

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ERIK T. ENGELSON, ROBERT HERGENROTHER
and JOSEPH EDER

Appeal No. 1999-0610
Application No. 08/601,186¹

ON BRIEF

Before COHEN, JOHN D. SMITH and BAHR, Administrative Patent
Judges.

BAHR, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 49 through 60, which are all of the claims pending in this application.

¹ Application for patent filed February 14, 1996. According to appellants, the application is a continuation of Application No. 08/060,401, filed May 12, 1993, now U.S. Patent No. 5,531,715.

Appeal No. 1999-0610
Application No. 08/601,186

We AFFIRM and remand the application to the examiner for further consideration as discussed *infra*.

BACKGROUND

The appellants' invention relates to a catheter assembly having at least a distal portion thereof coated with a lubricious coating. An understanding of the invention can be derived from a reading of exemplary claim 49, which reads as follows:

49. A catheter assembly, said catheter comprising an elongate tubular member having proximal and distal ends and an inner lumen extending between said ends, said member comprising:

- (a) a relatively stiff proximal segment;
- (b) a relatively flexible distal segment; and
- (c) a transition section between said proximal and said distal segments that is less flexible than the distal segment but more flexible than the proximal segment,

wherein at least the distal segment has been coated with a lubricious coating consisting essentially of a lubricity-causing polymer or oligomer comprising monomers of polysaccharides.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Castillo et al. (Castillo) 1992	5,171,232	Dec. 15,
Eury 30, 1994	5,342,621	Aug.

(filed Sep. 15, 1992)

Engelson et al. (Engelson) 5,531,715 Jul. 2,
1996

Additional references of record relied on by this panel
of the Board are:²

Sahatjian et al. (Sahatjian) 5,135,516 Aug.
4, 1992

Lentz et al. (Lentz I) 4,668,224 May 26,
1987

Lentz et al. (Lentz II) 4,773,902 Sep. 27,
1988

A reference made of record by this panel of the Board is:³

Whitbourne 5,001,009 Mar. 19,
1991

The following rejections are before us for review.

1. Claim 49 stands 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 the invention.

² Sahatjian was cited by the examiner in Paper No. 6 and a copy thereof
is of record in the application file. The Lentz patents were cited by
appellants in Paper No. 4.

³ A copy of this reference accompanies this decision.

2. Claims 49 through 60 stand rejected under the judicially created doctrine of double patenting as being unpatentable over claims 1 through 16 of U.S. Patent No. 5,531,715.

3. Claims 49 through 60 stand rejected under 35 U.S.C. § 103 as being unpatentable over Castillo in view of Eury.

Reference is made to the brief (Paper No. 13) and the answer (Paper No. 14) for the respective positions of the appellants and the examiner with regard to the merits of these rejections.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The indefiniteness rejection

The examiner's basis for rejecting claim 49 as being indefinite is that the claim contains the closed language "consisting essentially of" followed by the open-ended

language "comprising." The examiner points out that, in view of the use of the language "comprising," the polymer or oligomer need not consist essentially of monomers of polysaccharides; rather, the polymer or oligomer may contain other unclaimed elements (answer, page 3).

While we appreciate the examiner's position that the polymer need not consist essentially of monomers of polysaccharides, but, rather, may contain other unspecified elements, we do not agree that this renders claim 49, or any of the claims depending therefrom, indefinite. As pointed out by appellants (brief, page 8), "consisting essentially of" is directed to the coating, while "comprising" is directed to the polymer or oligomer. In other words, the claimed coating is limited to a lubricity-causing polymer or oligomer and other materials that do not materially affect the basic and novel characteristics of the claimed coating⁴; however, that lubricity-causing polymer or oligomer may also contain other components in addition to the monomers of

⁴ See In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

polysaccharides. For example, the polymer or oligomer may include two different types of monomers, such as amylose and ethylene, instead of being a homopolymer. We find nothing wrong or indefinite in that.

