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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JESSICA ASH WARRING, AMIR BELSON, and
WINFIELD SCOTT FISHER

Appeal 2018-008921
Application 14/250,093
Technology Center 3700

Before BENJAMIN D. M. WOOD, JILL D. HILL, and
MICHAEL L. WOODS, *Administrative Patent Judges*.

WOOD, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant¹ appeals under 35 U.S.C. § 134 from a November 6, 2017
Final Action rejecting claims 1–13. Claims 14–25 have been canceled.
Appeal Br. 5. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part, and enter a new ground of rejection.

¹ “Appellant” refers to the applicant as defined in 37 C.F.R. § 1.42.
Appellant identifies the real party in interest as Vascular Pathways, Inc.
Appeal Br. 5.

THE CLAIMED SUBJECT MATTER

The claims are directed to an intravenous catheter insertion device and method of use. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1 A method for accessing a blood vessel lumen, comprising:

providing a catheter insertion device having an access needle, a catheter disposed coaxially over the access needle and a guidewire disposed in a lumen of the access needle and having a distal tip preformed into a coil configuration;

advancing the access needle through a patient's skin to position a distal tip of the access needle in a lumen of the blood vessel;

advancing the guidewire from the distal end of the access needle into the blood vessel lumen, wherein the distal tip of the guidewire is maintained in a straightened configuration in the access needle and recovers the coil configuration in the blood vessel lumen, and wherein the distal tip of the guidewire inhibits puncturing or damaging the blood vessel wall as the guidewire is advanced; and

advancing the catheter over the guidewire.

REFERENCES

Chuttani	US 5,054,501	Oct. 8, 1991
Lewis	US 5,246,426	Sep. 21, 1993
Wilson	US 6,197,001 B1	Mar. 6, 2001
Wensel	US 6,436,112 B2	Aug. 20, 2002
Whiting	US 8,029,470 B2	Oct. 4, 2011
Lederman	US 2003/0032936 A1	Feb. 13, 2003

REJECTIONS

Claims 10 and 11 are rejected under 35 U.S.C. § 112(a) as failing to comply with the enablement requirement.

Claims 1–7 are rejected under 35 U.S.C. § 103 as unpatentable over Lewis and Lederman.

Claim 8 is rejected under 35 U.S.C. § 103 as unpatentable over Lewis, Lederman, and Whiting.

Claim 12 is rejected under 35 U.S.C. § 103 as unpatentable over Lewis, Lederman, and Wensel.

Claim 13 is rejected under 35 U.S.C. § 103 as unpatentable over Lewis, Lederman, and Chuttani.

Claims 1–3 and 5–7 are rejected under 35 U.S.C. § 103 as unpatentable over Wilson and Lederman.

Claim 4 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Lederman, and Lewis.

Claim 8 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Lederman, and Whiting.

Claim 12 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Lederman, and Wensel.

Claim 13 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Lederman, and Chuttani.

Claims 1–3, 7–9, and 13 are rejected under 35 U.S.C. § 103 as unpatentable over Wilson and Chuttani.

Claim 4 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Chuttani, and Lewis.

Claim 5 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Chuttani, and Lederman.

Claim 12 is rejected under 35 U.S.C. § 103 as unpatentable over Wilson, Chuttani, and Wensel.

ANALYSIS

Claims 10 and 11—Rejected as Failing the Enablement Requirement

Claim 10 depends from claim 6. Claim 6 depends from claim 1 and additionally recites “wherein the coil configuration includes a first coil extending from a straight portion of the guidewire, the first coil lying substantially in a first coil plane.” Appeal Br. 46 (claims app.). Claim 10 additionally recites “wherein the coil configuration includes a second coil extending from the first coil, the second coil lying in a second coil plane parallel to the first coil plane.” *Id.* Claim 11 depends from claim 10. *Id.*

The Examiner determines that “[i]t is unclear how two coils can each lie in separate ‘coil planes’ that are parallel to each other since the connection between the two coils must follow an incline from the first to the second coil; due to this incline joining the two coils, it does not appear that the individual coils can each lie in a respective single plane.” Final Act. 3. The Examiner explains that:

While Fig 25B shows two coil[s] that have portions that lie parallel to one another (i.e. the portions of the coils that are facing out of the page in Fig 25B), it cannot be said that coils themselves lie in coil planes that are parallel since planes are inherently two-dimensional while two joined coils that are ‘stacked’ (for lack of a better word) as seen in Fig 25B must each be three-dimensional.

