

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* DENNIS R. BOULAIS,  
Appellant

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Appeal 2008-4290  
Application 10/421,812<sup>1</sup>  
Technology Center 1700

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Decided: September 05, 2008

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Before TERRY J. OWENS, CATHERINE Q. TIMM, and  
MARK NAGUMO, *Administrative Patent Judges*.

NAGUMO, *Administrative Patent Judge*.

DECISION ON APPEAL

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<sup>1</sup> Application 10/421,812, *Expandable Mask Stent Coating Method*, filed 24 April 2003. The specification is referred to as the “812 Specification,” and cited as “Spec.” The real party in interest is listed as Boston Scientific Scimed, Inc. (Second Amended Appeal Brief, filed 7 December 2007 (“Br.”), 1.)

**A. Introduction**

Dennis R. Boulais (“Boulais”) timely appeals from the final rejection of claims 1-6, 8-10, and 13. Claims 14-18, the only other pending claims, have been withdrawn from consideration by the Examiner and are not before us. We REVERSE.

The claimed subject matter relates to methods of coating selected areas of stents. Stents are described by the 812 Specification as cylinders typically having thin walls formed from a non-reactive metal lattice. (Spec. 5:[10].) According to the 812 Specification, it is often desired to coat the stents with polymers that can absorb drugs and then release the drugs when implanted in the body. (Spec. 1[3]-5:[9].) Various processes of applying the coating are known and these methods are said typically to coat all surfaces of the stent. (Spec. 6:[12]-[13].) Because the drug-containing coating may be expensive, and because the coating may interfere with delivering the stent to the implant site, it is said to be desirable to coat, e.g., only the outside of the stent. (Spec. 6:[14]-[15].)

Independent claim 10, which is representative of the issues necessary to resolve this appeal, is reproduced on the following page from the Claims Appendix to Boulais’s principal brief on appeal.

Claim 10:

A method for applying a coating to a selected area of a stent, comprising the steps of:

- [i] placing an expandable masking apparatus comprising an inflatable balloon and a coating repelling sleeve inside the stent,
- [ii] inflating the balloon until an outer surface of the expandable masking apparatus contacts an inner surface of the stent;
- [iii] applying a coating to the stent while the balloon is inflated; and
- [iv] deflating the balloon and removing the expandable masking apparatus from the stent.

(Claims App., Br. 19; square bracketed labels and indentation added.)

Claim 1 is similar, but includes further limitations on the coating repelling sleeve. In particular, claim 1 requires that

- [ia] the coating repelling sleeve comprises a sheet of material with the ends of the coating repelling sleeve overlapping such that the coating repelling sleeve surrounds the inflatable balloon;

and that, when the balloon is inflated,

- [iia] the coating repelling sleeve has sufficient length in the circumferential direction that its ends remain overlapping when the balloon is inflated,

wherein limitations [ia] and [iia] are further limitations on the respective placing [i] and inflating [ii] steps recited in claim 10.

The Rejection

The Examiner has maintained the following rejection:

Claims 1-6, 8-10, and 13 stand rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Sirhan,<sup>2</sup> Hillstead,<sup>3</sup> and Jung.<sup>4</sup>

Boulais argues claims 1-6, 8, and 9 as a group that stands or falls together, and claims 10 and 13 as a second group that stands or falls together. (Br. 5.) The difference between the two groups relates to the additional limitations in claim 1 that require the sleeve to be a sheet having overlapping ends that are long enough to overlap even when the balloon is inflated. (Br. 15-16; Reply Brief filed 7 March 2008 (“Reply Br.”), 7.)

**B. Findings of Fact**

Findings of fact (FF) throughout this Decision are supported by a preponderance of the evidence of record.

