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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* DANIEL C. ROSENMAN, PETER A. ALTMAN,  
BRIAN K. HAKIM, DANIEL J. KAYSER, ROBERT E. MASTON, and  
DOUGLAS McETCHIN

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Appeal 2018-000079<sup>1</sup>  
Application 14/257,895  
Technology Center 3700

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Before LISA M. GUIJT, BRADLEY B. BAYAT, and  
PAUL J. KORNICZKY, *Administrative Patent Judges*.

BAYAT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the decision rejecting claims 1–28, which are the only claims pending in the application. An oral hearing was held on October 22, 2019. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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<sup>1</sup> “Appellant” refers to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as “BioCardia, Inc.” Appeal Br. 1.

*Claimed Invention*

Appellant's invention relates "to site-specific delivery of therapeutic agents, structures and catheter systems to achieve site-specific delivery of therapeutic agents, and means for implanting and using these systems to enable delivery of therapeutic agents to the body." Spec. 1:11–15.

Independent claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. A system for delivering a drug to a target site within a patient's body comprising:
  - a steerable guide catheter comprising:
    - a guide catheter having a distal end, a proximal end and a longitudinal axis; and
    - a steering pullwire for deflecting the guide catheter;
    - a first handle, disposed at the proximal end of the guide catheter, said first handle having a control means operably connected to the steering pullwire; and
    - a drug delivery catheter operably connected to the guide catheter, the delivery catheter comprising:
      - a second handle secured to the proximal end of the drug delivery catheter, said second handle disposed proximal to the first handle and having a longitudinal axis, a distal end, and a proximal end;
      - a delivery catheter having a lumen, said delivery catheter protruding out of the distal end of the second handle and aligned substantially along the longitudinal axis of the second handle and extensible beyond the distal end of the guide catheter;
      - a helical drug delivery needle operably connected to the distal end of the delivery catheter; and

said second handle being operable to rotate and advance the drug delivery catheter within the guide catheter.

Appeal Br. (Claims App.).

### *Rejections*

Claims 1–3, 13–17, 27, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh et al. (US 2001/0007933 A1, pub. July 12, 2001) (“Lesh”) and Badger et al. (US 5,030,204, iss. July 9, 1991) (“Badger”).

Claims 4 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh, Badger, and Weaver et al. (US 5,843,028, iss. Dec. 1, 1998) (“Weaver”).

Claims 5–12 and 19–26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh, Badger, and Berg et al. (US 5,911,715, iss. June 15, 1999) (“Berg”).

### ANALYSIS

#### Claims 1–3, 13–17, 27, and 28

In rejecting independent claim 1 as unpatentable over Lesh and Badger, the Examiner finds Lesh discloses all of the limitations of claim 1 except that “it does not disclose a steerable guide catheter having a first handle with control means operably connected to a steering pullwire and which is disposed distal of the second handle.” Final Act. 3. To cure this deficiency, the Examiner finds:

Badger discloses a guide catheter for cardiovascular procedures (abstract). The guide catheter has a distal end, a proximal end and a longitudinal axis; a steering pullwire 16 for deflecting the guide catheter; and a first handle 20 (not just luer

but entire section), disposed at the proximal end of the guide catheter, said first handle having a control means 24 operably connected to the steering pullwire. The guide catheter is designed to have a second catheter inserted into it where the second catheter extends beyond the distal end of the guide catheter (fig 2). An inserted catheter is capable of rotating and advancing through the guide catheter via twisting and pushing of the inserted catheter. Also, the second handle of an inserted device would be disposed proximal the first handle of the guide catheter as the inserted device is inserted via the proximal end of the device of Badger. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a guide catheter with pullwire for the device of Lesh as taught by Badger to assist in placing the catheter of Lesh (Badger discloses its particular guide catheter provides stiffness and strength in addition to a deformable tip - Col.2 ll. 48–54).

*Id.*

Alleging error in the rejection, Appellant argues that “[t]his is not a motivation to make a combination: This is merely a conclusory statement that the combination would be obvious. It is inadequate to support a rejection.” Appeal Br. 10 (“The proposed combination would result in a system with duplicative steering systems, for no reason apparent in the art.”). In particular, Appellant contends:

Mere incantation of a characteristic appearing in a prior art device does nothing to establish a motivation for altering that device. It does not demonstrate why an artisan would be motivated to make any particular modification, or whether an artisan would seek to increase strength at the expense of stiffness, increase stiffness at the expense of strength, increase both, or decrease both. So, the mere incantation of strength and stiffness does not constitute identification of a motivation to make the Examiner’s proposed combination, and no prima facie case of obviousness is established by merely mentioning strength and stiffness.

Reply Br. 2. Appellant's arguments are persuasive.

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter 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 Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). An invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 418. Instead, a determination of unpatentability on a ground of obviousness must include “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). The obviousness evaluation “should be made explicit” and it “can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*

We find the Examiner's rationale to combine the teachings of the references is predicated upon a conclusory statement that lacks articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In response to Appellant's arguments as to a lack of motivation to combine Lash and Badger, the Examiner asserts that “Badger provides stiffness and strength in addition to steering, as stated in the original rejection, stiffness and strength being a motivation by themselves.” Answer 8. Lesh is directed to an infusion catheter for delivery of ablation liquids to cardiac tissue using a novel hollow infusion needle for controlling the location and extent of the ablation, designed such that it can be imbedded

in and secured to the tissue to be treated. Lesh ¶¶ 9, 11. Badger is directed to an improved guiding catheter with a deflectable distal segment with sufficient stiffness and strength to support dilation catheters for their placement within a patient's coronary vasculature. Badger 2:48–54. According to Badger, the segment's shape and stiffness “aid in providing support to a dilation catheter when the balloon thereof is being advanced across a tight lesion.” *Id.* 2:39–44. The Examiner does not support adequately why one of ordinary skill would have been concerned with “stiffness” and “strength” to modify the apparatus of Lesh, which is concerned with “direct endocardial infusion of sclerosing agents at the precise location of tachycardia.” Lesh ¶ 10. The Examiner's reasoning is inadequate because it fails to explain why one of ordinary skill in the art would have been motivated to modify Lesh's catheter with Badger to reach the claimed invention. It is well settled that obviousness cannot be sustained by mere conclusory statements. *Kahn*, 441 F.3d at 988; *accord KSR*, 550 U.S. at 418. As such, a prima facie case of obviousness has not established as to independent claim 1.

Accordingly, we do not sustain the rejection of independent claim 1 under 35 U.S.C. § 103(a), as well as dependent claims 2 and 3. *Cf. In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (“dependent claims are nonobvious if the independent claims from which they depend are nonobvious.”). We also do not sustain the rejection of independent claims 13, 15, and 27, and dependent claims 14, 16, and 28, because the Examiner relies on the same deficient reasoning as claim 1. *See* Final Act. 4–6.

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Claims 4–12 and 18–26

The rejections of dependent claims 4–12 and 18–26, which depend from either independent claim 1 or 15, are not sustained for the same reasons discussed above with respect to claims 1 and 15.

Summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1–3, 13–17, 27, 28	103	Lesh, Badger		1–3, 13–17, 27, 28
4, 18	103	Lesh, Badger, Weaver		4, 18
5–12, 19–26	103	Lesh, Badger, Berg		5–12, 19–26
<b>Overall Outcome</b>				1–28

CONCLUSION

The decision to reject claims 1–28 under 35 U.S.C. § 103(a) is reversed.

REVERSED