

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RAM H. PAUL,
DANIEL J. SIROTA, and
PAUL D. AMARANT

Appeal No. 2006-2037
Application No. 10/414,939

ON BRIEF

Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, 6-11, 15-18, and 20-24. The examiner objected to claims 12, 13, and 14, the only remaining pending claims, "as being dependent upon a rejected base claim," however, the examiner has indicated that these claims would be "allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Brief, page 2.

Accordingly, claims 1-4, 6-11, 15-18, and 20-24 are before us on appeal.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A medical device for at least partial implantation, comprising:
 - a main body having a first end, a second end, and a lumen extending therebetween,
 - a first section proximal the first end of said main body and having a first therapeutic agent, said first therapeutic agent comprising one or more members selected from the group consisting of antiproliferatives, anticoagulants, antithrombotics, thrombolytics, and fibrinolytics; and
 - a second section proximal the second end of said main body and having a second therapeutic agent, said second therapeutic agent comprising an antimicrobial;
 - said main body having a length such that when said device is at least partially implanted said first end accesses a body vessel and at least a portion of said second section is disposed within a subcutaneous space of a patient.

The references relied upon by the examiner are:

| | | |
|--------------------------|-----------|-----------------------------|
| Ragheb et al. (Ragheb) | 6,299,604 | Oct. 9, 2001 |
| Pacetti et al. (Pacetti) | 6,663,662 | Dec. 16, 2003 |
| | | (102(e) date Dec. 28, 2000) |

GROUNDS OF REJECTION

Claims 1, 2, 15, 18, and 20-24 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ragheb.

Claims 1, 3, 4, 6, 7, 10, 11, 15, 16, and 20-24¹ stand rejected under 35 U.S.C. § 102(e) as anticipated by Pacetti.

Claims 8, 9, and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Pacetti.

We reverse.

¹ The examiner included claim 5 in this rejection. However, as appellants emphasize (Reply Brief, page 2), claim 5 was previously cancelled.

DISCUSSION

Claim Construction:

For clarity, we refer to figures 1 and 12, reproduced below, to assist in our construction of appellants' claimed invention.

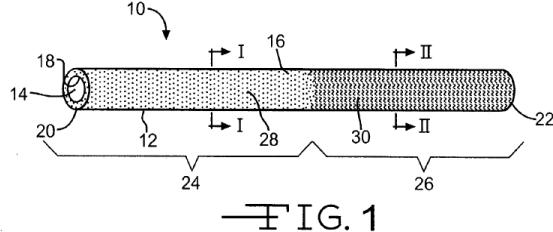


FIG. 1

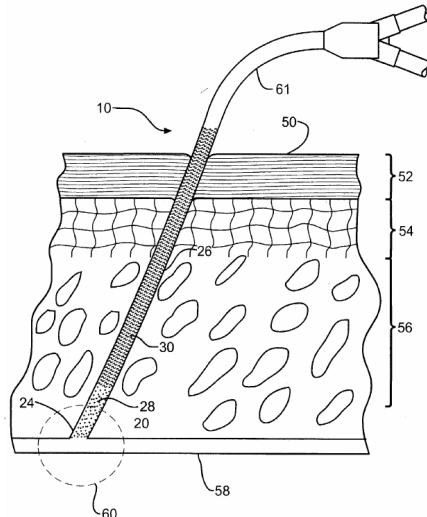


FIG. 11

Claim 1 is drawn to a medical device. The device comprises three parts:

1. a main body **12**;
2. a first section **24**; and
3. a second section **26**.

The main body has three parts:

1. a first end **20**;
2. a second end **22**; and
3. a lumen **14** extending between the first and second ends.

The main body **12** has a length such that when the device is at least partially implanted the first end **20** accesses a body vessel **58** and at least a portion of the second section **26** is disposed within a subcutaneous space **56** of a patient.

The first section **24** is proximal to the first end **20** of the main body **12** and has a first therapeutic agent **28**. The first therapeutic agent **28** comprises one or more members selected from the group consisting of antiproliferatives, anticoagulants, antithrombotics, thrombolytics, and fibrinolytics.

The second section **26** is proximal the second end **22** of the main body **12** and has a second therapeutic agent **30**. The second therapeutic agent **30** comprises an antimicrobial.

Anticipation:

Ragheb:

Claims 1, 2, 15, 18, and 20-24 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ragheb. The examiner directs attention to the Final Rejection, mailed March 31, 2005, for a statement of the rejection. Given its brevity, we reproduce the statement of the rejection in its entirety below:

Ragheb discloses a medical device comprising: a main body having a first end, a second end, and a length extending from the first end to the second end (12); a first section along the length having a first therapeutic agent (figs. 1-5); a second section along the length having a second therapeutic agent (figs. 1-5); as to claim 2, (col. 6); as to claim 15, (see claim 2); as to claims 18 and 20-24, (figs. 1-5).

Final Rejection, page 3.