The 812 Specification

1. Figure 2, reproduced on the following page, shows an unclaimed version of the invention:

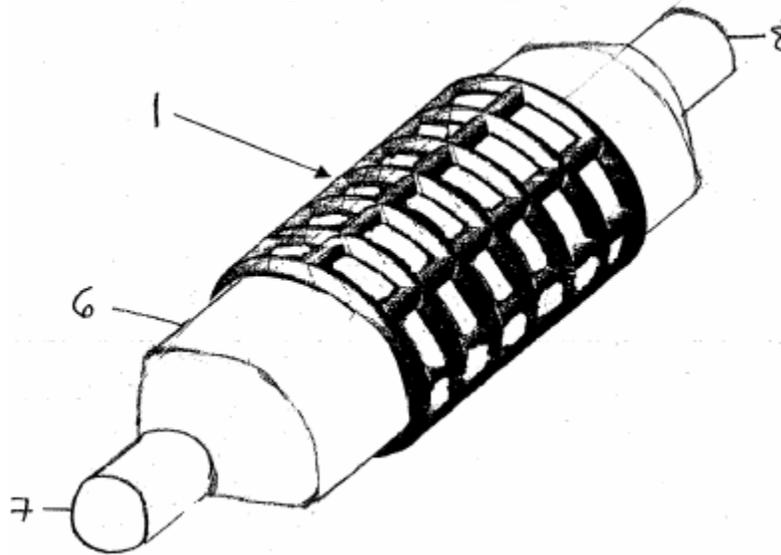
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<sup>2</sup> Motasim Sirhan and John Yan, *Apparatus and Methods for Variably Controlled Substance Delivery from Implanted Prostheses*, U.S. Patent Application Publication US 2003/0083646 A1 (1 May 2003), based on application 10/017,500 filed 14 December 2001.

<sup>3</sup> Richard A. Hillstead, *Dilatation Balloon within an Elastic Sleeve*, U.S. Patent 5,116,318 (1992).

<sup>4</sup> Eugene Jung and Kazuo Sasamine, *Balloon Protector*, U.S. Patent 5,352,236 (1994).

{812 Specification Figure 2}<sup>5</sup>



{Figure 2 is said to show a stent and an expandable masking apparatus}

2. Figure 2 shows a stent **1** into which a balloon **6** has been inserted and inflated via port **7**. (Spec. 8-9:[24].)
3. A summary of the claimed inventions is provided in paragraphs [30] and [31] of the 812 Specification.
4. Paragraph [30] reads in relevant part:

An additional embodiment of the present method employs the same balloon expansion step as the forgoing embodiments, with the addition of an expandable sleeve (not illustrated) between the outer surface of the balloon and the inner surface of the stent. Such a sleeve may be formed from a thin, flat sheet of material such as [[[insert materials:]]] \_\_\_\_\_ and \_\_\_\_\_ that is curled into a cylindrical shape with overlapping ends [ia], . . . When the balloon is

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<sup>5</sup> The text in curly braces before and after the Figures is provided to ensure compliance with section 508 of the U.S. Rehabilitation Act for publication of this Decision on the USPTO website pursuant to the Freedom of Information Act. It is not part of the Decision.

expanded in the inflating step, its outer surface presses radially outward on the sleeve, causing the sleeve diameter to increase as its overlapping ends slide over one another. The sleeve continues to expand until its outside surface contacts and masks the inner surface of the stent. When the deflating and removing step is performed, the sleeve ends slide over one another to permit the sleeve diameter to decrease and disengage from the coated stent. In order to ensure the entire inner surface of the stent is masked by the sleeve, it should be of sufficient length in the circumferential direction that its ends remain overlapping when expanded to its maximum diameter within the stent [iia]

(Spec: 10:[30]; square bracketed editorial instructions original; square bracketed labels added, showing correspondence with the corresponding limitations recited in the claims.)

5. According to paragraph [31] of the 812 Specification:

it is preferred that the balloon or the sleeve discourage the adherence of the coating to their surfaces, both to discourage the formation of coating ‘bridging’ between the stent lattice openings and to minimize the amount of costly stent coating material lost to application on surfaces other than the stent lattice. The repelling of coating material from the balloon or sleeve surfaces may be enhanced with materials that discourage the formation of films.

(Spec:10:[31].)

#### Sirhan

6. Sirhan describes methods of coating stents with, e.g., drug delivery materials, wherein the inner “luminal” surface of the stent is shielded from the coating material by a mandrel (Sirhan 16:[158]) or an expansible balloon (*id.* at 16:[160]).