Id. at 3–4.

Appellant first responds that the Examiner should not have rejected claims 10 and 11 under 35 U.S.C. § 112(a) because, according to MPEP § 707.07(g), “[c]ertain technical rejections (e.g., negative limitations, indefiniteness) should not be made where the examiner, recognizing the limitations of the English language, is not aware of an improved mode of

definition.” Appeal Br. 11–12. According to Appellant, “[t]he Examiner *clearly* recognizes the limitations of the English language in describing the coil configuration of claim 10: ‘[T]wo joined coils [...] are ‘stacked’ (for lack of a better word) as seen in Fig 25B[.]’” *Id.* (quoting Final Act. 3–4) (alterations made by Appellant). Appellant also disagrees with the Examiner’s implicit interpretation of claim 10 as requiring “that the first coil lies *entirely* in the first coil plane, the second coil lies *entirely* in the second coil plane, and the first and second coil planes are parallel.” *Id.* at 12. Appellant asserts that “the claims do not specify how much of the first coil lies in the first coil plane nor how much of the second coil lies in the second coil plane,” and “any three points of a coil can define a plane, or ‘coil plane.’” *Id.*

Section 112 requires a written description to enable “those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004) (internal citation omitted). Whether undue experimentation is needed is not a single, simple factual determination, but is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The *Wands* factors include: (a) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* “[T]he PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the

description of the invention provided in the specification of the application.” *In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993).

The Examiner has not made any findings regarding whether undue experimentation is required for one of ordinary skill in the art to make and use the invention of claim 10, much less considered any of the *Wands* factors. Therefore, the Examiner has not established a *prima facie* case of lack of enablement, and we do not sustain this rejection.

NEW GROUND OF REJECTION UNDER 37 C.F.R. § 41.50(b)

*Claims 10 and 11—Rejected Under 35 U.S.C. § 112(a) as Failing the
Written Description Requirement*

To satisfy the written description requirement, a disclosure must reasonably convey to one skilled in the art that the applicant had possession of the subject matter in question when the application was filed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Determining possession requires an objective inquiry into the “four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.* at 1351.

Although we agree with the Examiner that claims 10 and 11 should be rejected under 35 U.S.C. § 112(a), the proper basis to do so is under the written-description requirement. For claim 10, we are unable to discern any disclosure in the Specification for a coil configuration that includes a first coil in a first coil plane and a second coil in a second coil plane that is parallel to the first coil plane. For example, Figure 4B depicts a first and second coil in the same plane rather than each in separate, parallel planes. Spec. ¶ 52, Fig. 4B. Figures 25A and 25B depict two coils that are three

dimensional, and thus cannot be said to be “in” a two-dimensional plane, as claim 10 requires.

Appellant contends that a “coil plane” can be defined by any three points on each of the coils depicted in Figure 25B. Appeal Br. 12. But the Specification does not support this contention—the Specification does not appear to use the term “coil plane,” much less define it as any three randomly selected points on a coil. Such a definition would mean little, as there would be an infinite number of possible planes that could be defined by the selection of any three of an infinite number of points on each coil.

For the above reasons, we determine that claim 10 is not adequately described by the Specification. Claim 11 depends from claim 10 and therefore is likewise not adequately described.

Claims 1–7—Rejected as Unpatentable over Lewis and Lederman

Appellant argues claims 1, 2, and 4–7 as a group, and argues claim 3 separately. Appeal Br. 13–25. We select claim 1 as representative of the grouped claims, and decide the appeal of the rejection of these claims on the basis of claim 1 alone. 37 C.F.R. § 41.37(c)(1)(iv). We discuss claim 3 separately.

