

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KATHERINE S. TWEDEN
and PEGGY T. MALIKOWSKI

Appeal No. 1999-2646
Application No. 08/794,398

ON BRIEF

Before McCANDLISH, Senior Administrative Patent Judge, and
STAAB and McQUADE, Administrative Patent Judges.

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Katherine S. Tweden et al. appeal from the final rejection of claims 1 through 20, all of the claims pending in the application. We affirm-in-part.

THE INVENTION

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The invention relates to "biocompatible annuloplasty prostheses that are resorbed by the patient following implantation" (specification, page 1). Claims 1 and 14 are illustrative and read as follows:

1. An annuloplasty prosthesis for use in remodeling a diseased annulus of a natural heart valve, consisting essentially of a biocompatible, resorbable member that is sized and shaped to extend about at least a substantial portion of the circumference of said annulus, wherein, following surgical implantation, said member is resorbed at a rate allowing regeneration of reinforcing tissue in said annulus.

14. A method for treating a patient having a diseased or defective heart valve, comprising:

- a) providing the annuloplasty prosthesis of claim 1; and
- b) surgically implanting said annuloplasty prosthesis in the heart of said patient.

THE PRIOR ART

The references relied upon by the examiner to support the final rejection are:

Carpentier et al. (Carpentier)	4,055,861	Nov. 1, 1977
Ross et al. (Ross)	4,343,048	Aug. 10, 1982
Duran (Duran '021)	5,258,021	Nov. 2, 1993
Buscemi et al. (Buscemi)	5,464,450	Nov. 7, 1995
Duran (Duran '297)	5,489,297	Feb. 6, 1996
Reimold et al. (Reimold)	5,584,879	Dec. 17, 1996

THE REJECTIONS

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Claims 1, 2, 4, 5, 7, 11, 14, 16, 19 and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, and in the alternative under 35 U.S.C. § 103(a) as being unpatentable over, Duran '021.

Claims 1, 2, 4, 5, 7, 11, 14, 16, 19 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Reimold.

Claims 3, 15 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Carpentier in view of Duran '021.

Claim 6 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Ross.

Claims 8 through 10 and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Duran '297.

Claims 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Buscemi.

Attention is directed to the appellants' main and reply briefs (Paper Nos. 16 and 18) and to the examiner's answer (Paper No. 17) for the respective positions of the appellants

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and the examiner with regard to the merits of these rejections.

DISCUSSION

I. Grouping of claims

On pages 3 and 4 in the main brief, the appellants set forth the following grouping of claims: claims 1 through 5, 7 through 13 and 17; claim 6; claims 14 through 16, 19 and 20; and claim 18. Therefore, and in accordance with the arguments advanced in both briefs, claims 2 through 5, 7 through 13 and 17 shall stand or fall with claim 1, claim 6 shall stand or fall alone, claims 15, 16, 19 and 20 shall stand or fall with claim 14 and claim 18 shall stand or fall alone.

II. The 35 U.S.C. § 102(b) rejection of claim 1 as being anticipated by Duran '021

Duran '021 discloses sigmoid valve annuloplasty rings or stents for "permanent implantation . . . in the annulus of human sigmoid valves (aortic or pulmonary) to remodel them so as to make the valve competent and avoid its replacement with an artificial heart valve" (column 1, lines 7 through 11). The rings/stents may comprise "biocompatible solid metal single wire, plastic or reabsorbable polymer structure"

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(column 3, lines 67 and 68), the latter being "reabsorbed by the organism after a certain time after their implantation" (column 6, lines 5 and 6). Of particular interest is Duran's teaching that

[f]or implantation the stent [or ring] 1 is covered with biocompatible cloth. In this regard biocompatible cloth comprises a fabric mesh of biocompatible material, preferably polyester (polyacetate) fabric. The use of such biocompatible fabric mesh to enclose various plastic or metal members which are subsequently surgically implanted in the human body is well known in the art. As is further known, after implantation into the human body, an ingrowth of fibrous tissue usually forms in the interstitial spaces of the fabric, and endothelial cells cover the fabric to provide a nonthrombogenic autologous surface [column 6, line 60, through column 7, line 3].

Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). It is not necessary that the reference teach what the subject application teaches, but only that the claim read on something disclosed in the reference, i.e., that all of the limitations in the claim be found in or fully met by the reference. Kalman v. Kimberly

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Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

The appellants' position that the subject matter recited in claim 1 is not anticipated by Duran '021 (see pages 4 through 11 in the main brief and pages 3 through 5 in the reply brief) essentially rests on two lines of argument focusing on the "resorbable" and "consisting essentially of" limitations in the claim. The first argument is that Duran '021 discloses an annuloplasty ring which is permanent as evidenced by Duran's teaching of permanent implantation, rather than one which is "not permanent in nature since it is resorbed over time" (main brief, page 6). The second argument is that Duran '021 requires the annuloplasty ring disclosed therein to have a cloth covering which is both (1) inconsistent with the "resorbable" nature of the claimed ring and (2) excluded by the "consisting essentially of" transitional phrase in claim 1. Neither of these arguments is persuasive.