For the foregoing reasons, we shall not sustain the examiner's 35 U.S.C. § 112 rejection of claim 49.⁵

The double patenting rejection

The examiner has rejected claims 49 through 60 under the judicially created doctrine of double patenting as being unpatentable over claims 1 through 16 of U.S. Patent No. 5,531,715, the parent application from which the instant application claims benefit under 35 U.S.C. § 120. The examiner has, however, indicated that this rejection may be overcome by the timely filing of a terminal disclaimer in compliance with 37 CFR § 1.321(b), an action which appellants have so far elected not to take.

⁵ As claims 50 through 60 depend from claim 49 and, thus, incorporate the language addressed by the examiner, we presume that the examiner's failure to include these claims in the 35 U.S.C. § 112 rejection was an inadvertent omission. Thus, to the extent that this rejection is directed to claims 50 through 60, it is reversed as to those claims as well.

Appellants' only argument with regard to the rejection of claims 49 through 60 under the judicially created doctrine of double patenting is that "no such terminal disclaimer is necessary under the current law where there is no possible extension of patent term beyond the 20-year term of the parent" (brief, page 10). In essence, appellants' argument is that, under the terms of 35 U.S.C. § 154(a)(2)⁶, the term of a patent issuing on the instant application cannot possibly extend beyond the term of U.S. Patent No. 5,531,715. This assertion is not correct.

While section 154(c)(1) would appear to set the end of the term of U.S. Patent No. 5,531,715 on July 2, 2013 (the longer of 20 years from the filing date and 17 years from the issue date) and section 154(a)(2) would appear to limit the term of any patent issuing on the instant application to May 12, 2013 (20 years from the earliest filing date claimed under section 120), appellants' argument overlooks the fact that

⁶ Public Law 103-465 (1994) amended 35 U.S.C. § 154(a)(2) to provide that any patent issuing on a utility or plant application filed on or after June 8, 1995 will expire 20 years from its filing date, or, if the application claims the benefit of an earlier filed application under 35 U.S.C. § 120, 121 or 365(c), 20 years from the earliest filing date for which a benefit under 35 U.S.C. § 120, 121 or 365(c) is claimed.

section 154(b) provides for possible extensions of the term of a patent if the issue of the patent is delayed due to (1) an interference proceeding or secrecy order or (2) appellate review, where the patent is issued pursuant to a decision in the review reversing an adverse decision on patentability. Thus, section 154 does not, as appellants suggest, ensure that a patent issued on the instant application will expire 20 years from the earliest filing date claimed under section 120 and, hence, does not ensure that the issuance of a patent on the instant application could not result in a timewise extension of the "right to exclude" granted by U.S. Patent No. 5,531,715.

Moreover, a second recognized objection to double patenting is the potential for harassment of an accused infringer by multiple parties with patents covering subject matter which is not patentably distinct. See, eg., In re Van Ornum, 686 F.2d 937, 944-48, 214 USPQ 761, 767-70 (CCPA 1982). Thus, even assuming, *arguendo*, that a patent issuing on the instant application would necessarily expire on or before the expiry of the term of U.S. Patent No. 5,531,715 under the

terms of 35 U.S.C. § 154, the 20-year term limitation of section 154 does not address this second concern.⁷

For the foregoing reasons, we shall sustain the examiner's rejection of claims 49 through 60 under the judicially created doctrine of double patenting.

The obviousness rejection

Before addressing the examiner's rejections based upon prior art, it is an essential prerequisite that the claimed subject matter be fully understood. Analysis of whether a claim is patentable over the prior art under 35 U.S.C. §§ 102 and 103 begins with a determination of the scope of the claim. The properly interpreted claim must then be compared with the prior art. Claim interpretation must begin with the language of the claim itself. See *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 882, 8 USPQ2d 1468, 1472 (Fed. Cir. 1988). Accordingly, we will initially direct

⁷ In order to address this concern, 37 CFR § 1.321(c)(3) also requires that a terminal disclaimer filed in an application to obviate a double patenting rejection include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the basis for the rejection.

our attention to appellants' claim 49 to derive an understanding of the scope and content thereof.

