

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 FALOTICO, GREGORY A. KOPIA,  
GEORGE LANDAU, GERARD H. LLANOS,  
PALLASSANA V. NARAYANAN, and  
GEORGE PAPANDREOU

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Appeal 2007-3503  
Application 09/850,482  
Technology Center 3700

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DECIDED: January 25, 2008

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Before TONI R. SCHEINER, DONALD E. ADAMS, and NANCY J. LINCK,  
*Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge.*

**DECISION ON APPEAL**

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 1-3, 5-9, and 11-15, all the claims remaining, as obvious over the prior art.<sup>1</sup> We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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<sup>1</sup> Two provisional obviousness-type double patenting rejections, reiterated on pages 10 and 11 of the Examiner's Answer, are no longer applicable - in

## BACKGROUND

“The present invention relates to the administration of drug combinations for the prevention and treatment of vascular disease, and more particularly to an intraluminal medical device for the local delivery of drug combinations for the prevention and treatment of vascular disease” (Spec. 1: 15-18).

## STATEMENT OF THE CASE

Claims 1, 2, 5-8, and 11-15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ragheb<sup>2</sup> and Chudzik.<sup>3</sup>

Claims 3 and 9 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Ragheb, Chudzik, and Morris.<sup>4</sup>

Appellants do not present separate arguments for the patentability of the claims with respect to either rejection. Therefore, we select claims 1 and 3 as representative of the claimed subject matter for the purpose of deciding this appeal. 37 C.F.R. § 41.37(c)(1)(vii). Claims 2, 5-8, and 11-15 will stand or fall with claim 1, while claim 9 will stand or fall with claim 3.

Claims 1, 2, and 3 read as follows:

1. An intraluminal medical device comprising:
  - a stent having a substantially tubular body, the tubular body having an inner surface and an outer surface;
  - a layer of one or more anti-proliferative compounds incorporated in a polymeric matter and affixed to the outer surface of the tubular body; and

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one case, because the rejected claims have been canceled, in the other, because the named application has been abandoned.

<sup>2</sup> U.S. Patent 6,299,604 B1 to Ragheb et al., issued October 9, 2001.

<sup>3</sup> U.S. Patent 6,214,901 B1 to Chudzik et al., issued April 10, 2001.

<sup>4</sup> U.S. Patent 5,516,781 to Morris et al., issued May 14, 1996.

a layer of one or more anti-coagulant compounds affixed to the inner surface of the tubular body.

2. The intraluminal medical device according to Claim 1, wherein the substantially tubular body comprises a plurality of interconnected bands, each band having an inner surface and an outer surface.

3. The intraluminal medical device according to Claim 2, wherein the layer of one or more anti-proliferative compounds comprises rapamycin.

#### FINDINGS OF FACT<sup>5</sup>

##### *Ragheb*

1. Ragheb describes a “vascular stent or other implantable medical device that provides a controlled release of an agent, drug or bioactive material in the vascular . . . system” (Ragheb, col. 3, ll. 7-11).

2. “[O]ne or more different bioactive materials or drugs may be delivered . . . to the blood stream from the lumen surface of the stent, and a different treatment may be delivered on the vessel surface of the stent” (Ragheb, col. 8, ll. 2-5).

3. Thrombolytics and antithrombogenics “are especially useful bioactive materials when the structure is a vascular stent” (Ragheb, col. 8, ll. 13-17). Particularly preferred antithrombogenics include heparin (Ragheb, col. 8, ll. 19-20 (reference number omitted)).

4. “[B]ioactive materials having other functions can also be successfully delivered by the device . . . For example, an antiproliferative agent . . . will

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<sup>5</sup> Abbreviated “FF”.

inhibit over-proliferation of smooth muscle cells and thus inhibit restenosis of the dilated segment of the blood vessel” (Ragheb, col. 8, ll. 37-42).

5. Ragheb’s device “also comprises at least one porous layer posited over the layer of bioactive material” (Ragheb, col. 10, ll. 35-36 (reference numbers omitted)).

6. “[T]he porous layer is composed of a polymer deposited on the bioactive material layer” (Ragheb, col. 10, ll. 42-43 (reference number omitted)). “[P]referably, the polymer in the porous layer is polyimide, parylene or a parylene derivative” (Ragheb, col. 10, ll. 54-55 (reference number omitted)).

7. “The purpose of the porous layer is to provide a controlled release of the bioactive material when the device is positioned in the vascular system of a patient. The thickness of the porous layer is chosen so as to provide such control” (Ragheb, col. 10, 38-42 (reference numbers omitted)).