7. Use of the balloon is said to allow easier removal from the stent after coating. (Sirhan 16:[160].)

8. Sirhan does not describe the use of a sleeve in conjunction with the balloon.

Hillstead

9. Hillstead describes a dilatation balloon assembly that is used to implant an endoprosthesis device, such as a stent within a blood vessel. (Hillstead 1:7-10.)

10. According to Hillstead, a common problem is “the inability of the deflated balloon to disengage from the stent after the stent has been expanded.” (Hillstead 2:14-18.)

11. Apparently, on deflation, the balloons can produce flat or ‘wing-like’ configurations that exceed the inflated diameter of the balloon, and thus the diameter of the expanded stent. (Hillstead 2:18-25.)

12. In addition to the disengagement problem, Hillstead indicates that the projections can also damage blood vessels. (Hillstead 2:25-30.)

13. Hillstead solves these problems by providing an elastic sleeve around the conventional balloon assembly. (Hillstead 2:31-34.)

14. According to Hillstead, the balloon expands within the sleeve, and when the balloon collapses, the elastic sleeve collapses around the collapsed balloon “forcing it to a small diameter or small lateral extent eliminating the creation of a ‘blade-like’ or ‘wing-like’ shape in the deflated balloon.” (Hillstead 2:37-41.)

15. Hillstead does not describe whether the elastic sheets are “coating repellent.”

Jung

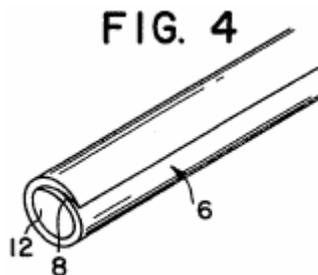
16. Jung teaches elastomeric balloon protectors for a “balloon catheter comprising an elastomeric sleeve adapted to circumscribe the balloon of a balloon catheter, the sleeve having an inner diameter smaller than the outer diameter of the balloon so it exerts continuous compressive force on the balloon.” (Jung 3:13-18.)

17. In Jung’s words, “[t]he preferred balloon protector **1** has a lubricious inner surface which permits easy insertion of the balloon into the protector during manufacture and easy removal before the catheter is used.” (Jung 4:36-39.)

18. In a particular embodiment, Jung describes a lubricious inner surface formed from a Teflon™ tube. (Jung 4:45-46.)

19. According to Jung, because Teflon™ is not sufficiently elastomeric, the tube is slit longitudinally, which allows the tube to be rolled into a smaller tube that can be easily inserted into an elastomeric sleeve during manufacture. (Jung 4:46-51.)

20. In Jung’s words, referring to Figure 4, which is reproduced below,



{Jung Figure 4 is said to show a slit Teflon™ tube.}

“[o]nce slit, the two ends **18** and **20** of the Teflon™ tube tend to slide over each other while the balloon protector is in place.” (Jung 4:51-53.)

The Examiner's Arguments

The Examiner finds that Sirhan teaches a variety of stent structures including an open lattice structure on which a deflated balloon might easily catch. (Ans. 4, citing Sirhan 16:[159].) The Examiner finds further that Hillstead teaches the use of protective sleeves “to promote ease of disengagement.” (*Id.*) The Examiner also finds that Jung teaches that a protective sleeve of elastomeric material may be lined with a lubricious material such as silicone or PTFE [polytetrafluoroethylene, sold under the trademark “Teflon™” by DuPont]. (*Id.*) In particular, the Examiner finds that Jung teaches a protective sleeve made from PTFE “that has overlapping ends that function in the fashion claimed by the applicant.” (*Id.*) The Examiner concludes that “it would have been obvious to one skilled in the art to modify the process of Sirhan so as to employ the protective sleeve of Jung with the expectation of facilitating disengagement of the balloon from the stent surface as suggested by Hillstead.” (*Id.*)

Boulais's Rebuttal Arguments

Broadly, Boulais argues that Sirhan, Hillstead, and Jung relate to solving such different problems that the combination requires picking and choosing features based on hindsight reconstruction using the claimed subject matter as a road map. (Br. 12.) Thus, according to Boulais, a person carrying out the Sirhan process of coating stents, which does not occur within a blood vessel, would not look to Hillstead's solution to the problem of avoiding injury to patient blood vessels in which stents are implanted. (Br. 12-13.)

