

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 A. HERRMANN,  
FREDERICK H. STRICKLER,  
WENDY NAIMARK, and  
PETER L. DAYTON

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Appeal 2007-3840  
Application 10/116,647  
Technology Center 1700

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Decided: December 14, 2007

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Before EDWARD C. KIMLIN, THOMAS A. WALTZ and  
LINDA M. GAUDETTE, *Administrative Patent Judges*.

GAUDETTE, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1, 2, 4, 5, 7, and 9-11. Claims 3, 6, 8, and 12-33 are also pending in the application but have been withdrawn from consideration. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

The invention relates to a method of making a medical device having a polymer coating that releases a therapeutic agent. Spec. [0001]. Such devices include, for example, coronary stents. Spec. [0002]; claim 5.

Claim 1 is illustrative of the invention and is reproduced below:

1. A method of providing a medical device with a therapeutic agent-releasing polymer coating comprising:
  - (d) covalently bonding at least one reactive species to a medical device surface, said reactive species leading to chain growth polymerization in the presence of monomer;
  - (e) then contacting said reactive species with at least one monomer species, thereby forming a polymer coating on the surface of the medical device; and
  - (f) providing at least one therapeutic agent within said polymer coating during or after the formation of the polymer coating.

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

Wang	WO 01/17575 A1	Mar. 15, 2001
Ding	US 6,673,385	Jan. 6, 2004

The Examiner made the following rejections:

1. Claims 1, 2, 4, 7, and 10-11 under 35 U.S.C. § 102(b) as anticipated by Wang.
2. Claim 5 under 35 U.S.C. § 103 as unpatentable over Wang.
3. Claim 9 under 35 U.S.C. § 103 as unpatentable over Wang in view of Ding.

The Examiner contends that Appellants' process steps are the same as Wang's and, therefore, the results obtained by Appellants' process must necessarily be the same as those obtained by Wang. (Answer 6). Appellants contend that the Examiner's anticipation rejection is based on an inaccurate finding that Wang's process inherently provides covalent bonding of a reactive species to a medical device as required in the first step of Appellants' claimed method. Based on the contentions of the Examiner and the Appellants, the issue before us is: Has the Examiner established, by a preponderance of the evidence, that Wang's process necessarily or inherently results in the formation of covalent bonds between the medical device surface and reactive species in Wang?

The following enumerated findings of fact are relevant to our consideration of this issue:

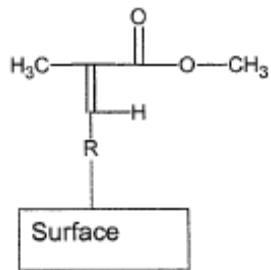
- 1) Wang discloses a method in which a coating is covalently bonded to the substrate, such that the coating has "strong adhesion to the substrate." (P. 20, ll. 20-21).
- 2) According to Wang, preferred substrates include polymethylmethacrylate, silicone polymers, vinyl polymers, and vinyl-monomer-containing copolymers. (P. 13, ll. 3-12).
- 3) According to Wang's method, an initiator-coated substrate is placed in a reaction vessel containing a medium in which one or more monomers are dissolved or dispersed in an appropriate solvent or solvent mixture. (P. 10, ll. 18-21).
- 4) Wang discloses that, as an alternative, a substrate which has optionally been coated with initiator is placed into a

reaction vessel containing the above-noted medium as well as initiator. (P. 10, ll. 16-17).