Ragheb is directed to a medical device with drugs or bioactive agents incorporated onto it. Ragheb, column 1, lines 10-12. Ragheb discloses that it has become common practice to “treat a variety of medical conditions by introducing an implantable medical device partly or completely into” the patient,

e.g., the patient's vascular system. Ragheb, column 1, lines 15-19. Ragheb discloses, "[h]owever, when such a device is introduced into and manipulated through the vascular system, the blood vessel walls can be disturbed or injured." Ragheb, column 1, lines 22-24. Ragheb discloses that the problems associated with the introduction and manipulation of a medical device in a patient can be solved by providing the controlled release of an agent, drug or bioactive material into the location in the body where the device is positioned. Ragheb, column 3, lines 6-11. In this regard, Ragheb

discovered that the degradation of the agent, a drug or a bioactive material that is applied to such a device can be avoided by positing a coating layer on one surface of the device structure. The agent, drug or bioactive material is posited over at least a portion of the coating layer, wherein the coating layer provides for a controlled release of the bioactive material posited thereon.

Ragheb, column 3, lines 11-18.

For clarity, we reproduce Ragheb's figure 1, which is a cross-sectional view of one of Ragheb's preferred embodiments²:

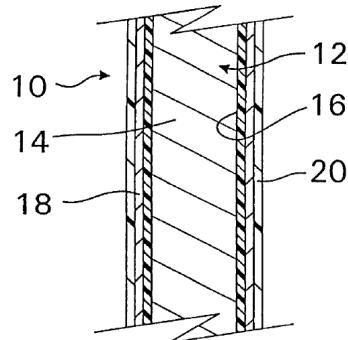


Fig.1

Accordingly, Ragheb discloses a device **10**, which comprises a structure **12** that is shaped and sized for introduction into a patient. Ragheb, column 6,

² Ragheb, column 6, lines 3-4, "Fig. 1 is a cross-sectional view of a first preferred embodiment of the present invention."

lines 35-39. The structure **12** is composed of a base material **14** suitable for the intended use of the structure **12**. Ragheb, column 7, lines 15-16. At least one layer **18** of a bioactive material is posited on one surface of the structure **12**. Ragheb, column 7, lines 62-65. According to Ragheb, the other surface of the structure **12** “will either contain no bioactive material or one or more different bioactive materials.” Ragheb, column 7, line 65 – column 8, line 1. Ragheb discloses that this configuration allows for the delivery of one or more bioactive materials or drugs to the blood stream from the lumen surface of the stent, while a different treatment is delivered on the vessel surface of the stent. Ragheb, column 8, lines 1-5. In addition, Ragheb discloses that the device **10** “also comprises at least one porous layer **20** posited over the layer **18** of bioactive material and the bioactive-material-free surface.” Ragheb, column 10, lines 34-37. According to Ragheb, “[t]he purpose of the porous layer **20** is to provide a controlled release of the bioactive material when the device **10** is positioned in the vascular system of a patient.” Ragheb, column 10, lines 37-41. Ragheb discloses that the device **10** “can further comprise at least one additional coating layer **16** posited between the structure **12** and the at least one layer **18** of bioactive material.” Ragheb, column 11, lines 5-8.

Therefore, Ragheb discloses a device **10** (for simplicity, a tube³) that has a particular structure **12**. As illustrated in Figure 1, a cross-sectional view of the

³ According to the examiner, many of Ragheb’s “devices are nothing more than mere tubes.” Answer, page 6.

tube's composition reveals that it is composed of several layers, which from the inside (lumen surface) to the outside (vessel surface) are:

1. a porous layer **20**;
2. a first bioactive layer **18**, or no bioactive layer **18** if a first bioactive layer **18** is present on the other surface of the device;
3. an optional coating layer **16**;
4. a base material **14**;
5. an optional coating layer **16**;
6. a first bioactive layer **18**, or no bioactive layer **18** if a first bioactive layer **18** is present on the other surface of the device;
7. a porous layer **20**.

There is no doubt that Ragheb's device can read on a tube. Cf. Answer, page 6. It is true that a tube generally has "a main body having a first end, a second end and a length extending from the first end to the second end. . ." Id. It is also true that a tube is generally regarded as having a lumen extending between the first and second ends. Cf. Answer, page 7.

However, we disagree with the examiner's assertion that Ragheb discloses "a first section that is disposed 'proximal to the first end of the main body' . . ." as required by appellants' claimed invention. Id. We also disagree with the examiner's assertion that Ragheb discloses a second section "disposed 'proximal the second end of the main body . . .'" as required by appellants' claimed invention. To the contrary, Ragheb, at best, discloses two sections on either side (e.g., lumen surface and vessel surface) of the tube's base material **14**.

As the examiner recognizes the first bioactive layer **18** extends from the distal (e.g., first) end to the proximal (e.g., second) end of the tube. Answer, page 8. Contrary to the examiner's assertion, this is not what appellants' have claimed. Cf. Answer, page 9. As discussed above, appellants' device comprises three parts, which define separate sections located at different ends of the device.⁴ In contrast, as the examiner recognizes Ragheb's device defines separate sections in terms of layers positioned on either side of the device's base material, which may run the full length of device. Therefore, it is our opinion that Ragheb describes a different device than that set forth in appellants' claims.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). As discussed above, Ragheb does not describe appellants' invention. Accordingly, we reverse the rejection of claims 1, 2, 15, 18, and 20-24 under 35 U.S.C. § 102(b) as anticipated by Ragheb.

