

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MICHAEL S. H. CHU, ALFRED P. INTOCCIA JR.,
and KENNETH J. DAIGNAULT

Appeal 2008-5170
Application 10/405,417
Technology Center 3700

Decided: December 11, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving a claim to a stent system. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

“Due to a number of different medical conditions . . . body lumens may become constricted, thereby limiting or preventing the transport of fluid within the body. To alleviate the constriction and return patency to a patient, a medical professional may insert a stent into the patient's body lumen” (Spec. 1 ¶ 0002). The Specification notes that stents “need to be expandable and have a high hoop strength, such that a stent placed within a constricted portion of a body lumen will be able to alleviate the constricted passageway and maintain patency therethrough” (Spec. 1 ¶ 0003). According to the Specification, “[c]onventional expandable stents are made from metal in order to achieve proper hoop strength. Plastic stents, while less expensive and generally more biocompatible have yet to achieve proper hoop strength, such that prior art expandable plastic stents are unable to adequately maintain patency through a constricted body lumen” (Spec. 1 ¶ 0004).

The Claims

Claims 14 and 19-23 are on appeal.¹ We will focus on claim 14, which is representative and reads as follows:

14. A system for maintaining patency through an anatomical lumen, the system comprising:
 - a tubular member including a distal end and a proximal end and defining a lumen extending at least partially therethrough, the tubular member comprising:
 - a thermoplastic material; and

¹ The Examiner withdrew claims 1-13, 16-18, and 24-27 from consideration based upon a restriction requirement.

fibers selected from the group consisting of woven and wound fibers at least partially embedded within the thermoplastic material, wherein the fibers are woven or wound prior to becoming embedded within the thermoplastic material, and the thermoplastic material maintains the tubular member in at least one of an expanded state and a collapsed state; and

a transitioning means for transitioning the tubular member between the collapsed state and the expanded state.

The prior art

The Examiner relies on the following prior art reference to show unpatentability:

Phan US 5,674,242 Oct. 7, 1997

The issue

The Examiner rejected claims 14 and 19-23 either under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) over Phan (Ans. 3-4).

The Examiner found that “Phan teaches use of a tubular stents [sic] comprising metal fibers that are encased in a thermoplastic material, but is silent as to whether the stent may be assembled by winding before the fibers are encased with thermoplastic” (*id.* at 4). The Examiner found that “even though Phan is silent as to the process used to form the stent prior to embedding it in thermoplastic, it appears that the product in Phan would be the same or similar as that claimed” (*id.*).

Appellants contend that “Phan simply does not teach or suggest the use of woven or wound fibers” (App. Br. 5). Appellants further contend that “even if the structural member [of Phan] is somehow considered as corresponding to the claimed ‘fibers,’ there is no teaching or suggestion in

Phan that ‘the fibers are woven or wound prior to becoming embedded within the thermoplastic material’ (independent claim 14)” (*id.* at 6). Appellants contend that the “limitation is not a product-by-process limitation, but instead recites a structural characteristic of the claimed woven or wound fibers” (*id.* at 7).

In view of these conflicting positions, we frame the anticipation and obviousness issues before us as follows:

Did the Examiner err in finding that Phan either teaches or renders obvious a stent which comprises woven and wound fibers embedded within the thermoplastic material of the stent?

Findings of Fact (FF)

1. Phan teaches a stent as shown in Fig. 1a reproduced below:

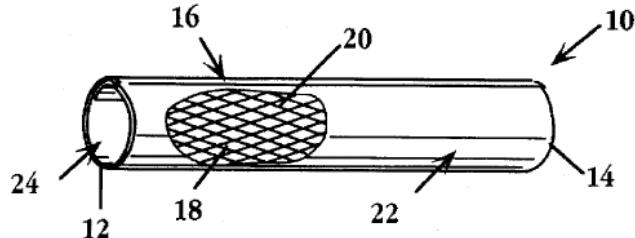


Fig. 1A

“FIGS. 1A . . . illustrate an endoprosthetic device . . . where the structural member is encased by the polymer member, and where the device is shown in a contracted, predeployed state (FIG. 1A)” (Phan, col. 2, ll. 62-66).

2. Phan teaches that the “device is generally tubular or cylindrical in shape, and has first and second ends 12, 14” (Phan, col. 4, ll. 3-5).

3. Phan teaches that “the device is composed of a structural member and a polymer member” (Phan, col. 3, ll. 59-60).

4. Phan teaches a “first embodiment of the device is shown in FIGS. 1A-1D, where the structural member is encased by the polymer member” (Phan, col. 3, l. 66 to col. 4, l. 1).