8. According to Ragheb, “precise control over the deposition of the parylene . . . permits close control over the release rate of material from the at least one layer of bioactive material. It is for this reason that the bioactive material lies under the at least one porous layer rather than being dispersed within or throughout it” (Ragheb, col. 10, ll. 62-67 (reference numbers omitted)).

9. “The porous layer . . . also protects the bioactive material layer during deployment of the device, for example, during insertion of the device through a catheter and into the vascular system . . . [of] the patient” (Ragheb, col. 10, l. 67 to col. 11, l. 4 (reference numbers omitted)).

*Chudzik*

10. Chudzik teaches that there are several requirements for implantable devices capable of releasing bioactive agents, including “1) the requirement . . . for long term release of bioactive agents; 2) the need for a biocompatible, non-inflammatory device surface; 3) the need for significant durability, particularly with devices that undergo flexion and/or expansion when being implanted or used in the body; [and] 4) . . . [the need for a device that can] be manufactured in an economically viable and reproducible manner” (Chudzik, col. 1, ll. 49-62).

11. According to Chudzik, of the various polymers “previously . . . described for use as drug release coatings, . . . only a small number possess the physical characteristics that would render them useful for implantable medical devices . . . . Many polymers which demonstrate good drug release characteristics, when used alone as drug delivery vehicles, provide coatings that are too brittle to be used on devices which undergo flexion and/or expansion” (Chudzik, col. 2, ll. 22-31). “Some polymers show good durability and flexibility characteristics when applied to devices without drug, but lose these favorable characteristics when drug is added . . . often times the higher the concentration of drugs or the thicker the application of polymer to the device surface, the poorer the physical characteristics of the polymer become” (Chudzik, col. 2, ll. 36-42).

12. Chudzik solves these problems by combining the bioactive agent with a mixture of particular polymeric components “that exhibits an optimal combination of physical characteristics (e.g., adherence, durability, flexibility) and bioactive release characteristics as compared to the polymers

when used alone or in admixture with other polymers previously known” (Chudzik, col. 3, ll. 5-9).

13. Chudzik’s polymeric components preferably comprise “at least one poly(alkyl)(meth)acrylate . . . and poly(ethylene-co-vinyl acetate)(“pEVA”)” (Chudzik, col. 3, ll. 10-12).

14. The bioactive agent, mixed with the polymeric components to form a coating composition, can be “used to coat stents, e.g., either self-expanding stents . . . or balloon-expandable stents” (Chudzik, col. 5, ll. 45-47).

15. “Coatings . . . which contain a mixture of both polymers, are very durable, with no signs of wear in the Durability Test and no cracking in the Flexibility Test. Drug release from these coatings can be manipulated by varying the relative concentrations of the polymers. For instance, the rate of drug release can be controllably increased by increasing the relative concentration of pEVA” (Chudzik, col. 8, ll. 39-45).

16. “This obviates the need to control the bioactive release rate by polymer selection, multiple coats, or layering of coats, and thus greatly simplifies the manufacture of bioactive-releasing implantable medical devices” (Chudzik, col. 3, ll. 25-29).

17. Bioactive agents suitable for incorporating into the polymeric coatings on Chudzik’s implantable devices include antithrombogenic agents, like heparin, as well as antiproliferative agents (Chudzik, col. 5, ll. 8-19).

*Morris*

18. Morris teaches that hyperproliferative vascular disease in a mammal can be prevented or treated “by administering an antiproliferative effective

amount of rapamycin to said mammal . . . via a vascular stent impregnated with rapamycin” (Morris, col. 3, ll. 45-50).

## DISCUSSION

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007).

### *Claims 1, 2, 5-8, and 11-15*

The Examiner contends that it would have been “obvious to one with ordinary skill in the art to have . . . [Ragheb’s] bioactive agent(s) dispersed in [Chudzik’s] polymeric matter/matrix rather than as two separate layers for the purpose of reducing the amount of layers while still permitting controlled release of the agent, both amount and rate of release . . . and provid[ing] superior results when used on flexible stents” (Answer 6).

Appellants contend that Ragheb “does not provide any teaching, suggestion, or motivation to reduce the amount of layers” coating the stent

(Br. 4), and in fact, “expressly teaches away from the present invention with material respect to the amount of layers” (Br. 5).

The principal issue raised by this appeal with respect to claim 1, then, is whether it would have been obvious at the time of the invention to coat an implantable stent with an anti-proliferative compound incorporated in a polymer, given the scope and content of the prior art, the level of ordinary skill in the art, and the differences between the claimed invention and the prior art. A related issue with respect to claim 3 is whether it would have been obvious to use rapamycin as the anti-proliferative compound.