Claim 1

The Examiner relies on Lewis to teach the method of claim 1, except for the limitation requiring the distal tip of the guidewire to be preformed into a coil configuration that is maintained in a straightened configuration in the access needle and that recovers the coil configuration in the blood vessel lumen. Final Act. 5 (citing Lewis, 10:22–25, 35–40, 47–50, Figs. 1, 8B). For the limitation missing from Lewis, the Examiner relies on Lederman, particularly Lederman’s guide wire 24 and its distal end pigtail 42. *Id.* at 5–

6 (citing Lederman ¶¶ 37–38, Fig. 3). The Examiner finds that Lederman teaches that distal end pigtail 42 reduces the chance of accidentally puncturing or damaging blood vessels, and that one of ordinary skill in the art would have been motivated to modify Lewis’s device such that its guidewire includes Lederman’s preformed coil configuration for that purpose. *Id.* at 6 (citing Lederman ¶ 38, Fig. 3).

We have reviewed each of Appellant’s arguments for patentability of claim 1, but find them unpersuasive of Examiner error. Accordingly, we sustain the Examiner’s rejection of claim 1 as unpatentable over Lewis and Lederman for essentially those reasons expressed in the Final Action and Answer. We add the following primarily for emphasis.

Appellant argues that “the proposed modification would change the function and the principle of operation of Lewis.” Appeal Br. 18. Appellant asserts that “changing the spherical tip of the Lewis guidewire . . . into the pigtail shown in Lederman, would both obstruct and interfere with the entry of blood into the first flashback chamber” through a needle port adjacent the distal tip of the needle. *Id.* at 18–19 (citing Lewis, 8:65–66, 9:13–15, Fig. 8B). In support of this assertion, Appellant provides an annotated version of Lewis’ Figure 8B purporting to show the Lewis’ guidewire, modified to have Lederman’s pigtail, entering the distal flashback port 70d on Lewis’ needle 14. *Id.* at 19. According to Appellant, “the Lederman pigtail would at least partially recoil in the first flashback chamber once the restraint provided by the inner wall of the needle is removed.” *Id.* at 20.

The Examiner disagrees with Petitioner’s analysis. The Examiner asserts that Appellant’s position “that the pigtail would *necessarily* enter into port 70d and the hypothetical visual depiction of it is not supported by

evidence.” Ans. 12. According to the Examiner, “one of ordinary skill in the art would find that the distal end of Lewis could be modified to have a pigtail without interfering with entry of blood into Lewis’ flashback chamber,” by, e.g., changing the radius of curvature of Lederman’s pigtail, or changing the direction in which the pigtail curves (i.e., away from the port). *Id.* In its Reply Brief, Appellant responds that changing the radius or curvature would still result in interference between the guidewire and the flashback port because the guidewire is “subject to being torqued,” which may turn the pigtail into the flashback port.

Appellant’s argument is not persuasive of Examiner error. The argument is based on the bodily incorporation of Lederman’s pigtail into Lewis’ device, rather than the combination of teachings as proposed by the Examiner in the articulation of the rejection. “The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . [r]ather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983) (“Claims may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference.”). One of ordinary skill can use his or her ordinary skill, creativity, and common sense to make the necessary adjustments and further modifications to result in a properly functioning device. *See KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for

a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ”).