5. Phan teaches that in “a preferred embodiment of the invention, the polymer member is prepared from a polymer that is sensitive to heat. Typically, these polymers are thermoplastic polymers which soften and take on a new shape by the application of heat and/or pressure” (Phan, col. 6, ll. 10-14).

6. Phan teaches that the device may be formed where “the polymer member is . . . cowound with the structural member” (Phan, col. 9, ll. 45-47).

7. Phan further teaches that the “structural member and the polymer member, having the same geometry are heated to above their respective transition temperatures and cowound around a stainless steel rod” (Phan, col. 9, ll. 52-54).

8. Phan teaches that “the stent is composed of a structural member **118** having a wire-mesh configuration, and a polymer member **120** encasing the structural member” (Phan, col. 11, ll. 18-21).

9. Phan teaches a transitioning means comprising a balloon catheter (Phan, col. 11, ll. 40-47).

10. Phan teaches that the “structural member of the device is formed preferably of a metal or an alloy, including shape-memory alloys” (Phan, col. 5, ll. 19-20).

11. The Specification teaches that the “wound fibers 18 may be made of metal, such as titanium, a metal alloy, or even a shape memory alloy, such as, for example, a nickel-titanium alloy” (Spec. 8 ¶ 0022).

Principles of Law

“Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.” *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). “Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, on ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO’s inability to manufacture products or to obtain and compare prior art products.” *Id.*

“The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (internal citations omitted).

“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.” *PPG Indus., Inc. v. Guardian Indus. Corp*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

In *KSR*, the Supreme Court rejected the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, stating that

The principles underlying [earlier] cases are instructive when the question is whether a patent claiming

the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

“As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 1741.

Analysis

Phan teaches a stent which comprises a tubular member with two ends and a lumen (FF 1-2). Phan teaches that the stent is composed of two materials, a thermoplastic material and metal structural members which may be cowound (FF 3-8). Phan teaches that the structural member is embedded in the thermoplastic material (FF 4, 5, 7, 8). Phan teaches a transitioning means to convert the tubular member from the collapsed to the expanded state (FF 9).

Phan teaches metal structural members composed of shape memory alloys (FF 10) which are structurally the same as the wound fibers disclosed by the Specification (FF 11).

If Phan differs from the instant claim 14 at all, the difference is that Phan does not teach that the “fibers are woven or wound prior to becoming embedded within the thermoplastic material.” This difference, however, represents a process step embedded in a product claim. “The patentability of a product does not depend on its method of production. If the product in a

product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d at 697.

We are not persuaded by Appellants’ argument that “Phan simply does not teach or suggest the use of woven or wound fibers” (App. Br. 5). In fact, Phan teaches that the “structural member and the polymer member, having the same geometry are heated to above their respective transition temperatures and cowound around a stainless steel rod” (Phan, col. 9, ll. 52-54; FF 7). Phan teaches that the structural member is a length of metal (FF 10) which is wound (FF 7) around a stainless steel rod. This satisfies the structural requirements imposed by the claim. The Specification does not provide any specific definition of the term “fiber” that serves to distinguish the fiber recited in the claims from the wound metal of Phan. Additionally, Phan teaches a mesh structure, which also appears structurally identical to the “woven” material claimed by Appellants (FF 1). *See In re Best*, 562 F.2d at 1255. (“Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.”)

Appellants have failed to rebut the findings of fact above and “the burden is shifted to applicant to show an unobvious difference” (Ans. 4). Appellants have provided no evidence which demonstrates any structural difference between the stent of Phan and the claimed stent.

We also do not find persuasive Appellants' argument that "even if the structural member [of Phan] is somehow considered as corresponding to the claimed 'fibers,' there is no teaching or suggestion in Phan that 'the fibers are woven or wound prior to becoming embedded within the thermoplastic material' (independent claim 14)" (App. Br. 6). Phan clearly teaches a product in which the structural member is embedded within the thermoplastic material (FF 4, 5, 7, 8).

We also find that the limitation regarding "fibers are woven or wound prior to becoming embedded within the thermoplastic material" is a product by process limitation, since Appellants have failed to show that there is any structural difference imposed by winding or weaving the fibers prior to their becoming embedded. *See In re Thorpe*, 777 F.2d at 697.

Conclusions of Law

The Examiner did not err in finding that Phan teaches and renders obvious a stent which comprises woven and wound fibers embedded within the thermoplastic material of the stent.

SUMMARY

In summary, we affirm the rejection of claim 14 as anticipated under 35 U.S.C. § 102(b) or in the alternative as obvious over 35 U.S.C. § 103(a) over Phan. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 19-23 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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