With respect to claim 1, Appellants argue that “two goals motivate Ragheb: rate control and bioactive material protection; and these goals are expressly achieved using the two-layer system” (Br. 5). Appellants point to Ragheb’s teaching that “[t]he purpose of the porous layer is to provide controlled release of the bioactive material when the device is positioned in the vascular system of a patient” (Ragheb, col. 10, ll. 37-40 (reference numbers omitted)), and also to “protect[ ] the bioactive material layer during deployment of the device” (*id.* at col. 11, ll. 1-2). Appellants emphasize that Ragheb teaches that “[c]areful and precise control over the deposition of the . . . [porous layer] permits close control over the release rate of material from the at least one layer of bioactive material. It is for this reason that the bioactive material lies under the at least one porous layer rather than being dispersed within or throughout it” (Ragheb, col. 10, ll. 61-67 (reference numbers omitted)).

Nevertheless, we agree with the Examiner that the invention of claim 1 would have been obvious over the combined teachings of Ragheb and

Chudzik. It is true that Ragheb emphasizes the importance of “rate control and bioactive material protection,” but so does Chudzik (FF 10, 11, 14). Moreover, Chudzik expressly teaches an alternative means for achieving these same goals: incorporating bioactive materials, including anti-proliferatives and anti-thrombogenics (FF 17), into a mixture of polymeric components comprising “at least one poly(alkyl)(meth)acrylate . . . and poly(ethylene-co-vinyl acetate)” (*id.* at col. 3, ll. 10-12; FF 12, 13), before applying them to the implantable device. According to Chudzik, this combination of polymeric components “exhibits an optimal combination of physical characteristics (e.g., adherence, durability, flexibility) and bioactive release characteristics” (Chudzik, col. 3, ll. 4-9; FF 12). In addition, Chudzik notes that incorporating the bioactive material in the polymeric coating “obviates the need to control the bioactive release rate by polymer selection, multiple coats, or layering of coats, and thus greatly simplifies the manufacture of bioactive-releasing implantable medical devices” (Chudzik, col. 3, ll. 19-29; FF 16).

We agree with the Examiner that one skilled in the art would have recognized Ragheb’s and Chudzik’s approaches as alternative, predictable solutions to the same problems, and it would have been obvious to substitute Chudzak’s approach for Ragheb’s. That is, it would have been obvious for one skilled in the art to coat a stent with an anti-proliferative compound incorporated in a polymer, in order to provide control over the release rate of the anti-proliferative compound, and to protect the anti-proliferative compound from degradation. Again, “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this

leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *KSR*, 127 S. Ct. at 1742.

“Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR*, 127 S. Ct. at 1734.

We find that the Examiner has established a *prima facie* case that the invention of claim 1 would have been obvious over the prior art, which Appellants have not overcome by argument or evidence. As discussed above, claims 2, 5-8, and 11-15 fall with claim 1. Accordingly, the Examiner’s rejection of claims 1, 2, 5-8, and 11-15 under 35 U.S.C. § 103(a) as unpatentable over Ragheb and Chudzik is affirmed.

### *Claims 3 and 9*

Neither Ragheb nor Chudzik discloses a stent coated with the anti-proliferative compound rapamycin. The Examiner cites Morris as evidence that vascular stents coated with rapamycin were conventional in the art at the time of the invention (Morris, col. 3, ll. 45-50; FF 18), and that it would have been obvious “to include rapamycin for the purpose of its superior qualities as an antiproliferative as taught by Morris” (Final Rejection<sup>6</sup> 5).

Appellants argue that “Ragheb and Chudzik cannot be combined for the reasons given above” (Br. 8), thus, “the combination of Ragheb and Morris or the combination of Chudzik and Morris must teach or suggest all the claim limitations to establish a *prima facie* case of obviousness” (*id.*).

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<sup>6</sup> Final Rejection mailed February 2, 2003.

This argument is not persuasive. As discussed above, we agree with the Examiner that the invention of claim 1 would have been obvious over the combined teachings of Ragheb and Chudzik (*supra* at pp. 9-11). Moreover, we agree with the Examiner that it would have been obvious for one skilled in the art to coat a vascular stent with rapamycin, as required by claim 3, for the reason given by the Examiner. As discussed above, claim 9 falls with claim 3.

Accordingly, the rejection of claims 3 and 9 under 35 U.S.C. § 103(a) as unpatentable over Ragheb, Chudzik, and Morris is affirmed.

#### SUMMARY

We affirm the both rejections of the claims under 35 U.S.C. § 103(a). 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

Ssc:

PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003