Appellant also argues that “there is no teaching in Lederman of the pigtail of the guidewire being maintained in a straightened configuration in the access needle, as required.” Appeal Br. 21. In response, the Examiner points to Lederman Paragraphs 26 and 35 and Figures 2–5 as teaching this limitation. Ans. 13. According to the Examiner, “Paragraph 26 explicitly states ‘guide wire 24 has been inserted into guide wire lumen 12 via guide collar 24’ which means that the distal end 42 (which has the coil configuration when outside the lumen 12) is inserted distally into lumen 12 through guide collar 22 prior to it extending distally out from port 40.” *Id.*

Appellant disagrees with this reading of Lederman. Appellant asserts that “[u]se of the term ‘via’ is wholly ambiguous in this regard as it can simply mean ‘through.’” Reply Br. 15. According to Appellant, this reading “allows for the end of the guidewire opposite the pigtailed-end to be inserted into the guide wire lumen 12 first then through the guide collar 22.” *Id.* Appellant provides an annotated version of Lederman Figure 1 that illustrates this process. *Id.* Appellant further contends that Lederman discloses inserting the guidewire prior to the catheter being introduced, and that the pigtail aids “in guiding the catheter 10 by providing a capture for the catheter 10 as it slides along the guide wire 24 via guide wire lumen 12.” *Id.* at 15–16 (quoting Lederman ¶ 38). Appellant asserts that “[t]he capture mechanism of the pigtail relies on the pigtail maintaining the coil configuration for the capture,” and “maintaining the coil configuration of the pigtail permits the catheter to be steered by the pigtail.” *Id.*

This argument does not persuade us of Examiner error. We agree with the Examiner that the most reasonable reading of Paragraph 26 of Lederman is that distal pigtail end 42 of guide wire 24 is inserted through guide collar 22, then through into the proximal end of guide wire lumen 12, finally “emerging from the distal end 20 of catheter 10.” Lederman ¶ 26. Because guide wire 24 fits “snugly” into guide wire lumen 12 (Lederman ¶ 35), it is reasonable to infer that the pigtail must be “maintained in a straightened configuration” while it is still in guide wire lumen 12 and before it emerges from the distal end of catheter 10. Appellant maintains that “via” can mean “through,” but it is not entirely clear how interpreting “via” in this manner demonstrates error in the Examiner’s reading of Paragraph 26.² For example, it is difficult to square Appellant’s apparent belief that guide wire 24 first enters catheter 10 at its distal end 20 with Paragraph 26’s teaching that guide wire 24 “*emerg[es]* from the distal end 20 of catheter 10.” Lederman ¶ 26 (emphasis added). Appellant also does not explain why the fact that the pigtail acts as a “capture” and permits steering of the guide wire demonstrates error in the Examiner’s finding.³

² Because Lederman can be fairly read to teach the coil being maintained in a straightened configuration while in the needle, it is not necessary to rely on Lederman inherently disclosing it. *See In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994) (holding that a “reference must be considered not only for what it expressly teaches, but also for what it fairly suggests”) (internal quotation marks omitted).

³ Appellant argues that the Examiner has not provided a motivation or reasonable expectation of success “to support any additional modification of the Lederman-tipped Lewis guidewire to include a straightened configuration when in an access needle.” Appeal Br. 23–24. This argument is moot, however, because we agree with the Examiner that Lederman fairly teaches the straightened configuration when in an access needle, and thus

Claim 3

Claim 3 depends from claim 1 and additionally recites “wherein the advancing the catheter over the guidewire comprises advancing the catheter over the distal tip of the guidewire to straighten the distal tip of the guidewire.” Appeal Br. 45 (claims app.). The Examiner finds that Lewis teaches this additional limitation. Final Act. 6 (citing Lewis, 10:47–50). Appellant responds that the references do not teach straightening the pigtail because Lederman does not teach a straightened configuration of the pigtail. Appeal Br. 25. Appellant relies on arguments made in connection with claim 1 above (*id.*), which we found unpersuasive. Accordingly, we sustain the Examiner’s rejection of claim 3 as unpatentable over Lewis and Lederman.