- 5) Wang further states that, “[o]ptionally, the solution containing the initiator can contain a small amount of polymer which is soluble in the medium to adhere the initiator on the substrate temporarily.” (P. 10, ll. 12-14).
- 6) Wang discloses that suitable initiators include peroxides. (P. 15, ll. 18-19). According to Wang, preferred monomers are vinyl or acrylic monomers. (P. 17, ll. 17-18).
- 7) Wang discloses that “[a]ny residual monomer, homopolymer, initiator, and decomposed fragments of initiator which are present on the substrate can be removed by washing in appropriate solvents at elevated temperature.” (P. 12, ll. 17-21).
- 8) The medical device surface used in the method of the invention can be formed from a material that provides chemically reactive groups, can be treated with a reagent that places chemically reactive groups on the surface, or can be coated with a material that supplies such groups. Spec. [0026].
- 9) “Where a free radical species is used, it can be provided, for example, by a process comprising (a) covalently attaching a free-radical initiator molecule to the surface or (b) covalently attaching a species that acquires a free-radical upon exposure to a free radical initiator molecule.” Spec. [0010].
- 10) In one embodiment, “a substrate surface is provided, which contains free hydroxyl groups. Subsequently a molecule

including a vinyl group is covalently bonded to the surface. For example, vinyltrimethoxysilane can be reacted with the –OH groups on the surface, leaving a vinyl group attached to the surface for subsequent polymerization (e.g., free-radical polymerization) with a number of monomeric species.” Spec. [0033].

- 11) In one embodiment, “a methyl methacrylate derivative is covalently attached to the medical device surface



as shown, where  $\text{R}$  is an organic radical, typically a hydrocarbon chain. A free radical initiator such as a peroxide compound is added, generating a free radical species within the attached molecule. Subsequently, methyl methacrylate monomer is added to commence chain growth polymerization, which proceeds from the attached molecule. The result is a medical device with a covalently attached polymethylmethacrylate coating.” Spec. [0034].

- 12) “Covalent attachment may be carried out using numerous known reaction chemistries.” Spec. [0026].
- 13) The Specification states that “polymerization proceeds upon contact with a liquid that contains the selected monomer, as well as any other desired components, such as initiators, co-

initiators, catalysts, co-catalysts, electron donors and so forth.”

Spec. [0051].

- 14) According to the Specification, the monomer containing liquid typically includes an appropriate solvent system, and can be applied by spraying or rinsing the medical device with the liquid or, more preferably, the medical device can be immersed in the monomer containing liquid. Spec. [0051-0052].
- 15) According to the Specification, suitable free radical initiator compounds include peroxide. Spec. [0032]. Preferred monomers include vinyl monomers and acrylic acid monomers. Spec. [0024].
- 16) “After the polymer coating is formed, the medical device may be washed in an appropriate solvent to remove unreacted monomer (as well as any other residual species, including initiators, co-initiators, catalysts, co-catalysts and so forth).” Spec. [0057].

Based on our consideration of Wang and the facts and reasons relied on by the Examiner in rejecting the claims, we are in agreement with the Examiner’s determination that the claimed and prior art methods for preparing coated medical devices appear to be identical (Ans. 4). *Compare* Findings of Fact 1-6 *with* Findings of Fact 8, 9 and 13-15. Thus, the burden to prove that Wang’s process does not necessarily or inherently result in the formation of covalent bonds between the medical device surface (i.e., Wang’s substrate) and reactive species in Wang was properly shifted to Appellants. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (“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.”). We have thoroughly considered Appellants’ arguments, but do not find them persuasive for the reasons discussed below.

Appellants argue that Wang does not disclose “anything remotely similar to appellants’ step (a), ‘covalently bonding’ a reactive species.” (Br. 4). More specifically, Appellants maintain that the first step of Wang’s process is the formation of free radical sites *directly* on the surface of a medical device. (Br. 4). Appellants explain that where, for example, a peroxide initiator is used, the peroxide does not covalently bond to Wang’s substrate, but merely creates a free radical on the substrate at the reactive site. (Reply Br. 4).