Pacetti:

Claims 1, 3-7, 10, 11, 15, 16, and 20-24 stand rejected under 35 U.S.C. § 102(e) as anticipated by Pacetti. The examiner directs attention to the Final Rejection, mailed March 31, 2005, for a statement of the rejection.

⁴ See e.g., Brief, page 11. While the examiner asserts (Answer, page 8) that this spatial relationship is not required for appellants' claim 1, the examiner has not explained how the claim can be constructed to avoid this spatial relationship of different sections at different ends of the device. Accordingly, we are not persuaded by the examiner's assertion.

According to the examiner “Pacetti discloses a medical device comprising: a main body having a first end, a second end, and lumen extending there[]between . . . ; a first section proximal the first end of said main body and a second section having proximal the second end of said main body. . . .” Final Rejection, page 2. The examiner finds that Pacetti teaches that the first section has a “first therapeutic agent comprising one or more members selected from the group consisting of antiproliferatives . . . , anticoagulants, antithrombotics, thrombolytics, and fibrinolytics. . . .” Id. In addition, the examiner finds that Pacetti teaches that the second section has a “second therapeutic agent comprising an antimicrobial. . . .” Id. According to the examiner, Pacetti’s device is fully capable of being positioned in the manner required by appellants’ claimed invention.

Pacetti is directed to “a coating disposed on an implantable device, . . . [e.g.,] a stent, for inhibiting the release rate of an active ingredient carried by the device.” Pacetti, column 1, lines 7-12. For clarity, we reproduce Figure 2A⁵.

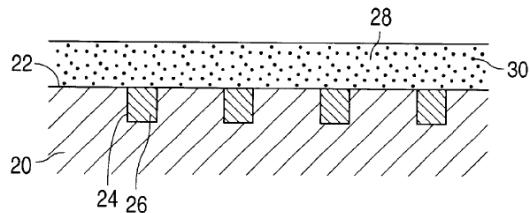


FIG. 2A

Pacetti discloses a stent **20** having a surface **22**. Pacetti, column 18, lines 2-3. Pacetti’s “[s]tent **20** includes cavities or micro-pores **24** formed in the body for releasably containing an active ingredient **26**” Pacetti, column 18,

⁵ Figure 2A illustrates a diffusion barrier layer deposited over a stent in accordance with one embodiment of Pacetti’s invention. Pacetti, column 4, lines 12-14.

lines 3-5. In addition, “[a] diffusion barrier layer **28** is disposed on surface **22** of stent **20** covering cavities **2428** contains particles **30** for reducing the rate of release of active ingredient **26**.⁶

In response appellants assert that “Pacetti does not teach or suggest the very specific and sequential arrangement of agents as specified in claim 1.” Brief, page 7. We agree. As discussed above, appellants’ device comprises three parts, which define separate sections located at different ends of the device.⁶ Contrary to the examiner’s assertion⁷ (Answer, page 4), we find no teaching in Pacetti that describes a device with the arrangement of parts set forth in appellants’ claimed invention. While we agree with the examiner in that the devices described by appellants and Pacetti can be tubes, we find no evidence in Pacetti and the examiner failed to identify any specific teaching in Pacetti that describes a device that is the same as those required by appellants’ claimed invention.

“Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim.” Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). As discussed above, Ragheb does not describe appellants’ invention. Accordingly, we reverse

⁶ We disagree with the examiner that “there is nothing in applicant’s claim 1 that teaches or suggests a very specific and sequential arrangement of agents.” Answer, page 3. The examiner has not explained how the claim can be constructed to avoid the defined spatial relationship of different sections at different ends of the device as set forth in appellants’ claimed invention. Accordingly, we are not persuaded by the examiner’s assertion.

⁷ According to the examiner (Answer, page 4), appellants’ device and Pacetti’s device appear to be identical in structure.

the rejection of claims 1, 3-7, 10, 11, 15, 16, and 20-24 under 35 U.S.C. § 102(e) as anticipated by Pacetti.

Obviousness:

Claims 8, 9, and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Pacetti. The examiner directs attention to the Final Rejection, mailed March 31, 2005, for a statement of the rejection. The examiner offers nothing more than an assertion that the discussion of Pacetti set forth in the rejection under 35 U.S.C. § 102(e) leads to a finding that claims 8, 9 and 18 would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made. Final Rejection, pages 11-12. We disagree for the reasons set forth above.

Accordingly, we reverse the rejection of claims 8, 9 and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Pacetti.

REVERSED

)
Donald E. Adams)
Administrative Patent Judge)
)
) BOARD OF PATENT
)
Demetra J. Mills) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
)
)
Lora M. Green)
Administrative Patent Judge)

Joseph N. Breaux
Suite A
10630 N. Oak Hills Pkwy.
Baton Rouge, LA 70810

DEA/jlb