Turning first to the "consisting essentially of" limitation, it is well settled that this transitional phrase renders a claim open only for the inclusion of unspecified

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elements which do not materially affect the basic and novel characteristics of the claimed invention. See In re Janakirama-Rao, 317 F.2d 951, 952, 137 USPQ 893, 894 (CCPA 1963); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948). In this light, and as conceded by the examiner, claim 1 excludes cloth covers of the sort disclosed by Duran '021. Moreover, the fair teachings of this reference support the appellants' interpretation that such covers are added to all of the disclosed rings or stents 1, including those made of reabsorbable polymers, for implantation. Nonetheless, to the extent that the "consisting essentially of" limitation excludes a cloth covering from the claimed annuloplasty prosthesis, it is met by the reabsorbable rings or stents 1 disclosed by Duran '021 as they exist prior to being covered with cloth for implantation. It is not apparent, nor have the appellants cogently explained, why these uncovered reabsorbable rings or stents 1 do not constitute, either expressly or under principles of inherency, annuloplasty prostheses.

As for the "resorbable" limitation, it is not disputed that the terms "reabsorbable" as used by Duran '021 and

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"resorbable" as used by the appellants have the same meaning. Thus, the "resorbable" limitation in claim 1 is met by the reabsorbable rings or stents 1 disclosed by Duran '021 as they exist prior to being covered with cloth for implantation. Considered in context, the comments in Duran '021 relating to permanent implantation merely mean that the annuloplasty rings disclosed therein are not intended to be removed once implanted. It is the implantation, and not the rings themselves, which are described as being permanent. In any event, to the extent that the claimed annuloplasty prosthesis has a non-permanent nature by virtue of the "resorbable" limitation, the reabsorbable rings or stents 1 disclosed by Duran '021 as they exist prior to being covered with cloth for implantation also have a non-permanent nature.

Thus, the appellants' position that the subject matter recited in claim 1 defines over Duran '021 is unconvincing. We shall therefore sustain the standing 35 U.S.C. § 102(b) rejection of this claim as being anticipated by Duran '021.

We also shall sustain the standing 35 U.S.C. § 102(b) rejection of claims 2, 4, 5, 7 and 11 as being anticipated by Duran '021 since these claims stand or fall with claim 1.

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III. The 35 U.S.C. § 102(b) rejection of claim 14 as being anticipated by Duran '021

The arguments advanced by the appellants against the 35 U.S.C. § 102(b) rejection of method claim 14 as being anticipated by Duran '021 are the same as those advanced in connection with claim 1, and are similarly unpersuasive. The prosthesis providing step in claim 14 finds response in Duran's provision of the reabsorbable rings or stents 1 as they exist prior to being covered with cloth for implantation, and the prosthesis implanting step in claim 14 finds response in Duran's implantation step even though the reabsorbable rings or stents 1 are covered with cloth at this time. The "comprising" transitional phrase in claim 14 leaves the claim open for the inclusion of unspecified elements. See PPG Industries Inc. v. Guardian Industries Corp., 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998); Ex parte Davis, supra. Among such elements would be the step of covering the prosthesis provided in the first step of the claim before implanting it in the second step.

Thus, the appellants' position that the subject matter recited in claim 14 distinguishes over Duran '021 is

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unconvincing. We shall therefore sustain the standing 35 U.S.C. § 102(b) rejection of this claim as being anticipated by Duran '021.

We also shall sustain the standing 35 U.S.C. § 102(b) rejection of claims 16, 19 and 20 as being anticipated by Duran '021 since these claims stand or fall with claim 14.

IV. The 35 U.S.C. § 103(a) rejections of claims 1 and 14

It is well settled that lack of novelty in claimed subject matter, i.e., anticipation, is the ultimate or epitome of obviousness. See In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982)). Inasmuch as the subject matter recited in claims 1 and 14 is anticipated by Duran '021, we shall sustain the standing 35 U.S.C. § 103(a) obviousness rejections of these claims as being unpatentable over Duran '021 alone or further in view of Reimold.

