Best, supra*.

According to appellants' specification, the mechanical loss tangent and modulus of transverse elasticity are linked to a feeling of physical disorder experienced by patients, which disorder appellants want to avoid with their polyurethane composition. Appellants state on pages 5 and 6 of the specification that

[t]he organic polymer formulating the medical tube of the present invention has a mechanical loss tangent ($\tan \delta$) of at least 0.5 at body temperature Where $\tan \delta$ is less than 0.5, the tube is so stiff as to thrust against the surrounding tissue while inserted in the body, and gives a feeling of physical disorder

The medical tube of the present invention has a modulus of transverse elasticity (G_j) of 1-1000 MPa at body temperature With a G_j over 1000 MPa, said medical tube always thrusts against the surrounding tissue due to the exceeding stiffness thereof while inserted in the body, and gives a feeling of physical disorder, which is the same defect as that of the tube having a $\tan \delta$ of less than 0.5. On the other hand, those having a G_j of less than 1 MPa can be squeezed by internal pressure due to a low mechanical strength. Since cannula, ED catheter, etc. are usually indwelled in the body for a long period, it is desirable to reduce the feeling of physical disorder to the least possible extent.

* * *

The preferred medical tube is made of an organic polymer having a water absorption of not more than 5 wt% When the water absorption exceeds 5 wt%, the swollen tube presses the surrounding tissue and gives a feeling of physical disorder

From the viewpoint of penetration force, the medical tube of the present invention desirably has the above-mentioned flexibility after being inserted into the body, namely, at body temperature, and has a sufficient rigidity at room temperature before the insertion, or at a low temperature artificially prepared (e.g. 10-15E C).

As pointed out, *supra*, Solomon discloses that his catheter can comprise a polyurethane. He discloses two polyurethanes having water absorption of less than 5 wt%. In addition, Solomon discloses that his “catheter must be stiff enough to be inserted into, for example, a blood stream, without kinking” and that “once in contact with the blood, it should preferably soften and become sufficiently flexible to bend and be advanced through the tortuous path of the vessel” (col. 4, lines 14-20). Solomon further discloses that polyurethane 80 A and 55 D meet this mechanical criteria (col. 4, lines 21-34). While Solomon is silent as to components of the polyurethanes and the molar ratios of the components, in the absence of any

objective evidence to the contrary, we find that Solomon's polyurethane medical tube is substantially identical to that claimed by appellants and that Solomon's polyurethane medical tube would inherently possess appellants' claimed properties in that it meets appellants' objective of providing a tube which is stiff enough to be easily inserted into the body and absorbs water once in the body to soften the tube to give less pain and less feeling of physical disorder. Therefore, the burden is on appellants to prove that Solomon's polyurethane tube does not inherently possess the characteristics or properties attributed to the claimed medical tube. On this record, appellants have not presented any objective evidence or sufficient arguments to meet their burden.

For the foregoing reasons, we affirm the rejection of claims 12, 13, 16-22 and 25-30 as being anticipated by Solomon. Since anticipation is the epitome of obviousness, the rejection of the same claims under 35 U.S.C. § 103 over Solomon is also affirmed. *In re Pearson*, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974).

As for the rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as anticipated by Lambert, appellants' arguments with respect to this rejection are the same as those made with respect to Solomon. Lambert discloses a medical tube comprising a hydrophilic base polyurethane (HPEU) coated with a hydrophobic polyurethane having a water absorption of 10% or less (col. 1, line 64 to col. 2, line 7). Both polyurethanes comprise three components: an isocyanate component, a polyol and a chain extender (col. 4, line 32 to col. 5, line 40). However, while the water absorption range overlaps with appellant's range of less than 5 wt%, we do not consider that the water absorption of less than 10%

disclosed by Lambert to be a description of sufficient specificity to constitute a description within the purview of 35 U.S.C. § 102(b) anticipation. *In re Schaumann*, 572 F.2d 312, 315, 197 USPQ 5, 8 (CCPA 1978). Lambert does not specifically disclose a range of less than 5 wt% nor does Lambert give an example having a value of less than 5 wt%. For this reason alone, we cannot sustain the examiner's rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as anticipated by Lambert.