Further, in proceedings before it, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

Claim 49 requires a "lubricious coating" on the distal segment of the catheter assembly. We interpret the term "lubricious" as used in the claims as a term of art describing a surface presenting a low coefficient of friction. In other words, one of ordinary skill in the art reading the appellants' disclosure (note specification, pages 17 through 19, and page 3, lines 29 and 30), would have understood a "lubricious" coating to be a coating presenting a coefficient

of friction approximating that of silicone, for example, or lower.⁸

In rejecting claims 49 through 60 under 35 U.S.C. § 103, the examiner relies upon the combined teachings of Castillo and Eury. The examiner and appellants agree that Castillo discloses a catheter comprising a relatively flexible distal segment (tip 14), a relatively stiff proximal segment (catheter body 15), carrying a reinforcing braid (column 3, lines 20-22) and a transition zone (13) which is free of the reinforcing braid, and thus more flexible than the proximal segment, but less flexible than the distal segment (column 3, lines 49-53). The examiner concedes, however, that Castillo does not disclose a coating on the distal segment of the catheter.

Eury discloses an antithrombogenic surface coating for use on biomedical devices, such as catheters, which come into contact with a patient's blood flow, to present a blood contacting surface which is as hemocompatible as possible so

⁸ This accords with the use of the term "lubricious" in the biomedical field as exemplified by Sahatjian (column 1, lines 49 to 52, and column 2, lines 32 to 35) and Whitbourne (column 1, lines 15 to 19).

as to prevent or minimize the coagulation of blood (column 1, lines 11-22). Eury achieves such a surface by incorporating into the surface a substance that releases an anticoagulant (heparin) for an extended period of time (column 1, lines 41-45). In one embodiment of the invention, Eury coats the biomedical device with a heparin-containing coating.

The coating is produced by first forming an ionic complex (HPTC) of heparin and phosphatidylcholine (PTC, commonly referred to as lecithin) by combining lecithin dissolved in ethyl acetate with heparin dissolved in water in a lecithin/heparin ratio of approximately 4.17:1. The mixture is stirred, evaporated to dryness, subsequently dissolved in methylchloride and added to the polymer polycaprolactone (or poly L-lactic acid film) to form an HPTC/polymer combination having a final heparin concentration of approximately 5% (or 7.5%) by weight.

The examiner's position is that it would have been obvious to one of ordinary skill in the art at the time of appellants' invention to coat the Castillo catheter with the antithrombogenic heparin coating taught by Eury to prevent or minimize the coagulation of blood. Further, the examiner

contends that, since the coating comprises a heparin-PTC complex, which includes a polysaccharide-based polymer, the coating structure meets the appellants' claims and, thus, must inherently meet appellants' functionality, namely lubriciousness (answer, page 7).

Appellants do not appear to challenge the sufficiency of the references to suggest the proposed modification of Castillo to coat the distal end thereof with a coating as disclosed by Eury. Rather, appellants' arguments are directed to the issue of whether the coating taught by Eury is "lubricious" as claimed (brief, pages 6 and 7).

When relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See In re King, 801 F.2d 1324, <jump>, 231 USPQ 136, 138 (Fed. Cir. 1986); Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int. 1990). Further, under principles of inherency, when a reference is silent about an asserted inherent characteristic, it must be clear that the

missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The examiner's sole basis for the determination that the coating taught by Eury is inherently "lubricious" is that Eury's coating has incorporated therein a heparin complex and that appellants (specification, page 6) specifically disclose cross-linked heparin as a polysaccharide particularly suitable for the invention (answer, page 10).

We do not find this reasoning sufficient to reasonably support the determination that the allegedly inherent characteristic of lubriciousness of the coating necessarily flows from the teachings of the applied prior art. Specifically, we note that the coating disclosed by Eury is not, as the examiner suggests, the structural equivalent of the cross-linked heparin polymer disclosed by the appellants. First, we note that there is no indication in Eury that the heparin from which the HPTC complex is formed is cross-linked, as is the polymer disclosed by the appellants. Secondly, even

if the heparin used in the Eury complex were lubricious, the examiner has not provided any reasoned basis for concluding that the complex, comprising approximately only 20% by weight heparin, necessarily maintains this property of lubriciousness. Finally, the examiner has not provided any reasoned basis for determining that the final coating, which comprises the complex dissolved in a polycaprolactone or poly L-lactic acid film, in a heparin concentration of 5% or 7.5% by weight, respectively, is necessarily lubricious. From our viewpoint, the mere presence of approximately 5% or 7.5% heparin in a polymer coating is not sufficient, without more, to reasonably support the examiner's determination that the Eury coating is inherently lubricious, as required by claim 49.