Claim 8—Rejected as Unpatentable over Lewis, Lederman, and Whiting

Claim 8 depends from claim 7. Appeal Br. 46 (claims app.). Claim 7 depends from claim 1 and additionally recites “wherein the coil configuration has a coil width (cw) and coil span (cs).” *Id.* Claim 8 additionally recites “wherein the coil configuration comprises a preformed spiral including a plurality of turns.” *Id.* The Examiner relies on Whiting for the additional limitation of claim 8. Final Act. 7. The Examiner finds, *inter alia*, that Whiting’s coil and Lederman’s coil are “art recognized equivalents”:

[S]ince the spiral of Whiting has the same peripheral shape as the spiral of Lederman, the spiral of Whiting would also have the same benefits as those of Lederman. Since Lederman’s spiral configuration and Whiting’s spiral configuration provide the

additional modification of the Lederman-tipped Lewis guidewire is not necessary to include this configuration.

same function and could be used to achieve the same result, both spiral configurations were art-recognized equivalents at the time the invention was made and it would have been obvious to one of ordinary skill in the art to form Lederman's spiral with a plurality of turns since it has been held that substituting equivalent configurations involves only routine skill in the art.

Final Act. 7–8.

Appellant does not appear to dispute the Examiner's finding that Whiting Figure 2 depicts a coil configuration that comprises a preformed spiral including "a plurality of turns." Appeal Br. 26–27.⁴ Further, Appellant does not address the Examiner's finding that Whiting's and Lederman's coil configurations are "art-recognized equivalents" and would have "achieve[d] the same result," except on the basis of arguments that we previously found unpersuasive. *Id.* at 26. "[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR*, 550 U.S. at 416. As Appellant has not shown error in the Examiner's findings that Lederman's coil and Whiting's coil are art-recognized equivalents that would have achieved the same result, we sustain this rejection.

⁴ We note, however, that it is not entirely clear what the term "turns" means in claim 8. The Specification does not use "turns" in the context of describing coils or coil configurations. Instead, the Specification describes coils in terms of their diameter, coil width, coil span, how much of a "revolution" they comprise, and their "angular displacement" through which the coils "move" (presumably from a "straight configuration" to the distal end of the coil). Spec. ¶¶ 52–53, 107).

Claim 12—Rejected as Unpatentable over Lewis, Lederman, and Wensel

Appellant relies on dependency from claim 1 for patentability of claim 12. Appeal Br. 27. Because we sustained the Examiner’s rejection of claim 1, we likewise sustain the Examiner’s rejection of claim 12.

Claim 13—Rejected as Unpatentable over Lewis, Lederman, and Chuttani

Claim 13 depends from claim 1, and additionally recites “wherein the guidewire has a first diameter region, a taper or transition region, and a second diameter region formed into the coil configuration.” Appeal Br. 46 (claims app.). The Examiner finds that Chuttani teaches this additional limitation. Final Act. 9 (citing Chuttani, 3:20–24). The Examiner determines that one of ordinary skill in the art would have modified the Lewis/Lederman guidewire such that it has a first diameter region, a taper and a second diameter region formed into a coil configuration “for the purpose of increasing flexibility.” *Id.*

Appellant argues that the Examiner’s rationale for modifying Lederman’s guidewire in accordance with Chuttani, to increase flexibility, would interfere with the functionality of a “bend or kink” in Lederman’s pigtail, which Lederman teaches “may be used to assist manipulation of the catheter into apposition with the target structure.” Appeal Br. 28 (citing Lederman ¶ 38, Fig. 7). Appellant also asserts that increased flexibility would diminish the transmission of torque to Lederman’s pigtail. *Id.*

These arguments are not persuasive of Examiner error. First, as the Examiner notes, “Lederman does not *require* a bend or kink as asserted by Appellant; rather, Lederman only discloses an *optional* bend or kink.” Ans. 19. More importantly, the Examiner is not combining Lederman’s teaching of this optional bend or kink, or Lederman’s teaching that its pigtail be

“torquable,” or the capture and steering capability of Lederman’s guidewire, with Lewis’ guidewire. As the Examiner states:

[I]t appears that the Appellant may be under the impression that the combination used in the rejections would replace Lewis’ guidewire with Lederman’s guidewire; this is incorrect, as the rejections clear[ly] set forth that Lewis’s own guidewire is modified to have a preformed coil configuration of the type taught by Lederman, not replaced with Lederman’s guidewire.

