Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BRIAN L. BATES, NEAL E. FEARNOT, THOMAS G. KOZMA, THOMAS A. OSBORNE, ANTHONY O. RAGHEB, JOSEPH W. ROBERTS and WILLIAM D. VOORHEES III

Appeal No. 2001-2004
Application No. 08/956,715

ON BRIEF

Before ABRAMS, McQUADE, and BAHR, Administrative Patent Judges.

ABRAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-14, which are all of the claims pending in this application.

We AFFIRM-IN-PART.

BACKGROUND

The appellants' invention relates to an implantable medical device. An understanding of the invention can be derived from a reading of exemplary claim 1, which has been reproduced below.

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

Scales et al. (Scales)	4,476,590	Oct. 16, 1984
Fox, Jr. et al. (Fox)	5,019,096	May 28, 1991
Bosley	5,289,831	Mar. 1, 1994
Burrell et al. (Burrell)	5,454,886	Oct. 3, 1995
Schwartz et al. (Schwartz)	5,607,463	Mar. 4, 1997
Ragheb et al. (Ragheb)	5,873,904	Feb. 23, 1999 (filed Feb. 24, 1997)

The rejections before us on appeal:

(1) Claims 1-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of Ragheb in view of Bosley.

The following under 35 U.S.C. § 103(a):

(2) Claims 1-3 on the basis of Bosley.

(3) Claims 1 and 2 on the basis of Scales in view of Bosley.

(4) Claims 1-3 and 6-10 on the basis of Burrell in view of Bosley.

(5) Claims 4 and 5 on the basis of Burrell in view of Bosley and Fox.

(6) Claims 11-14 on the basis of Burrell in view of Bosley and Schwartz.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the Answer (Paper No. 22) and the final rejection (Paper No. 12) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 19) for the appellants' arguments thereagainst.

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 appellants' invention relates generally to implantable medical devices, and more particularly to including silver coatings on such devices to prevent clot formation or thrombosis at the site where the devices are installed, thereby precluding stenosis or occlusion (Specification, pages 1 and 2).

Claim 1

An implantable medical device, comprising:

> a structure adapted for introduction into a patient, the structure being comprised of a base material and a layer of elemental silver having a uniform thickness posited on said base material, the elemental silver layer further having a specific surface energy density of about 20 to 30 dyne[s] per centimeter.

(1)

Claims 1-12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of Ragheb in view of Bosley. It is the examiner's position that the Ragheb claims include all of the subject matter of application claims 1-12 except for the requirement that the layer of silver have a specific surface energy density of about 20 to 30 dynes per centimeter, but that it would have been obvious to provide the elemental silver surface recited in the Ragheb claims with this characteristic in view of the teachings of Bosley.

The appellants have not provided arguments in rebuttal to this rejection, but have stated that they "have agreed to provide a Terminal Disclaimer with respect to the application upon receipt of a Notice of Allowability" (Brief, page 4). However, the intention to perform this future act leaves the double patenting rejection of claims 1-12 standing uncontroverted and uncured, and we therefore will sustain it.

(2)

The first of the rejections under 35 U.S.C. § 103(a) is that claims 1-3 are unpatentable over Bosley.[1] The examiner is of the view that Bosley's statement that it was known in the art that a surface energy of 20 to 30 dynes per centimeter "has been

[1]The initial burden of establishing a basis for denying patentability to a claimed invention rests upon the examiner. See In re Piasecki. 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). The question under 35 U.S.C. §103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made. See Merck & Co. v. Biotech Labs., Inc. 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

found to be resistant to the formation of blood thrombus on the surface of a device in contact with blood" (column 17, lines 19-23) would have suggested to one of ordinary skill in the art that the silver interface layer 2005 placed on the outer surface of the implantable medical device shown in Figure 20 (column 17, lines 54-64) be provided with this characteristic. The essence of the appellants' arguments in opposition to this conclusion is that a detailed analysis of the reference does not support the examiner's conclusion that the reference would have suggested the claimed feature to one of ordinary skill in the art.

Bosley is directed to implantable medical devices such as stents, catheters and cannula, and has as its objective improving the sonic characteristics of these devices so that acoustic imaging of them is enhanced. At the outset, we must agree with the examiner that there are several passages in Bosley that appear, when taken in the abstract, to support the examiner's conclusion. The first of these is that Bosley defines the technical field of the invention as being "surface-treated stents . . . and the like, which have a surface that is resistant to the formation of thrombus, fungus, bacteria, and encrustations thereon" (column 1, lines 24-27). Surface materials disclosed in Bosley include silver (column 4, line 7; column 13, line 65; column 17, line 64; claim 15). Moreover, as stated above, Bosley makes reference to a disclosure in a technical publication that a surface energy range of 20-30 dynes per centimeter has been found to be resistant to the formation of blood thrombus on surfaces that are in contact with

blood (column 17, lines 18-26). The examiner also notes that claim 5 recites that in the treated surface catheter, stent or cannulae of claim 4 (which depends from claim 1 through claims 2 and 3), "said interface layer has a surface energy in the range of 20 to 30 dynes per centimeter." Notwithstanding these passages, our analysis of the Bosley reference leads us to agree with the appellants that the examiner's rejection is not well-founded. Our reasoning follows.

