The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte
MATTHEW M. GRAF, DAVID A. DREWES, JR., and SCOTT E. EELS

Appeal 2007-2018
Application 09/810,377
Technology Center 3700

Decided July 18, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a catheter introducer sheath. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

According to the Specification:

> An introducer sheath is utilized in the percutaneous placement of a guide wire or catheter into a blood vessel, and comprises a

> flexible tube that itself is introduced into the blood vessel over a dilator. Once in position, the dilator is removed from within the sheath and withdrawn from the patient, and the guide wire or catheter is inserted through the sheath into the patient.

(Specification 1.) The Specification describes an "introducer sheath that includes a short distal tip section that is substantially more radiopaque than the radiopaque material of the remainder of the polymeric sheath shaft" (*id.* at 3). The distal tip may be made "of fluorinated ethylene propylene (FEP) containing a filler of tungsten or similar metal particles between about 20 to 75% by weight, while the sheath shaft is also of FEP with a substantially lower radiopaque filler content" (*id.*).

DISCUSSION

1. CLAIMS

Claims 1, 2, 4-6, 13, 14, and 17-23 are pending and on appeal. Appellants argue the claims in the following groups: claims 1 and 13; claims 2 and 4; claims 5 and 6; claim 14; claims 17-19, 22, and 23; and claims 20 and 21. (Br. 4-11.) The claims within each of these groups stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claims 1, 2, 5, 14, 17, and 20, which are representative and read as follows:

> 1. An introducer sheath comprising:
>
> a shaft extending from a proximal end portion to a distal end portion; and
>
> a distal tip section at said distal end portion of said shaft;
>
> said shaft and said distal tip section comprising fluorinated ethylene propylene and being joined by a thermal bond, said distal tip section containing between about 20% and 75% by weight of a radiopaque material selected from the

group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and

said shaft being distinctly less radiopaque than said distal tip section.

2. The introducer sheath according to claim 1, wherein said distal tip section contains between about 50% to 55% by weight of radiopaque material.

5. The introducer sheath according to claim [2, wherein said radiopaque material is tungsten], wherein said tungsten particles range in size from about 0.5 microns to about 25 microns.

14. An introducer sheath comprising:

a shaft extending from a proximal end to a distal end; and

a distal tip section at said distal end of said shaft,

said shaft and said distal tip section comprising fluorinated ethylene propylene, said distal tip section containing radiopaque particles, said shaft being distinctly less radiopaque than said distal tip section,

said distal tip section contains between about 50% and 55% by weight of tungsten particles that range in size from about 1.4 microns to about 1.8 microns.

17. An introducer sheath comprising:

a shaft having a proximal end portion and a distal end portion; and

a distal tip section bonded to said shaft at said shaft distal end portion, said distal tip section consisting essentially of fluorinated ethylene propylene containing between about 20% and 75% by weight of a radiopaque material, wherein said distal tip section is distinctly more radiopaque than said shaft section.

> 20. The introducer sheath of claim [17, wherein the shaft comprises fluorinated ethylene propylene, wherein said distal tip section radiopaque material is selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and] wherein said distal tip section contains between about 50 and 55% by weight of said radiopaque material.

2. REFERENCES

The Examiner relies on the following references:

Coneys	US 4,657,024	Apr. 14, 1987
Parker	US 5,221,270	Jun. 22, 1993
Hopkins	US 5,948,489	Sep. 7, 1999

3. OBVIOUSNESS

Claims 1, 2, 4, 13, and 17-23 stand rejected under 35 U.S.C. § 103 as obvious over Parker in view of Coneys. The Examiner relies on Parker for disclosing a sheath comprising a shaft and a distal tip, "the distal tip section comprising polymeric material 34 containing 35-65% of a radiopaque material such as tungsten, where the shaft is less radiopaque than the distal tip section, the polymeric material can be polyamide, and the tip member was originally a separate member" (Answer 3). The Examiner relies on Coneys for disclosing "that it is known in the art that fluorinated ethylene propylene [(FEP)] can be used as sleeves in catheters when used in combination with radiopaque materials of varying amounts" (*id.*). In particular, the Examiner argues that "Coneys clearly sets forth that FEP can be loaded up to 70-80% with radiopaque material" (*id.* at 7). The Examiner concludes that it would have been obvious "to modify the polymeric material in Parker to be made of . . . [FEP] as suggested by Coneys" because

FEP "is a known equivalent plastic that is used with catheters provided with varying amounts of radiopaque materials" and "is a material having more lubricious properties which would allow for easier insertion" (*id.* at 3).