However, we will affirm the rejection of these claims under 35 U.S.C. § 103 over Lambert. The disclosure of water absorption of less than 10 wt% would be suggestive of water absorption amounts of 5 wt% or less since this range is encompassed within Lambert's less than 10 wt%. *Ex parte Lee*, 31 USPQ 1105, 1106 (Bd. App. & Int. 1993). Moreover, Lambert discloses that his polyurethane medical tube should "remain stiff for the length of time required for insertion and placement to prevent binding, kinking or water absorption from the skin tissue" and that once inserted it would "absorb water rapidly from blood and quickly become soft for safety during the time required for advancement and positioning" of the tube (col. 3, lines 4-9). These properties of the tube would appear to meet appellants' objective of providing a tube comprising a polyurethane composition which is initially stiff, but once inserted into the body, will soften. Clearly, the softening would lessen pain or physical disorder which is associated with materials which remain stiff after being inserted into the body. These characteristics of Lambert's polyurethane would appear to meet the water absorption, $\tan^* \delta$ and G_J properties claimed by appellants. Although Lambert's medical tube is a hydrophilic polyurethane coated with a hydrophobic polyurethane, appellants' claims use the transitional term "comprising" which opens the claim to a multi-layered tube.

Also, while Lambert appears to disclose the molar composition of the hydrophobic polyurethane as being prepared using stoichiometric amounts, the exact molar composition of the polyurethane formed is not disclosed. However, in view of the similar stiffness and softening properties associated with Lambert's polyurethane polymer, we conclude that the molar composition of Lambert's hydrophobic polyurethane is substantially similar to that required by appellants' claims. *See Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985). In the absence of evidence by appellants on this record to prove that Lambert's tube does not inherently possess the characteristics or properties attributed to the claimed medical tube, we find that Lambert's polyurethane medical tube is the same or substantially similar to that defined by appellant's claims. We, therefore, affirm the rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 103.

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection. Claims 12-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The phrase "A medical tube for insertion into a mammal made of a hydrophobic non-halogenated polyurethane" is ambiguous for it is reasonable for a person having ordinary skill in the art to misconstrue the sentence as meaning that the mammal is made of polyurethane. Also, the phrase "comprising a tube of isocyanate component" is ambiguous because it is reasonable for a person having ordinary skill in the art to construe the isocyanate component as being a tube, which it is not.

Other Matters

At oral hearing, counsel for appellants submitted for our review an “advertisement” in the Japanese language. The “advertisement” appears to be published by “NIPRO”. A copy of the “advertisement” is attached. Counsel also provided an enlarged view of Fig. 1 of the “advertisement” which includes a translation of various graphs. One graph is labeled “FLEFLOCATH ... PRESENT INVENTION”. This application is being remanded to the jurisdiction of examiner to have the “advertisement” translated into English and for the examiner to determine whether the “advertisement” is prior art under 35 U.S.C. § 102. If it is, then the examiner should determine the patentability of all of the claims pending in this application under both 35 U.S.C. § 102 and 103 over the “advertisement” either taken alone or in combination with other prior art.

Conclusion

For the foregoing reasons, we reverse the examiner’s rejections of claims 12-29 under the second paragraph of 35 U.S.C. § 112 and claims 12, 13, 16-22 and 25-30 under 35 U.S.C. § 102(b) as anticipated by Lambert, and affirm the examiner’s rejection of claims 12, 13, 16-22 and 25-30 under 35 U.S.C. §§ 102(b) and 103 over Solomon or Lambert. This application is being remanded to the jurisdiction of the examiner consider new information presented to this merits panel at oral hearing. This decision also contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective December 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (October 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that “[a] new ground of rejection shall not be considered final for purposes of judicial review.” 37 CFR § 1.196(b) also provides

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that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

The decision of the examiner is affirmed-in-part and this application is being remanded to the examiner for further consideration consistent with this decision.

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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 and REMANDED
37 CFR § 1.196(b)

CHARLES E. FRANKFORT)
Administrative Patent Judge)
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) BOARD OF PATENT
CAMERON WEIFFENBACH)
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