The objective of the Bosley invention is to enhance the acoustic properties of an implanted medical device so that it can better be imaged during insertion and placement. A number of embodiments are disclosed, however, in only two of them is silver used as the outer layer, as is required by independent claim 1. The examiner has focused on the embodiment shown in Figure 20, which is explained in conjunction with Figure 19 in columns 16 and 17. Looking first to Figure 19, elongated member 1901 is comprised of a first base material 1904 of polyurethane or silicone rubber which has an outer surface 1903 that has been bombarded with argon ions under circumstances which smooth the surface and achieve a coefficient of friction of 0.124 for polyurethane and 0.125 for silicone rubber (column 17, line 14). This treatment "also results in a surface energy of 20 to 30 dynes per centimeter," which "has been found to be resistant to the formation of blood thrombus on the surface of the device" (column 17, lines 18-23). The further comment is made that any base material from the previously described

group of materials produces similar results (column 17, lines 40-42), but none of those base materials is metallic, much less silver (see column 16, lines 47-60).

Figure 20 shows an enlarged view of an alternative embodiment of the invention of Figure 19 where indentations are formed in the outer surface 2003 of first base material 2004. Previously, with reference to Figure 9A, it was explained that indentations scatter the sonic beam to produce another desirable component of the image (column 9, lines 25-27). As was the case with the embodiment of Figure 19, Bosley teaches with regard to Figure 20 that member 2001 "includes an outer surface 2003 which has been bombarded in a vacuum chamber environment with argon ions to reduce the coefficient of friction and to bring the surface energy of the outer surface within the range of 20 to 30 dynes per centimeter" (column 17, lines 58-62). Bosley goes on to explain, however, that an additional layer, interface layer 2005, which can include silver, is "deposited on outer surface 2003," and that the resulting coefficient of friction now becomes "approximately 0.184" (column 17, lines 58-68). Thus, while Bosley teaches treating the outer surfaces 1903 and 2003 of the polyurethane or silicone rubber base materials 1904 and 2004 in such a manner as to provide them with a surface energy of 20 to 30 dynes per centimeter, the layer of silver 2005 that is applied over surface 2003 is not so treated, as is apparent from the explanation, as well as the fact that the coefficient of friction that results on the silver coating is greater than that of the uncoated base material. It is noteworthy that in the Figures 15 and 16, which

show the other embodiment where silver is used as a coating for the surface of the base materials, there also is no teaching of treating the silver coating to achieve a surface energy of 20 to 30 dynes per centimeter (see column 13, line 41 et seq.).

As for claim 5, upon which the examiner also relied, we agree with the appellants, essentially for the reasons set out on pages 6-8 of their Brief, that claim 5 of Bosley is not consistent with the specification and cannot be relied upon as the basis for concluding that one of ordinary skill in the art would have been taught by the reference that a layer of elemental silver applied to the base material should have a specific surface energy density of about 20 to 30 dynes per centimeter. Claim 5 states that the interface layer provided in preceding claim 3 has a surface energy in the range of 20 to 30 dynes per centimeter. Claim 5 does not, however, state that the interface layer is of silver, and thus in and of itself does not establish silver as being one of the materials to which the 20 to 30 dynes limitation is to apply. Moreover, it is quite clear from the portions of the Bosley specification referenced above that, in the course of achieving the objective of enhanced acoustic characteristics, Bosley instructs the artisan to provide the surface of the base member, but not the silver layer that coats the base layer in some of the embodiments of the invention, with a surface energy of 20 to 30 dynes per centimeter.

Claim 1, from which claim 5 depends, is consistent with these instructions, for it recites that there is an elongated member and that an outer surface of the member has

an energy of 20 to 30 dynes per centimeter. Claim 5 is inconsistent with the instructions in the specification, for it states that the interface layer added to claim 1 by subsequent claim 3 also has a surface energy level of 20 to 30 dynes per centimeter. There is no support for such a limitation anywhere in the specification if this interface layer is intended to be broad enough to include metal coating 2005 of Figure 20. It would appear that the examiner is, in essence, relying upon claim 5 to overrule the instructions given in the Bosley specification regarding the only applicable embodiments, thus taking a single line of the reference out of context and combining it with the hindsight afforded one who first viewed the appellants' disclosure to render claimed subject matter obvious. From our perspective, considering the reference in its entirety leads one to conclude that the examiner's reliance on claim 5 is not on firm ground.