We conclude that the Examiner has set forth a prima facie case of obviousness. Parker describes a "guiding catheter having a main tubular portion and a soft tip" with "matching external and internal tapers for increasing the contact area of the thermal bond" (Parker, col. 1, ll. 55-56, and Abstract). "The main tubular portion includes a layered wall . . . advantageously includ[ing] an inner material layer . . . and an outer material layer" (*id.* at col. 1, ll. 61-67). The inner layer preferably comprises polytetrafluoroethylene and the outer layer "preferably comprises polyether block amide including by weight 10 to 30 percent radiopaque bismuth" (*id.* at col. 2, ll. 24-33). The soft tip "comprises another polyether block amide . . . and advantageously includes by weight 35 to 65 percent tungsten for increasing the radiopacity of the soft tip" (*id.* at col. 2, ll. 34-40).

Coneys describes a catheter including an extruded tube of flexible material comprising a plastic material, preferably polyfluorinated ethylenepropylene, and "an integrally extruded radiopaque layer **14** completely embedded within and surrounded by the plastic material" (Coneys, col. 3, ll. 16-32). "The radiopaque layer **14** comprises a blended mixture of radiopaque material and a binder material," which "may be the same plastic material as the virgin or pure plastic material" that surrounds the radiopaque layer (*id.* at col. 3, ll. 35-45). The radiopaque material may be bismuth trioxide or tungsten powder (*id.* at col. 3, ll. 47-49).

Coneys also discloses that "the blended mixture of the radiopaque material defining the layer **14** may include between twenty percent (20%) and thirty percent (30%) fluorinated ethylenepropylene with the remaining seventy percent (70%) to eighty percent (80%) being one of the radiopaque materials" and that "the radiopaque material preferably comprises between twelve percent (12%) and twenty-five percent (25%) of the total weight of the material making up the tube" (*id.* at col. 3, ll. 50-61). We agree that one of ordinary skill in the art would have been motivated to replace the polyether block amide in both the shaft and distal tip section of Parker's device with the polyfluorinated ethylenepropylene described in Coneys, since both were known to be useful materials for catheters. *Cf. KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1739, 82 USPQ2d 1385, 1395 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Appellants argue that neither Parker nor Coneys "teaches or suggests the use of highly-loaded FEP" (Br. 7). In particular, Appellants argues that, "[a]ccording to Coneys, when highly loaded FEP is used in a medical device, the highly loaded FEP layer must be surrounded by a covering of virgin FEP" (*id.* at 7-8). "As a result, due to the presence of the non-radiopaque envelope surrounding the loaded radiopaque layer, the actual radiopacity of the distal portion of the Coneys tube is limited to a level of between 12 and 25 percent by weight" (*id.* at 8).

We are not persuaded by this argument. Although Coneys discloses a catheter tube containing 12-25% by weight radiopaque material, Coneys does not suggest that more highly loaded FEP cannot be obtained. In fact, Coneys describes a FEP layer containing 70-80% radiopaque material (Coneys, col. 3, ll. 50-55). In addition, the range recited in claim 1 overlaps with the range of 12-25% by weight recited in Coneys. Thus, we agree with the Examiner that Coneys discloses that FEP is capable of being highly loaded with radiopaque material.

Furthermore, Parker discloses a distal tip section containing 35-65% by weight tungsten (Parker, col. 2, ll. 35-39). Based on this teaching and the teaching in Coneys that FEP can be highly loaded with a radiopaque material, such as tungsten, we agree with the Examiner that one of ordinary skill in the art would have been motivated to include FEP and 35-65% by weight tungsten in the distal tip section.

Appellants also argue that "[t]here is no teaching that a discrete FEP radiopaque distal tip section may simply be extruded and bonded onto a proximal section. Rather, the cumbersome steps of enveloping the highly loaded FEP in a layer of pure, virgin FEP were undertaken." (Br. 8).

We are not persuaded by this argument. First, Coneys states that the "blended mixture is extruded simultaneously with the pure composition" (Coneys, col. 3, ll. 56-58). More importantly, claim 1 does not require that the sheath be prepared by a particular method.

In addition, Appellants argue:

> When a primary purpose of the highly loaded FEP layer is to permit precise readings by radiography, the use of the outer layer of virgin FEP runs counter to such purpose (since it is not radiopaque), and detracts from the intended purpose of using a highly loaded layer in the first place. At the very least, it would dilute the strength of a radiographic signal when compared to a signal obtainable with the inventive sheath. Furthermore, there is no reason to believe that the Coneys structure (highly loaded

> FEP layer embedded in virgin FEP) would provide a sheath wherein the shaft is distinctly less radiopaque than the distal tip section.

(Br. 8.)

We are not persuaded by these arguments. First, the Examiner combines Parker with Coneys by replacing the polyether block amide in both the tip and the outer layer of the wall of the main tubular portion with FEP (Answer 8). This combination does not necessarily require that the FEP loaded with radiopaque material be surrounded by pure FEP.

Second, even if the high loading of FEP with radiopaque material would make it necessary to surround this highly loaded layer with pure FEP, claim 1 does not exclude this arrangement. Instead, claim 1 recites a "distal tip section containing between about 20% and 75% by weight of a radiopaque material." This recitation encompasses a distal tip section containing highly loaded FEP surrounded by pure FEP, as long as the distal tip section contains 20-75% by weight radiopaque material. In addition, even if this arrangement would dilute the strength of the radiographic signal as compared to a distal tip section containing the same amount of radiopaque material, but distributed throughout the FEP in the distal tip, which Appellants have not demonstrated to be the case, this argument would not be persuasive because claim 1 does not recite the overall strength of the radiographic signal.

Furthermore, the Examiner has set forth a prima facie case that the combination of Parker with Coneys would provide a shaft that is distinctly less radiopaque than the distal tip. Parker discloses a catheter having a soft tip including 35-65% by weight tungsten and a main tubular portion including an outer layer containing 10-30% by weight radiopaque bismuth (Parker, col. 2, ll. 31-40), which results in a shaft containing less radiopaque material than the distal tip. Even if the radiopaque material was surrounded by pure FEP as described in Coneys, Appellants have not provided any evidence that the difference in the amounts of radiopaque material described in Parker would not provide a shaft that is distinctly less radiopaque than the distal tip.

Appellants also argue that claims 2 and 20 require that the distal tip contain between 50 and 55 weight percent radiopaque material, "which is even further removed from the teachings of Coneys" (Br. 8; see also Br. 10). We are not persuaded by this argument.

Although Coneys does not describe a distal tip section containing between about 50-55% by weight radiopaque material, Coneys does teach that FEP can be loaded with 70-80% radiopaque material. In addition, Parker describes a distal tip containing 35-65% by weight radiopaque material. "[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004). Based on the teachings of the prior art, we conclude that it would have been obvious to include 50-55% by weight radiopaque material in FEP.

With regard to claim 17, Appellants argue that "it cannot be fairly said that Coneys teaches or suggests a distal tip of an introducer sheath that consists essentially of highly loaded FEP, since the composite 'tip' in

Coneys includes the virgin FEP that envelopes a loaded radiopaque section, and obviously affects the radiopacity of the tip." (Br. 9-10.)

We are not persuaded by this argument. First, as discussed above, the Examiner combines Parker with Coneys by replacing the polyether block amide in both the tip and the outer layer of the wall of the main tubular portion with FEP (Answer 8). This combination does not necessarily require that the FEP loaded with radiopaque material be surrounded by pure FEP.

Second, even if the high loading of FEP with radiopaque material would make it necessary to surround this highly loaded layer with pure FEP, we agree with the Examiner that the resulting distal tip section would consist essentially of FEP and radiopaque material. There is nothing in the language of claim 17 that requires that the radiopaque material be uniformly dispersed throughout the distal tip section.