Similarly, Boulais argues that “the Examiner provides absolutely no basis as to why a person of ordinary skill in the art would, after modifying Sirhan with Hillstead, then turn to Jung.” (Br. 13.) “Under the Examiner’s rejection,” Boulais continues, “that person has already solved the problem of removing the balloon from the coated stent in the Sirhan process . . .” (*Id.*) Moreover, Boulais argues, adding only a Teflon™ tube, as taught by Jung, would contradict Jung, which teaches that the Teflon™ tube is part of protector sleeve 5, and it is protector sleeve 5 that provides the compressive force on the balloon that is required by Jung, because the Teflon™ is, according to Jung, not elastic enough by itself (Br. 14.) Additionally, according to Boulais, adding only the Teflon™ tube of Jung to Hillstead to facilitate disengagement of the balloon from the stent would contradict Hillstead. (*Id.*) Hillstead, according to Boulais, requires an elastic sleeve, which the Teflon™ tube described by Jung would not provide. (*Id.*)

### **C. Discussion**

A prima facie case of obviousness is established only when the Examiner shows that the combined teachings of the references teach or suggest all of the limitations of the claimed subject matter. Moreover, although the substitution of equivalent functional structures is typically prima facie obvious, the fact finding of functional equivalence and the fact finding that the person having ordinary skill in the relevant arts would have recognized a functional equivalence must be supported by probative evidence in the record.

In the present appeal, with respect to claim 1 and the claims dependent on claim 1, the critical question is whether, as the Examiner

concluded, it would have been obvious to surround a balloon with the PTFE<sup>6</sup> sleeve taught by Jung, place the PTFE-sheet wrapped balloon inside a stent, then inflate the balloon until the PTFE sheet contacted the inner surface of the stent while still completely encompassing the balloon, coating the stent, and then deflating and removing the balloon and the sheet.

The first problem with the Examiner's rejection of claim 1 is that the Examiner's finding that Jung teaches a "protective sleeve made of PTFE . . . having overlapping ends that function in the fashion claimed by the applicant" (Ans. 4) is not sufficient to meet the requirements of claim 1. Limitation [iia] of claim 1 requires that the sheet be long enough that the ends of the sleeve surround the inflatable balloon even when the balloon is inflated. The function of the slit PTFE tube in Jung is not to accommodate an inflated balloon, but to protect an uninflated balloon. The Examiner has not directed our attention to any teaching in Jung or Hillstead that supports the use of a sheet having this property. The next problem concerns the Examiner's determination that "[i]t would have been obvious to one skilled in the art to modify the process of Sirhan so as to employ the protective sleeve of Jung with the expectation of facilitating disengagement of the balloon from the stent surface as suggested by Hillstead" (Ans. 4). This determination is further disconnected from the references because the sleeve taught by Hillstead must be sufficiently elastic that it can readily expand as the balloon is inflated, and also squeeze down on the balloon as the balloon is deflated. (Hillstead 2:37-41; FF14; see also Hillstead 4:36-47, 52-53, and 58-60, describing the elasticity of the sleeve in more detail.) Jung slits the

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<sup>6</sup> We shall use the generic term, "PTFE," for the material, except when quoting the record.

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PTFE tube because it is not sufficiently elastic. (Jung 4:46-51: FF 19.)  
Thus, Jung does not provide, with its slit PTFE tube, a functionally equivalent alternative structure for the elastic sleeve taught by Hillstead.

We conclude that the rejection of claim 1 and claims dependent on claim 1 must be REVERSED.

The situation regarding claim 10 is similar. The Examiner has not relied on any disclosure in Jung that provides a reason to use the disclosed slit PTFE tube as an alternative to the sleeve taught by Hillstead.

Therefore, the combination with Jung is fatal to the obviousness rejection.

#### **D. Summary**

In view of the record and the foregoing considerations, it is:

ORDERED that the rejection of claims 1-6, 8-10, and 13 under 35 U.S.C. § 103(a) in view of the combined teachings of Sirhan, Hillstead, and Jung is REVERSED.

**REVERSED**

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