This conclusion is supported by considering the manner in which other claims set forth the Bosley invention. Claim 15 recites an outer surface on the base material and an interface layer which can include silver deposited on that outer surface. However, while claim 15 recites that the member has an outer surface and an interface layer deposited on the outer surface, it specifies that the outer surface of the member have an energy level of 20 to 30 dynes per centimeter but is silent as to such a limitation regarding the interface layer. Claim 16 recites that the outer surface of the member has

an energy level of 20 to 30 dynes per centimeter, but does not require that there be an interface layer.

On the basis of the foregoing reasoning, it is our conclusion that the teachings of Bosley fail to establish a prima facie case of obviousness with regard to the subject matter recited in claim 1, and we will not sustain the rejection of claim 1 or of claims 2 and 3, which depend therefrom.

(3)

Claims 1 and 2 also stand rejected as being unpatentable over Scales in view of Bosley. It is the examiner's view in this rejection that Scales discloses surgical implants having a silver coating, and it would have been obvious in view of Bosley to provide the silver coating with a surface energy level of 20 to 30 dynes per centimeter.

Scales' objective is to render surgical implants antimicrobial by coating them with silver so as to provide a sustained release of silver ions in a concentration sufficient to provide a localized antimicrobial effect, but insufficient to cause significant damage to connective tissue (Abstract). Scales does not voice concern for the acoustic characteristics of the device or the formation of thrombus thereon. As we explained above, we do not agree with the examiner that Bosley would have taught one of ordinary skill in the art to provide the outer silver coating of an implant with a surface energy level of 20 to 30 dynes per centimeter and therefore Scales and Bosley, even if combined, would fail to meet the terms of the claim. Moreover, the examiner has not

explained in response to the appellants' challenge why an artisan would expect that providing the Scales silver coating with a surface energy level of 20 to 30 dynes per centimeter would not adversely affect the release of silver ions at the level that permits the implant to perform in the desired manner. In our view, if such a surface energy level is counterproductive to the necessary ion release, the artisan would regard this as a disincentive to make the proposed combination.

This rejection of claims 1 and 2 is not sustained.

(4)

Claims 1-3 and 6-10 stand rejected on the basis of Burrell in view of Bosley. Burrell also is concerned with providing implanted devices with a surface coating of anti-microbial metal which discharges ions. Burrell points out that there are problems concerned with use of silver for this purpose, and it solves the problems by creating atomic disorder of the material to cause release of ions. For the same reasons as were related above with regard to the rejection based on Scales and Bosley, we also will not sustain this rejection of claims 1-3 and 6-10.

(5)

The examiner has rejected claims 4 and 5, which depend from claim 1, as being unpatentable over Burrell in view of Bosley and Fox, the latter being cited for teaching coating the base material with a polymer. Be that as it may, Fox does not overcome the problems we pointed out above with regard to attempting to combine Burrell and Bosley

in the manner proposed by the examiner, and we therefore will not sustain this rejection.

(6)

Claims 11 and 12, which depend from independent claim 6, along with independent claim 13 and dependent claim 14, stand rejected as being unpatentable over Burrell in view of Bosley and Schwartz. These claims call for the implantable device to be a vascular stent, and the examiner looks to Schwartz for its teaching of applying a tissue-compatible material to a vascular stent, concluding that it would have been obvious to make the Burrell device a vascular stent.

We do not consider Schwartz to provide teachings which overcome the lack of suggestion to combine the Burrell and Bosley references in the manner proposed by the examiner to render independent claim 6 obvious, and therefore we will not sustain this rejection of claims 11 and 12.

Independent claim 13 is directed to a stent comprising elemental silver or silver alloys having at least 50% by weight silver, which have a specific surface density of about 20 to 30 dynes per centimeter. For the reasons discussed above with regard to the rejection of claims 1-3 and 6-10, it is our view that there is no suggestion to combine Burrell and Bosley in the manner proposed by the examiner in order to render claim 13 obvious. This conclusion is not overcome by further consideration of Schwartz, which does not overcome this problem.

The rejection of claims 13 and 14 is not sustained.

SUMMARY

The rejection of claims 1-12 under the judicially created doctrine of obviousness-type double patenting is sustained.

None of the rejections under 35 U.S.C. § 103(a) are sustained.

The decision of the examiner is affirmed-in-part.

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

NEAL E. ABRAMS Administrative Patent Judge	)
JOHN P. McQUADE Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
JENNIFER D. BAHR Administrative Patent Judge	)

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RETURN TO LESLEY

APPEAL NO. 2001-2004 - JUDGE ABRAMS
APPLICATION NO. 08/956,715

APJ ABRAMS

APJ BAHR

APJ McQUADE

DECISION: **AFFIRMED-IN-PART**

Prepared By: Lesley Brooks

GAU: 3700

OB/HD

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FINAL TYPED: