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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MELINA R. KIBBE
(APPLICANT: NORTHWESTERN UNIVERSITY)

Appeal 2017-010926
Application 13/652,058[1]
Technology Center 3700

Before DONALD E. ADAMS, RACHEL H. TOWNSEND, and DAVID COTTA, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 4–8, 16–18, and 21–24 (App. Br. 2). Examiner entered rejections under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellant identifies "Northwestern University" as the real party in interest (Appellant's March 23, 2017 (App. Br.) 1).

STATEMENT OF THE CASE

Appellant's disclosure "relates to catheters and their use for forming arterial stents. In particular, the field of the invention relates to balloon occlusion and infusion catheters for forming liquid cast biodegradable arterial stents" (Spec. ¶ 2). Appellant's claim 21 is representative and reproduced below:

> 21. A catheter for forming a liquid cast stent in an artery, the catheter comprising:
>
> (a) a catheter shaft comprising a proximal end and a distal end;
>
> (b) a proximal occlusion balloon;
>
> (c) a distal occlusion balloon;
>
> (d) an inflation lumen in fluid communication with the proximal occlusion balloon and the proximal end of the catheter shaft and in fluid communication with the distal occlusion balloon and the proximal end of the catheter shaft, wherein after the catheter is inserted and subsequently the proximal occlusion balloon and distal occlusion balloon are inflated, an interior space between the inflated proximal occlusion balloon and the inflated distal occlusion balloon is formed;
>
> (e) a middle balloon between the proximal occlusion balloon and the distal occlusion balloon, wherein the middle balloon is formed from material that is transparent or translucent and that permits transmission of light from the element to the interior space between the inflated proximal occlusion balloon and the inflated distal occlusion balloon;
>
> (f) an inflation lumen in fluid communication with the middle balloon and the proximal end of the catheter shaft;
>
> (g) at least one infusion/aspiration port between the proximal occlusion balloon and the distal occlusion

balloon and an infusion/aspiration lumen for delivering/removing a liquid to or from the infusion/aspiration port, the at least one infusion/aspiration lumen in fluid communication with the proximal end of the catheter shaft; and

(h) an element that when activated initiates or promotes curing of a polymer solution administered in the interior space between the inflated proximal occlusion balloon and the inflated distal occlusion balloon, wherein the element delivers light;

wherein at least a portion of the catheter shaft is transparent or translucent and the transparent or translucent portion is located between the proximal occlusion balloon and the distal occlusion balloon within the middle balloon, the catheter further comprising opaque bands that define a proximal end and a distal end of the transparent or translucent portion, wherein when the middle balloon is inflated, the middle balloon overlaps the opaque bands and the element delivers light through the transparent or translucent portion of the catheter shaft and through the middle balloon to initiate or promote curing of the polymer solution to form a stent that does not include downwardly turned edges.

(App. Br. 12–13.) Appellant's claims 4–8, 16–18, and 22–24 depend from Appellant's claim 21.

Grounds of rejection before this Panel for review:

Claims 4, 5, 17, 18, 21, 23, and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta[2] and Kume.[3]

Claims 6 and 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Madsen.[4]

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[2] Cioanta et al., US 2004/0230316 A1, published Nov. 18, 2004.
[3] Kume et al., US 5,411,016, issued May 2, 1995.
[4] Madsen et al., US 2010/0119833 A1, published May 13, 2010.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Kablik.[5]

Claims 16 and 22 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Hildebrand.[6]

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Cioanta "relates to methods for treating the prostate and/or prostatic urethral stents configured for use after thermal ablation treatments" (Cioanta ¶ 2).

FF 2. Cioanta discloses that an objective of its invention is "to provide a biodegradable and/or biocompatible prostatic stent that [] can be formed in situ via use of [a] treatment catheter and is suitable for inhibiting post thermal ablation therapy obstruction in the prostate" (Cioanta ¶ 9; *see generally* Final Act. 2–3).

FF 3. Cioanta discloses that certain portions of its catheter "can be configured to have radio-opaque indicia . . .[, wherein the] indicia [] can be any suitable radio-opaque feature such as a marker, surface, layer, or other feature so as to be imageable or visualized in an X-ray (to allow external positional verification of the device)" (Cioanta ¶ 78; *see generally* Final Act. 2–4).

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[5] Kablik et al., US 2006/0122619 A1, published June 8, 2006.
[6] Hildebrand, US 5,419,763, issued May 30, 1995.

FF 4. Cioanta's Figure 5A is reproduced below:

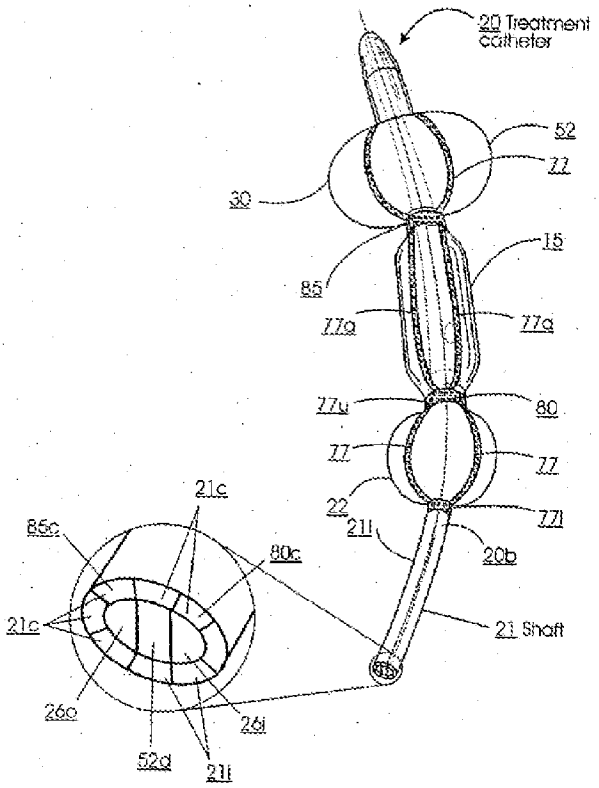


Fig. 5A

Cioanta's "FIG. 5A is a perspective view of a treatment catheter according to embodiments of the present invention configured to deliver and apply the biocompatible biodegradable stent to the targeted region in the body" (Cioanta ¶ 32 (emphasis omitted). Cioanta's

> FIG. 5A illustrates that a series of radio-opaque markers [77 (as denoted by the shaded region)] may be employed, some axially extending and some radially extending to help confirm the positional location of the catheter when in the subject, irrespective of its orientation in the body.

(*id.* ¶ 78 (emphasis omitted); *see generally* Final Act. 2–4.)

FF 5. Cioanta discloses that

> radio-opaque markers 77 can be circumferentially arranged on the catheter either or both above 77*u* and below 77*l* . . . the

> sealing balloon 22 so that the balloon 22 can be more readily accentuated and confirmed in the X-ray as located in the membranous urethra, above the sphincter. Alternatively, or additionally . . . one or more longitudinally extending radiopaque markers 77*a* can be arranged to extend substantially along the length of the treatment balloon 15 at various radial positions . . . . The radio-opaque markers are applied to block the transmission of X-ray for better contrast in images.

(Cioanta ¶ 79 (emphasis omitted); *see generally* Final Act. 2–4.)

FF 6. Examiner finds that Cioanta discloses a catheter for forming a liquid cast stent in an artery within the scope of Appellant's claim 21, with the exception of a

> middle balloon [] formed from material that is transparent or translucent and that permits transmission of light from the element to the interior space of the artery between the inflated proximal occlusion balloon and the inflated distal occlusion balloon. At least a portion of the catheter shaft is transparent or translucent and the transparent or translucent portion is located between the proximal occlusion balloon and the distal occlusion balloon. The element delivers light through the transparent or translucent portion of the catheter shaft and through the middle balloon to initiate or promote curing of the polymer solution to form a stent that does not include downwardly turned edges

and relies on Kume to make up for this deficiency in Cioanta (Final Act. 4–5; *see generally id.* at 2–5).

FF 7. Kume "relates to balloon angioplasty devices for use in combination with an angioscope" (Kume 1:8–10; *see id.* at 4:17–21 ("The balloon catheter of the present invention can also be used to deliver a stent such that the angioscope is used to monitor stent expansion through the balloon and confirm complete and accurate deployment of the stent"); *see also* Final Act. 5 (Examiner finds that Kume discloses a "transparent catheter with

translucent balloon for permitting light through for visualization of the treatment site")).