Ans. 11. Appellant does not allege that *Lewis*’ guidewire, modified to have Lederman’s pigtail, would be incompatible with the increased flexibility provided by including a first diameter region, a taper and a second diameter region formed into a coil configuration, as Chuttani teaches.

Claims 1–3 and 5–7—Rejected as Unpatentable over Wilson and Lederman

Appellant argues claims 1–3 and 5–7 as a group. Appeal Br. 29–32. We select claim 1 as representative of the grouped claims, and decide the appeal of the rejection of these claims on the basis of claim 1 alone. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner relies on Wilson to teach the method of claim 1, except for the limitation requiring the distal tip of the guidewire to be preformed into a coil configuration that is maintained in a straightened configuration in the access needle and that recovers the coil configuration in the blood vessel lumen. Final Act. 9–10 (citing Wilson, 7:36–37, 43–46, 54–57, Fig. 1). For the limitation missing from Wilson, the Examiner relies on Lederman, particularly Lederman’s guide wire 24 and its distal end pigtail 42. *Id.* at 10 (citing Lederman ¶¶ 37–38, Fig. 3). The Examiner finds that Lederman teaches that distal end pigtail 42 reduces the chance of accidentally puncturing or damaging blood vessels, and that one of ordinary skill in the

art would have been motivated to modify Lewis' device such that its guidewire includes Lederman's preformed coil configuration for that purpose. *Id.* (citing Lederman ¶ 38).

We have considered Appellant's arguments but are not persuaded that the Examiner erred in rejecting claims 1–3 and 5–7 as unpatentable over Wilson and Lederman. Appellant first argues that Wilson “would deter a person of ordinary skill from the proposed modification.” Appeal Br. 30. According to Appellant, “[a] configuration that prevents kinking is an important feature of Wilson's guidewire,” but “the Lederman pigtail includes a permanent or rigid bend or kink.” *Id.* As noted above, however, the bend or kink in Lederman's pigtail is an optional feature. *See* Lederman ¶ 38 (“A bend or kink within the pigtail distally *may* be used . . .”) (emphasis added). Moreover, the Examiner is not relying on this feature of Lederman's pigtail in its proposed combination, and there is nothing in Lederman that associates this feature with the Examiner's reason to combine Lederman and Wilson: protecting blood vessels from accident puncture.

Appellant also argues that Lederman's guidewire does not have the claimed straightened configuration, and that there is no motivation or reasonable expectation of success in modifying the Lederman-tipped Wilson guidewire to have such a configuration. Appeal Br. 31–32. We find these arguments unpersuasive, however, for the same reasons discussed above in connection with the Lewis-Lederman rejection.

For the above reasons, we sustain the Examiner's rejection of claims 1–3 and 5–7 as unpatentable over Wilson and Lederman.

Claim 4—Rejected as Unpatentable over Wilson, Lederman, and Lewis

Claim 4 depends from claim 1 and additionally recites “retracting the guidewire into the access needle, wherein the distal tip of the guidewire transitions from the coil configuration to the straightened configuration during the retracting.” Appeal Br. 45 (claims app.). The Examiner finds that Lewis teaches retracting guidewire 16 into an access needle 14 to ensure proper feeding of the guidewire in the access needle. Final Act. 11 (citing Lewis, 10:8–11, Figs. 1, 4). The Examiner determines that it would have been obvious to modify the Wilson-Lederman method—which includes using a guidewire having Lederman’s straightened configuration—to include the step of retracting the guidewire into the access needle, as taught by Lewis, “for the purpose of ensuring proper feeding of the guidewire in the access needle.” *Id.* at 11–12 (citing Lewis, 10:8–11).

Appellant raises a number of arguments against this rejection, none of which is persuasive. Appellant first argues that the Examiner’s reason to combine “relies upon impermissible hindsight.” Appeal. Br. 33. But Appellant then acknowledges that the Examiner’s reason to combine “is derived from a passage in Lewis.” *Id.* (citing Lewis, 10:1–21). As our reviewing court has stated, “[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.” *In re McLaughlin* 443 F.2d 1392, 1395 (CCPA 1971). The Examiner’s rationale “is derived from Lewis,” and therefore

relies on knowledge within the level of ordinary skill in the art at the time of the invention.

Appellant also contends that “it is self-evident that a person of ordinary skill would not be motivated to further modify the Lederman-modified vascular access device of Wilson to retract a guidewire to simply ensure a proper feeding of the guidewire.” Appeal Br. 33. This contention is attorney argument, unsupported by evidence or persuasive argument, and therefore is given no weight. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Appellant asserts that “modification of the Lederman-modified vascular access device of Wilson with Lewis . . . would require a substantial reconstruction and redesign of the Lederman-modified vascular access device of Wilson, as well as a change in the basic principle under which the Wilson’s device was designed to operate.” Appeal Br. 34. This, too, is unsupported attorney argument, and therefore not persuasive.

In its Reply Brief, Appellant argues that “retrieving the Wilson guidewire with Lederman’s pigtail, retracting the modified guidewire while loading the spring, and resetting the trigger for the modified guidewire would be problematic.” Reply Br. 24. But Appellant does not explain why the proposed modification would be “problematic,” or provide evidence in support of this contention.

For the above reasons, we sustain the Examiner’s rejection of claim 4 as unpatentable over Wilson, Lederman, and Lewis.

Claim 8—Rejected as Unpatentable over Wilson, Lederman, and Whiting

Appellant repeats the arguments for the patentability of claim 8 that it made in connection with the Examiner’s rejection of claim 8 over Lewis,

Lederman, and Whiting. Appeal Br. 34–36. Because we found these arguments unpersuasive, we sustain the Examiner’s rejection of claim 8 as unpatentable over Wilson, Lederman, and Whiting.

Claim 12—Rejected as Unpatentable over Wilson, Lederman, and Wensel

Appellant relies on dependency from claim 1 for patentability of claim 12. Appeal Br. 36. Because we sustained the Examiner’s rejection of claim 1, we likewise sustain the Examiner’s rejection of claim 12.

Claim 13—Rejected as Unpatentable over Wilson, Lederman, and Chuttani

Appellant repeats the arguments for the patentability of claim 13 that it made in connection with the Examiner’s rejection of claim 13 over Lewis, Lederman, and Chuttani. Appeal Br. 36–37. Because we found these arguments unpersuasive, we sustain the Examiner’s rejection of claim 13 as unpatentable over Wilson, Lederman, and Whiting.

*Claims 1–3, 7–9, and 13—Rejected as
Unpatentable over Wilson and Chuttani*

As with the above rejection based on Wilson and Lederman, the Examiner relies on Wilson to teach all of the limitations of claim 1 except for the distal tip of the guidewire preformed in a coil configuration that is maintained in a straightened configuration while in the access needle. Final Act. 14–16. The Examiner relies on Chuttani for the missing limitation, finding that Chuttani teaches using guidewire 10 having “distal tip 15+25,” preformed into a coil configuration. *Id.* at 15 (citing Chuttani, 4:67–5:19, Figs. 1–6). According to the Examiner, Chuttani’s distal tip:

inhibits puncturing or damaging the blood vessel wall as the guidewire is advanced (because coils 15 align distal-most portion 25 in the center of the lumen, as seen in Fig 1) for the purpose of

cannulating tubular or vascular organs to allow the passage of devices into these organs for diagnosis and treatment.

Id. (citing Chuttani, 2:24–26, 4:67–5:19, 5:23–26, Figs. 1, 3, 4, 6).

Appellant asserts that the coils on Chuttani’s guidewire are not located at the distal tip of the guidewire, as claim 1 requires. Appeal Br. 38.