We also shall sustain the standing 35 U.S.C. § 103(a) rejections of claims 2, 4, 5, 7, 11, 16, 19 and 20 as being unpatentable over Duran '021 alone or further in view of Reimold, the standing 35 U.S.C. § 103(a) rejection of claims 3, 15 and 17 as being unpatentable over Carpentier in view of Duran '021, the standing 35 U.S.C. § 103(a) rejection of

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claims 8 through 10 as being unpatentable over Duran '021 in view of Duran '297 and the standing 35 U.S.C. § 103(a) rejection of claims 12 and 13 as being unpatentable over Duran '021 in view of Buscemi since all of these claims stand or fall with claims 1 and 14.

V. The 35 U.S.C. § 103(a) rejection of claim 6 as being unpatentable over Duran '021 in view of Ross

Claim 6 depends ultimately from claim 1 and further requires the resorbable member to include a collar extending therefrom for attachment to the aortic complex above the commissures. The collar facilitates such attachment and contributes to a remodeling of the aortic complex (see page 22 in the underlying specification). The examiner concedes (see page 7 in the answer) that Duran '021 does not disclose such a collar.

Ross discloses a metal stent 1 for supporting an aortic replacement valve 17, the stent comprising a base ring 2 and three legs 3, 4 and 5 extending therefrom. Ross teaches that

when the stent has a valve installed therein and the valve is subjected to pressure conditions such as those to which it would be subjected when installed within a heart, the base ring should not deform to any substantial extent. . . . [R]igidity of the base ring is important to guard against unnatural

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distortion of the valve in use such as would impair proper sealing of the valve cusps [column 2, lines 25 through 32].

The examiner has concluded that “[i]t would have been obvious to one having ordinary skill in the art to have utilized the collar [presumably base ring 2] of Ross et al. with the resorbable prosthesis of Duran [’021] to increase the structural integrity of the prosthesis” (answer, page 7). The purpose and function of Ross’ collar (base ring 2), however, have no appreciable relevance to the annuloplasty rings or stents disclosed by Duran ’021. Thus, the appellants’ contention (see pages 15 and 16 in the main brief) that the proposed combination of Duran ’021 and Ross rests solely on impermissible hindsight is well taken.

Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 6 as being unpatentable over Duran ’021 in view of Ross.

VI. The 35 U.S.C. § 103(a) rejection of claim 18 as being unpatentable over Duran ’021 in view of Duran ’297

Claim 18 depends ultimately from claim 1 and further defines the resorbable member as being porous. This feature

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allows rapid clot stabilization and subsequent tissue ingrowth (see pages 12, 15 and 17 in the underlying specification).

Implicitly conceding that Duran '021 lacks any teaching that the reabsorbable stents or rings 1 disclosed therein are porous, the examiner has concluded (see page 5 in the answer) that it would have been obvious to one of ordinary skill in the art to employ the resorbable materials disclosed by Duran '297 (see column 11, lines 45 through 67) in the rings or stents 1 of Duran '021. According to the examiner, reconstituted collagen, one of the resorbable materials disclosed by Duran '297, "is made of fibrils forming an irregular porous surface" (answer, page 11). The appellants counter (see page 13 in the main brief and page 5 in the reply brief) that none of the resorbable materials disclosed by Duran '297, including reconstituted collagen, is necessarily porous.

Given the unsubstantiated nature of the examiner's finding that reconstituted collagen is porous and the appellants' challenge thereto, we are constrained to conclude that the examiner has failed to advance the factual basis necessary to support a conclusion that the subject matter

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recited in claim 18 would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Therefore, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 18 as being unpatentable over Duran '021 in view of Duran '297.

SUMMARY

The decision of the examiner:

a) to reject claims 1, 2, 4, 5, 7, 11, 14, 16, 19 and 20 under 35 U.S.C. § 102(b) as being anticipated by, and in the alternative under 35 U.S.C. § 103(a) as being unpatentable over, Duran '021 is affirmed;

b) to reject claims 1, 2, 4, 5, 7, 11, 14, 16, 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Reimold is affirmed;

c) to reject claims 3, 15 and 17 under 35 U.S.C. § 103(a) as being unpatentable over Carpentier in view of Duran '021 is affirmed;

d) to reject claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Ross is reversed;

e) to reject claims 8 through 10 and 18 under 35 U.S.C.

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§ 103(a) as being unpatentable over Duran '021 in view of Duran '297 is affirmed with respect to claims 8 through 10 and reversed with respect to claim 18; and

f) to reject claims 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Duran '021 in view of Buscemi is affirmed.

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

AFFIRMED-IN-PART

HARRISON E. McCANDLISH, Senior)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
LAWRENCE J. STAAB)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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AFFIRMED-IN-PART

August 27, 2001