FF 8. Kume's Figure 2 is reproduced below:

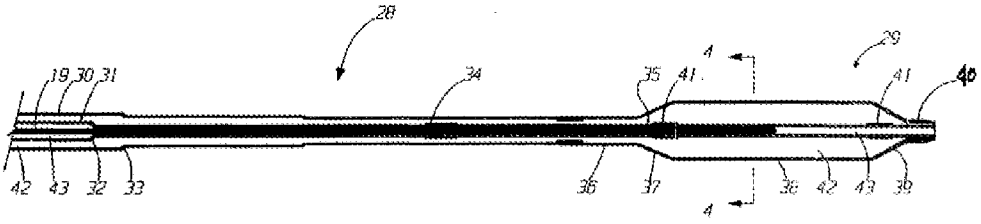


FIGURE 2

Kume's "FIG. 2 is a sectional drawing of a preferred embodiment of the distal portion of [Kume's] catheter" (Kume 4:30–32 (emphasis omitted)).

FF 9. Kume's "catheter shaft 28 [] includes an inner tube 31 which is connected . . . at its distal end to an optically-transparent tube 35" (Kume 6:1–4 (emphasis omitted)).

FF 10. Kume's device includes "[r]adiopaque marker bands 41 [] secured to the optically-transparent tube 35 to facilitate radiographic placement of the balloon catheter at the therapy site. The marker bands 41 are preferably aligned with the proximal balloon cone 37 and distal balloon cone 39 so as to not interfere with angioscopic visualization" (Kume 6:39–44 (emphasis omitted)).

FF 11. Examiner finds that Cioanta fails to disclose an element, such as a fiber optic, laser, or LED element, that delivers light having a wavelength of about 300-500 nm and relies on Madsen to disclose "[p]hoto-curing of thermoplastic coatings compris[ing] using UV or visible light to covalently

cross-link[] the composition and the UV or visible light having a wavelength of 100-750 nm" (Final Act. 6; *see id.* (Examiner finds that Madsen discloses the use of an "LED element")).

FF 12. Examiner finds that Cioanta fails to disclose an element that "delivers light having an intensity of at least about 10 $mW/cm^{[2]}$" and relies on Kablik to disclose:

> Devices and system for illuminating or irradiating a light-sensitive material for polymerization and cross-linking the methods of using the same comprise the method of using different intensities for curing different type of materials using a desired power density in the range of 15 $mW/cm^{[2]}$ to about 100 $mW/cm^{[2]}$ for polymerization and cross-linking the light sensitive material.

(Final Act. 6–7.)

FF 13. Examiner finds that Cioanta fails to disclose:

> An inflation lumen in fluid communication with the proximal occlusion balloon and the proximal end of the catheter shaft and a separate inflation lumen in fluid communication with the distal occlusion balloon and the proximal end of the catheter shaft, wherein the proximal occlusion balloon and the distal occlusion balloon can be inflated separately

and relies on Hildebrand to disclose "[a] prostatic drug-delivery balloon catheter . . . having proximal, distal and positioning balloons . . . for positioning and delivering drugs to the prostatic urethra, wherein the balloons . . . are being inflated by different inflation lumens" (Final Act. 8).

ANALYSIS

The rejection over the combination of Cioanta and Kume:

Based on the combination of Cioanta and Kume, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious

> to apply the teaching of transparent catheter and transparent balloon that permit light through visualization as taught by Kume into the middle balloon of Cioanta, since the middle balloon is at the area where the treatment site is, in order to permit light to go through for visualization of the treatment site before applying the stent material. Since the modified Cioanta having a translucent/transparent middle balloon allowing light to go through for visualization, it would have been obvious for the lights to initiate or promote curing of the stent material that is activated via exposure to light as taught by Cioanta to form a stent without including downwardly turned edge since Cioanta teaches markers that would prevents passage of light through the catheter.