Contrary to Appellants’ contention, Wang’s disclosure is not limited to processes in which free radical sites are formed *directly on* the surface of a medical device (Br. 4). Rather, Wang merely states that this is a preferred mechanism. *See, e.g.*, Wang, p. 14, ll. 13-16 (“Although not wishing to be bound by theory, it is believed that, as a result of differences in hydrophilicity in the system, initiator radicals or organic propagating radicals are directed to and attack the substrate, rather than the monomers in the medium.”). Thus, Appellants’ reliance on Wang’s statement that “[a]ppropriate initiators will preferably orient free radicals to attack the substrate surface and create the [reactive] radical sites on the substrate necessary to initiate graft polymerization” (Reply Br. 4 (*quoting* Wang, p. 9, ll. 11-13)) does not constitute the type of persuasive argument or evidence necessary to establish that formation of covalent bonds between the medical

device surface and reactive species is not a necessary or inherent result in Wang's process. *Cf. In re Bozek*, 416 F.2d 1385, 1390 (CCPA 1969) (a reference disclosure must be evaluated for all that it fairly teaches and not only for what is indicated as preferred).

We also see no basis for Appellants' assertion that the article found in the Evidence Appendix to Appellants' Brief (*Free Radicals*, World of Chemistry 1-3) demonstrates that the bonds formed between Wang's substrate and reactive species are not covalent (*see* Br. 5-6). *See C.R. Bard, Inc. v. Advanced Cardiovascular Sys.*, 911 F.2d 670, 674 n.2 (Fed. Cir. 1990) (attorney arguments are not evidence). Rather, Appellants should explain why one of the numerous known reaction chemistries resulting in covalent attachment (*see* Finding of Fact 12) does not necessarily or inherently occur in Wang's process. For example, Appellants have not articulated a reason why the formation of a covalently bonded reactive species to the substrate surface would not be an expected result of Wang's method of placing an initiator-coated substrate in a reaction vessel containing vinyl or acrylic acid monomers and optionally an initiator, or of temporarily adhering an initiator on the substrate with a polymer. *Compare* Findings of Fact 2-6 *with* Findings of Fact 10 and 11.

We are likewise unpersuaded by Appellants' reliance on Wang's removal of residual initiator and monomer by washing as evidence that the attachment of initiator, initiator fragments, and residual monomers to the substrate can only be by forces weaker than covalent bonds. (Br. 5). As pointed out by the Examiner (Ans. 6), Appellants disclose the use of a similar washing step. Appellants argue that it is clear from the Specification that their washing step only removes unreacted materials, i.e., those which

are not covalently bonded. (Reply Br. 4). Appellants' argument is not, however, supported by the Specification which, like Wang, refers to removal of *residual* species. *Compare* Finding of Fact 7 with Finding of Fact 16.

Accordingly, we find that the preponderance of the evidence weighs in favor of the Examiner's conclusion that claims 1, 2, 4, 7, and 10-11 are anticipated by Wang.

Appellants fail to raise any additional substantive arguments in response to the rejection of claim 5 under 35 U.S.C. § 103 as unpatentable over Wang. (*See* Br. 6-7). Accordingly, we likewise find that the preponderance of the evidence weighs in favor of the Examiner's conclusion that claim 5 is obvious in view of Wang.

With respect to the rejection of claim 9 under 35 U.S.C. § 103 as unpatentable over Wang in view of Ding, Appellants add the additional argument that Ding differs from both the process of Wang and Appellants' claimed invention by simply coating a device with a mixture of monomers and initiator. (Br. 7). Appellants do not, however, address the Examiner's reliance on Ding for a disclosure of using ethylene vinyl acetate in forming a polymeric coating on a stent and concomitant reasons for concluding that claim 9 is obvious in view of the combined teachings of Wang and Ding. Having determined that the Examiner properly established a *prima facie* showing of obviousness, we are not persuaded by Appellants' arguments which relate to Ding's disclosure, rather than the combined teachings of Wang and Ding.

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ORDER

The decision of the Examiner rejecting claims 1, 2, 4, 7, and 10-11 under 35 U.S.C. § 102(b) as anticipated by Wang is affirmed.

The decision of the Examiner rejecting claim 5 under 35 U.S.C. § 103 as unpatentable over Wang is affirmed.

The decision of the Examiner rejecting claim 9 under 35 U.S.C. § 103 as unpatentable over Wang in view of Ding is affirmed.

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

AFFIRMED

tf/ls

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