We conclude that the Examiner has set forth a prima facie case that claims 1, 2, 17, and 20 would have been obvious over Parker in view of Coneys, which Appellants have not rebutted. We therefore affirm the rejection of claims 1, 2, 17, and 20 under 35 U.S.C. § 103. Claim 13 falls with claim 1; claim 4 falls with claim 2; claims 18, 19, 22, and 23 fall with claim 17; and claim 21 falls with claim 20.

Claim 14 stands rejected under 35 U.S.C. § 103 as obvious over Parker in view of Coneys and Hopkins. The Examiner relies on Parker and Coneys for the teachings discussed above (Answer 4). The Examiner relies on Hopkins for disclosing the "use of radiopaque materials such as tungsten in a catheter, where it is known that the particles can be as small as 0.9 microns" (*id.*). The Examiner concludes that it would have been obvious "to modify the tungsten in Parker to be of a size at least as small as 0.9 microns and larger as such are known particle sizes of tungsten used in radiopaque catheters as suggested by Hopkins as such would be more easily visible" (*id.*).

We conclude that the Examiner has set forth a prima facie case of obviousness. Parker and Coneys are discussed above. For the reasons discussed above, we agree with the Examiner that one of ordinary skill in the art would have been motivated to replace the polyether block amide in both the shaft and distal tip section of Parker's device with the polyfluorinated ethylenepropylene described in Coneys, and to include between about 50% and 55% by weight tungsten particles in the distal tip.

Hopkins describes a catheter comprising a plastic material containing tungsten particles that are no greater than 2 microns in size (Hopkins, Abstract). Hopkins states that "tungsten is preferred for its low cost, high radiopaqueness and its availability in particles as small as 0.9 microns" (*id.* at col. 2, ll. 28-31). Based on the teachings in Hopkins, we also agree that it would have been obvious to include tungsten particles that range in size from 0.9 to 2.0 microns in the distal tip. "[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness." *Iron Grip Barbell*, 392 F.3d at 1322, 73 USPQ2d at 1228.

Appellants argue that "the combination of Parker and Coneys neither teaches nor suggests the use of highly loaded FEP as a distal tip material. Furthermore, the cited combination neither teaches nor suggests a distal tip section containing between about 50% and 55% by weight of tungsten particles." (Br. 10.) We are not persuaded by these arguments for the reasons discussed above.

Appellants also argue that "Hopkins neither teaches nor suggests the use of an FEP sheath having the features claimed herein" (*id.*). However, the Examiner is only relying on Hopkins for its teaching of radiopaque particle sizes. Therefore, we are not persuaded by this argument.

We conclude that the Examiner has set forth a prima facie case that claim 14 would have been obvious over Parker in view of Coneys and Hopkins, which Appellants have not rebutted. We therefore affirm the rejection of claim 14 under 35 U.S.C. § 103.

Claims 5 and 6 stand rejected under 35 U.S.C. § 103 as obvious over Parker in view of Coneys and Hopkins. The Examiner relies on Parker and Coneys for teaching the features of claims 1, 2, and 4, on which claim 5 depends (Answer 4). The Examiner relies on Hopkins for disclosing the "use of radiopaque materials such as tungsten in a catheter, where it is known that the particles can be as small as 0.9 microns" (*id.* at 4-5). As discussed above, we agree that it would have been obvious to include tungsten particles in the distal tip that range in size from 0.9 to 2.0 microns, which is within the broader range recited in claim 5. Overlapping ranges support a prima facie case of obviousness. *See In re Geisler*, 116 F.3d 1465, 1468, 43 USPQ2d 1362, 1363 (Fed. Cir. 1997).

Appellants argue that these claims are allowable for the same reasons that claim 14 is allowable (Br. 11). We are not persuaded by these arguments for the reasons discussed above with regard to claim 14.

We conclude that the Examiner has set forth a prima facie case that claim 5 would have been obvious over Parker in view of Coneys and Hopkins, which Appellants have not rebutted. We therefore affirm the rejection of claim 5 under 35 U.S.C. § 103. Claim 6 falls with claim 5.

SUMMARY

The Examiner's position is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 1, 2, 4-6, 13, 14, and 17-23 under 35 U.S.C. § 103.

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

AFFIRMED

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