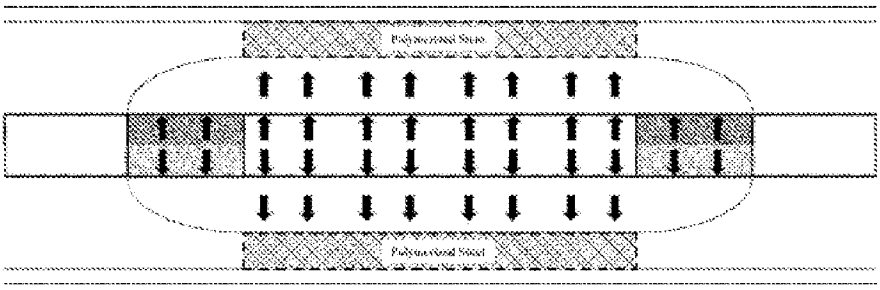
(Final Act. 5.) Although Kume discloses that its device may be used to deliver a pre-made stent, Kume does not disclose the use of its device to form a stent within the scope of Appellant's claimed invention. Nevertheless, Examiner explains that Kume "discloses radio-opaque markers 41 that define[] the proximal balloon cone 37 and distal balloon cone 39" are placed at the distal tapered regions of Kume's device (*see* Ans. 4 (citing Kume's FIG. 2). We are not persuaded.

Appellant's only independent claim, claim 21, requires, *inter alia*,

> at least a portion of the catheter shaft is transparent or translucent and the transparent or translucent portion is located between the proximal occlusion balloon and the distal occlusion balloon within the middle balloon, the catheter further comprising opaque bands that define a proximal end and a distal end of the transparent or translucent portion, wherein

> when the middle balloon is inflated, the middle balloon overlaps the opaque bands and the element delivers light through the transparent or translucent portion of the catheter shaft and through the middle balloon to initiate or promote curing of the polymer solution to form a stent that does not include downwardly turned edges.

(App. Br. 13.) Appellant illustrates the foregoing limitation of claim 21 as follows:



Polymerization of Stent Is Inhibited at Tapering Ends of Inflated Middle Balloon to Form a Stent Without Downturned Edges

(*see* App. Br. 6.) Specifically, Appellant's illustration shows that

> [t]he opaque bands in . . . [Appellant's] claimed catheter overlap the middle balloon. As such, the opaque bands define a boundary from which light is not emitted from the catheter shaft through the middle balloon. As such a stent can be polymerized where the stent does not have undesirable, downturned edges that are defined by the tapered ends of the middle balloon.

(*Id.*)

Although Cioanta discloses radiopaque markers circumferentially arranged on a catheter (FF 4–5), we agree with Appellant's contention that

> [t]here is no teaching or suggestion in Cioanta to relocate the opaque markers from positions that define a proximal end and a distal end of the sealing balloon 22 to positions that define a proximal end and a distal end of the treatment balloon 15 where

> the treatment balloon overlaps the opaque markers when inflated.

(App. Br. 8.) In addition, although Kume illustrates the placement of radio-opaque markers on tapered ends of its device, because Kume is not concerned with the use of its device to form a stent, Kume provides no incentive for person of ordinary skill in this art to place radio-opaque markers on a device, as required by Appellant's claimed invention, for the purpose of forming "a stent that does not include downwardly turned edges" as required by Appellant's independent claim 21 (App. Br. 13). Therefore, we agree with Appellant's contention that "[t]here simply is no teaching in the prior art to incorporate opaque bands into a catheter for forming a stent as . . . [Appellant] has done" (App. Br. 6).

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

> Absent some articulated rationale, a finding that a combination of prior art would have been "common sense" or "intuitive" is no different than merely stating the combination "would have been obvious." Such a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine.

In re Van Os, 844 F.3d 1359, 1361 (Fed. Cir. 2017).

The rejection over Cioanta in combination with Madsen, Kablik, or Hildebrand:

Examiner failed to establish an evidentiary basis on this record to support a conclusion that any of Madsen, Kablik, or Hildebrand make up for

the foregoing deficiency in Cioanta discussed above (*see generally* FF 11–13).

In addition, we note that Examiner's rejections based on Cioanta in combination with Madsen, Kablik, or Hildebrand does not rely upon Kume. In this regard, Examiner failed to establish an evidentiary basis on this record to support a conclusion that any of Madsen, Kablik, or Hildebrand make up for the deficiency in Cioanta, which required Examiner's reliance on Kume (*see* FF 11–13; *cf.* FF 6–10).

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness.

The rejection of claims 4, 5, 17, 18, 21, 23, and 24 under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Kume is reversed.

The rejection of claims 6 and 8 under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Madsen is reversed.

The rejection of claim 7 under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Kablik is reversed.

The rejection of claims 16 and 22 under 35 U.S.C. § 103(a) as unpatentable over the combination of Cioanta and Hildebrand is reversed.

REVERSED