Accordingly, we cannot sustain the examiner's 35 U.S.C. § 103 rejection of claim 49, and claims 50 through 60 which depend therefrom.

REMAND TO THE EXAMINER

The application is remanded to the examiner to consider whether any additional evidence exists that any of the claimed coating materials (i.e., polymers or oligomers comprising

monomers of polysaccharides) would have been recognized by one of ordinary skill in the art at the time of the appellants' invention as being biocompatible and lubricious and, accordingly, to determine whether the subject matter of any of claims 49 through 60 would have been obvious over Castillo et al. in view of references such as Sahatjian, Whitbourne and the Lentz patents, which disclose the use of lubricious coatings on catheters, either alone or in further view of such evidence.

From our viewpoint, the coating materials disclosed by appellants are known materials; the examiner should determine if any of them may further have been recognized by one of ordinary skill in the art at the time appellants' invention was made as being lubricious. In view of the teachings of references such as Sahatjian, Whitbourne and the Lentz patents to provide lubricious coatings on catheters, the examiner should assess whether it would have been obvious to have coated the Castillo catheter with other known coating materials recognized in the prior art at the time of the

appellants' invention as being biocompatible and lubricious.⁹ After all, the selection of a known material based on its suitability for its intended use has been held to be *prima facie* obvious. See, e.g., Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297, 301 (1945). Further, substitution of materials will not, in and of itself, create patentability if the same purpose or function could be achieved through the old materials. This applies even if the substituted material is more satisfactory, cheaper, or more durable. Substitution of materials to be patentable must bring about a new mode of construction, or new properties or uses of the article that were not obvious and, in effect, make the old material obsolete. See Lyle/Carlstrom Associates Inc. v. Manhattan Store Interiors, Inc., 635 F.Supp. 1371, 1385, 230 USPQ 278, 288 (E.D.N.Y. 1986), aff'd mem., 824 F.2d 977 (Fed. Cir. 1987); accord Graham v. John Deere Co., 383 U.S. 1, 11, 148 USPQ 459, 464 (1966). In this regard, we note for the

⁹ Of course, any determinations of obviousness made by the examiner should be made in accordance with the "Genus-Species Guidelines" set forth in Manual of Patent Examining Procedure (MPEP) § 2108.04.

record that appellants' specification, at page 6, discloses several polymers or oligomers suitable for carrying out the invention and does not suggest that use of the particularly claimed polymers or oligomers would have yielded different or superior results to those of the other disclosed materials.

CONCLUSION

To summarize, the decision of the examiner to reject claim 49 under 35 U.S.C. § 112, second paragraph, and claims 49 through 60 under 35 U.S.C. § 103 is reversed. The examiner's decision to reject claims 49 through 60 under the judicially created doctrine of double patenting is affirmed. Accordingly, the examiner's decision to reject claims 49 through 60 is affirmed. Additionally, the application is remanded to the examiner for consideration of the issues discussed above.

In addition to affirming the examiner's rejection of one or more claims, this decision contains a remand. 37 CFR § 1.196(e) provides that

Whenever a decision of the Board of Patent Appeals and Interferences includes or allows a remand, that decision shall not be considered a final decision. When appropriate, upon conclusion of proceedings on remand before the examiner, the Board of Patent Appeals and

Interferences may enter an order otherwise making its decision final.

Regarding any affirmed rejection, 37 CFR § 1.197(b)

provides:

(b) Appellant may file a single request for rehearing within two months from the date of the original decision

The effective date of the affirmance is deferred until conclusion of the proceedings before the examiner unless, as a mere incident to the limited proceedings, the affirmed rejection is overcome. If the proceedings before the examiner does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejections, including any timely request for rehearing thereof.

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

AFFIRMED and REMANDED

IRWIN CHARLES COHEN)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
JOHN D. SMITH)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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