

**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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* ROBERT S. SCHWARTZ

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Appeal No. 95-4847  
Application No. 08/079,222<sup>1</sup>

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ON BRIEF

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Before COHEN, ABRAMS and FRANKFORT, *Administrative Patent Judges*.

ABRAMS, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is an appeal from the decision of the examiner finally rejecting claims 1-11 and 29-32. At that point, claims 12-28 and 33-47 had been withdrawn from consideration

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<sup>1</sup>Application for patent filed June 17, 1993. According to appellant, this application is a continuation of Application 07/854,118, filed March 19, 1992, now abandoned.

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as being drawn to a non-elected invention, and no claims had been allowed. Along with the Appeal Brief (Paper No. 16), the appellant filed an amendment canceling claims 9-11 and 30-32, leaving claims 1-8 and 29 on appeal.

The appellant's invention is directed to an intraluminal stent (claims 1-8) and to a method of preventing restenosis in a body lumen (claim 29). The subject matter on appeal is illustrated by reference to claims 1 and 29, which can be found in an appendix to the Brief.

**THE REFERENCES**

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

Spears	5,092,841	Mar. 3,
1992		
European application	0,364,787	Apr. 25,
1990		
(Schatz)		

**THE REJECTION**

Claims 1-8 and 29 stand rejected under 35 U.S.C. § 103 as being unpatentable over Schatz in view of Spears.

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The rejection is explained in the Examiner's Answer.

The opposing viewpoints of the appellant are set forth in the Brief and the Reply Brief.

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**OPINION**

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness (see *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) which is established when the teachings of the prior art itself would appear to have suggested the claimed subject matter to one of ordinary skill in the art (see *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993)). This is not to say, however, that the claimed invention must expressly be suggested in any one or all of the references, rather, the test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art (see *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985)).

Schatz discloses a deformable metal stent which may, with reference to Figures 5 and 6, have a "biological compatible coating 90 upon wall surfaces 74" (page 7, column 2, lines 27-29). Examples of the coatings are absorbable polymers which could contain drugs whereby, as the coating dissolves, the

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drug is slowly released into the body passageway (page 7, column 2, lines 50-57). Thus, Schatz would have taught one of ordinary skill in the art to place a film on the outer surface of a stent which would interact with the body lumen in which the stent is installed. What Schatz does not explicitly teach is that this film could be of fibrin, as is required by claims 1 and 29.

For this the examiner looks to Spears, which is directed to a method for treating an arterial wall injured during angioplasty. The primary method disclosed is positioning an angioplasty catheter in the damaged area, and then delivering a bioprotective material between the arterial wall and the catheter so that it is entrapped therebetween and permeates into the fissures and small vessels of the arterial wall (see the Abstract and Figures 2 and 2A). One of the forms in which the bioprotective material is provided is as a shell of microspheres within which drugs can be encapsulated (column 7, lines 39 and 40). Among the materials listed as the encapsulating medium is fibrin (column 7, line 61). Spears goes on to state:

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Disclosure of the invention thus far has contemplated the injection of bioprotective material **26** between the inflating balloon and the arterial wall. Another method . . . contemplates applying a thin sleeve of such material to the external surface of the **LBA** balloon. The thin sleeve is then transferred to the luminal surface as a result of heat and pressure (column 9, lines 19-26).

From the above, it is our view that Spears would have suggested to one of ordinary skill in the art that fibrin in the form of a pre-formed film of drug-containing microspheres be placed on the external surface of the balloon element of an angioplasty catheter and placed in contact with the interior wall of a body lumen for the purpose of treating the wall.

It is our further view that one of ordinary skill in the art would have found it obvious to coat the stents of Schatz with fibrin in place of the coatings disclosed in Schatz, suggestion being found in the explicit teachings of Schatz and Spears referred to above, which establish the desirability of (1) coating a stent with materials to be applied to the walls of the body lumen and (2) utilizing fibrin as such a material. We note here that the prior art teachings relied upon need not disclose the same advantage that the appellant alleges, for all that is required is that there is a reasonable suggestion

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to combine the references. See *In re Kronig*, 539 F.2d 1300, 1304, 190 USPQ 425, 427-428 (CCPA 1976); and *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Int. 1985), *aff'd. mem.*, 759 F.2d 1017 (Fed. Cir. 1986).

Claims 1 and 29 further state that the fibrin is provided by contacting fibrinogen with a fibrinogen-coagulating protein. This is not explicitly set out in either reference. However, it constitutes a product-by-process limitation which, if the product is the same as a product of the prior art, adds no patentable distinction to the claim. This principle is discussed in *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). The appellant has argued that the fibrin disclosed in Spears is different from that which is recited in claims 1 and 29, in that it is denatured, but has not pointed out language in Spears which supports such a conclusion or offered evidence to that effect. Fibrin is defined as an insoluble blood protein resulting from the hydrolysis of fibrinogen by the action of thrombin, which polymerizes to form blood clots (see, for example, Hawley's Condensed Chemical Dictionary, Eleventh Edition, 1987), which would

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seem to cover the fibrin disclosed in Spears as well as that recited in the appellant's claims and disclosed in the appellant's specification.

We additionally note that claim 29 is directed to a method comprising the single step of applying a stent comprising a pre-formed fibrin film, which is followed by the product-by-process limitation. In addition to the problem we find with this which was explained above with regard to claim 1, claim 29 is limited to a single "step," and to consider the process limitation would add a second step and thus raise a question of indefiniteness regarding this claim language.

For the reasons set forth above, it is our conclusion that the combined teachings of Schatz and Spears establish a *prima facie* case of obviousness with respect to the subject matter recited in claims 1 and 29. This being the case, we shall sustain the rejection of these two claims and, owing to the appellant's decision that claims 3, 4, 5, 7 and 8 will stand or fall with claim 1 (Brief, page 8), the rejection of those claims also.

Claim 2 adds to claim 1 the requirement that "the fibrin is a fibrin in which residual coagulating protein has been

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neutralized." In our view this also is a limitation that goes to the process of manufacture of the fibrin. Therefore, for the same reasons as were set forth above with regard to the term "fibrin" as it is utilized in claim 1, we find claim 2 not to define over the combined teachings of the two references, and we will sustain the rejection of claim 2.

Dependent claim 6 further limits claim 1 by adding the limitation that "the fibrin is intermixed with a polymeric material." While polymeric material was disclosed in both of the applied references, their collective teachings did not include intermixing it with fibrin. We therefore will not sustain the rejection of this claim.

We have carefully considered all of the appellant's arguments. However, as to those rejections which we have sustained, the arguments have not persuaded us that the positions taken by the examiner were in error. We observe that there is a broad commonality of purpose in the appellant's invention and in those of the two references. The object of the appellant's invention is to repair vascular injury by coating a stent with fibrin to place the fibrin at the site to interact with the body (specification, page 3),

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the purpose of the Schatz invention is to place absorbable polymers or drugs into contact with the lumen wall at the site of the stent, and the function of the Spears invention is to repair an injured arterial wall (column 1), which it accomplishes by placing materials which include fibrin at the site to interact with the body (columns 5-7). Thus, it is our opinion that the references do not teach away from combining their teachings, and that their teachings are applicable to the appellant's invention.

**SUMMARY**

The rejection of claims 1-5, 7, 8 and 29 is sustained.

The rejection of claim 6 is not 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**

IRWIN CHARLES COHEN )

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	Administrative Patent Judge)	
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	NEAL E. ABRAMS	) BOARD OF
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	CHARLES E. FRANKFORT	)
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