Appellant also argues that Chuttani is “silent” regarding the coils “inhibiting punctures or damage to blood vessel walls,” but rather teaches that that function is performed by the “soft rounded end” of the guidewire. *Id.* at 39–40. Thus, according to Appellant, one of ordinary skill in the art would not have been led to include Chuttani’s coils for that purpose.

The Examiner responds that “the claims do not require that the claimed ‘distal tip’ be only the distal-most part of the guidewire or extend only a certain distance proximally; the claims also do not require that the *entire* claimed ‘distal [tip]’ be coiled.” Ans. 26. The Examiner thus considers the “distal tip” of Chuttani’s guidewire to include both the coiled section and the straight section. The Examiner also asserts that “[a]lthough Chuttani does not explicitly state that the vessels within which the device can be used are ‘blood vessels,’” the invention relates to “a flexible, steerable guide wire for retrograde or antegrade cannulation of *tubular or vascular organs*,” and “blood vessels (which are structures accessed by the Wilson device) are tubular and vascular organs.” *Id.* at 28 (citing Chuttani, 2:24–26). Thus, according to the Examiner, “one of ordinary skill in the art would recognize that the structure [coils or “helix” 15 and straight section 25] would benefit the Wilson guidewire in the same manner since Chuttani’s guidewire provides these benefits when used in tubular and vascular organs.” *Id.*

We do not sustain this rejection. The claim requires the coil configuration to be at the “distal tip” of the guidewire. Chuttani’s coils are set back from the distal tip of its guidewire, the distal tip occupied by a straight section of guidewire. Chuttani, Fig. 1. Moreover, there is nothing in Chuttani suggesting that its guidewire coils protect from accidental puncture. Rather, the coils are used to help maneuver the guidewire through spiraled channels, particularly the “valves of Heister” in the cystic duct. *Id.* at 5:10–19. Although the Examiner is correct that the invention “generally” relates to “a flexible, steerable guide wire for . . . cannulation of *tubular or vascular organs*,” Chuttani teaches using the coils on its guidewire (the specific structure that the Examiner proposes combining with Wilson) for a more specialized purpose: to help navigate spiral channels. Thus, we are not persuaded that one of ordinary skill in the art would have been motivated to include Chuttani’s coiled structure in a device not intended for use in a vessel that did not have spiral channels.

Remaining Rejections

The remaining rejections of claims 4, 5, and 12 rely on the erroneous finding that one of ordinary skill in the art would have combined Chuttani’s guidewire coils with Wilson’s guidewire. Final Act. 17–19. The additional references are not relied on to cure this deficiency. *Id.* Therefore, for the reasons stated above, we do not sustain these rejections.

DECISION

The following table summarizes our disposition of the rejections at issue in this appeal:

Appeal 2018-008921
Application 14/250,093

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
10, 11	112(a)	Enablement		10, 11	
10, 11	112(a)	Written Description			10, 11
1-7	103	Lewis, Lederman	1-7		
8	103	Lewis, Lederman, Whiting	8		
12	103	Lewis, Lederman, Wensel	12		
13	103	Lewis, Lederman, Chuttani	8		
1-3, 5-7	103	Wilson, Lederman	1-3, 5-7		
4	103	Wilson, Lederman, Lewis	4		
8	103	Wilson, Lederman, Whiting	8		
12	103	Wilson, Lederman, Wensel	12		
13	103	Wilson, Lederman, Chuttani	13		
1-3, 7-9, 13	103	Wilson, Chuttani		1-3, 7-9, 13	
4	103	Wilson, Chuttani, Lewis		4	
5	103	Wilson, Chuttani, Lederman		5	

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
12	103	Wilson, Chuttani, Wensel		12	
Overall Outcome			1–8, 12, 13	9	10, 11

FINALITY OF DECISION

This decision contains a new ground of rejection under 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” 37 C.F.R. § 41.50(b) also provides that Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, “must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record.”

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART
37 C.F.R. § 41.50(b)