UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/939,383	07/11/2013	Dennis A. Peiffer	2001.1495101	7362

11050 7590 02/10/2020

SEAGER, TUFTE & WICKHEM, LLP
100 South 5th Street
Suite 600
Minneapolis, MN 55402

EXAMINER	
HIGHLAND, RACHEL S	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
02/10/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BSC.USPTO@stwiplaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DENNIS A. PEIFFER, BRIAN JOSEPH TISCHLER, TIMOTHY J. LEY, CHRISTOPHER J. CLARK, and THYNA M. CHAU

Appeal 2019-000334
Application 13/939,383
Technology Center 3700

Before MICHAEL L. HOELTER, MICHAEL J. FITZPATRICK, and MICHELLE R. OSINSKI, *Administrative Patent Judges*.

OSINSKI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1–5, 7–16, 18, and 19.[2] We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We AFFIRM.

---

[1] We use the term "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Boston Scientific Scimed, Inc. Appeal Br. 3.

[2] Claims 6 and 17 are cancelled, and claim 20 is withdrawn. Appeal Br. 20–21 (Claims App.); Final Act. 1.

THE CLAIMED SUBJECT MATTER

Claims 1, 19, and 20 are independent. Claim 1 is reproduced below.

> 1. An occlusion device for an atrial appendage, the device having proximal and distal ends and a central axis and comprising a cage-like structure formed of struts, the struts having proximal strut ends and distal strut ends,
>
> wherein at the proximal end of the device the struts extend towards the central axis and are connected to each other at their proximal strut ends, and
>
> wherein at least some of the struts are connected to each other at their distal strut ends within the cage-like structure so that the struts form an atraumatic distal end of the device such that the distal ends of the struts point in a direction towards the proximal end of the cage-like structure,
>
> further wherein the cage-like structure has a proximal section defining a first maximum diameter, a distal section defining a second maximum diameter less than the first maximum diameter, and an intermediate section between the proximal section and the distal section which tapers from the first maximum diameter to the second maximum diameter,
>
> the occlusion device further comprising a filter membrane affixed at the proximal end of the device.

EVIDENCE

The Examiner relied on the following evidence in rejecting the claims on appeal:

Cox	US 2011/0022149 A1	Jan. 27, 2011
Ferrera	US 2011/0319917 A1	Dec. 29, 2011

REJECTIONS

I. Claims 1–5, 7–14, 16, 18, and 19 stand rejected under 35 U.S.C. § 103 as unpatentable over Cox. Final Act. 3–11.

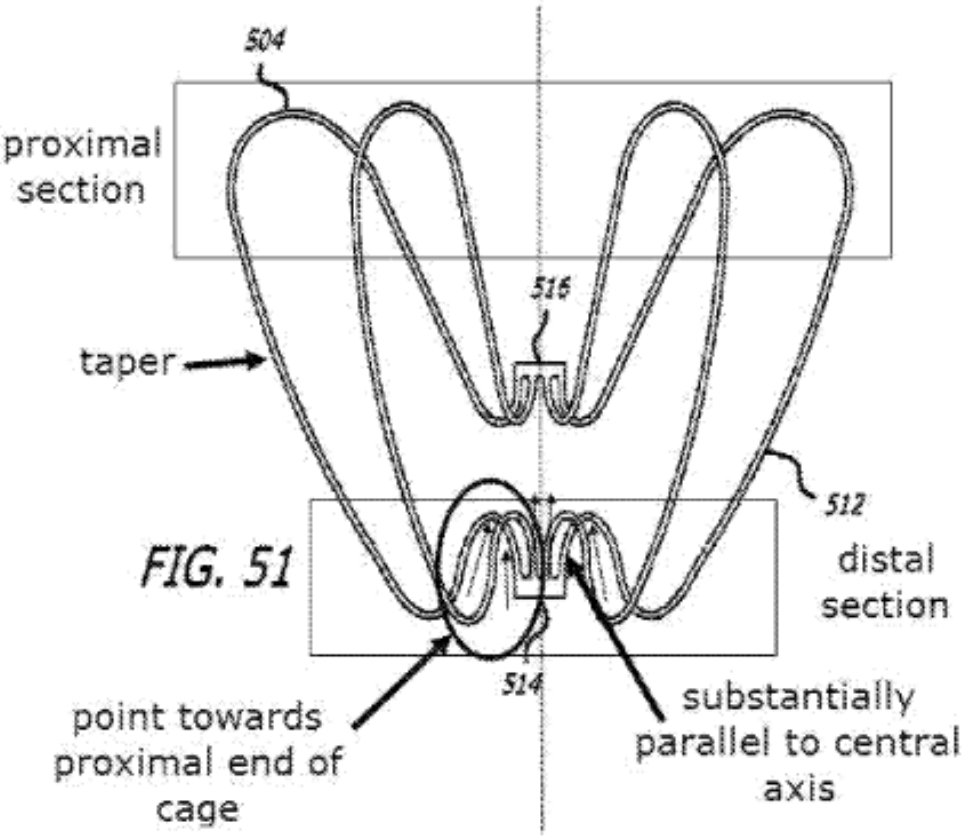
II. Claim 15 stands rejected under 35 U.S.C. § 103 as unpatentable over Cox and Ferrera. *Id.* at 11–12.

OPINION

Rejection I

Appellant presents arguments for independent claims 1 and 19 together (Appeal Br. 8–17) and relies on the same arguments for dependent claims 2–5, 7–14, 16, and 18 (*id.* at 17). We select claim 1 as representative of the issues that Appellant presents in the appeal, and claims 2–5, 7–14, 16, 18, and 19 stand or fall therewith. *See* 37 C.F.R. § 41.37(c)(1)(iv).

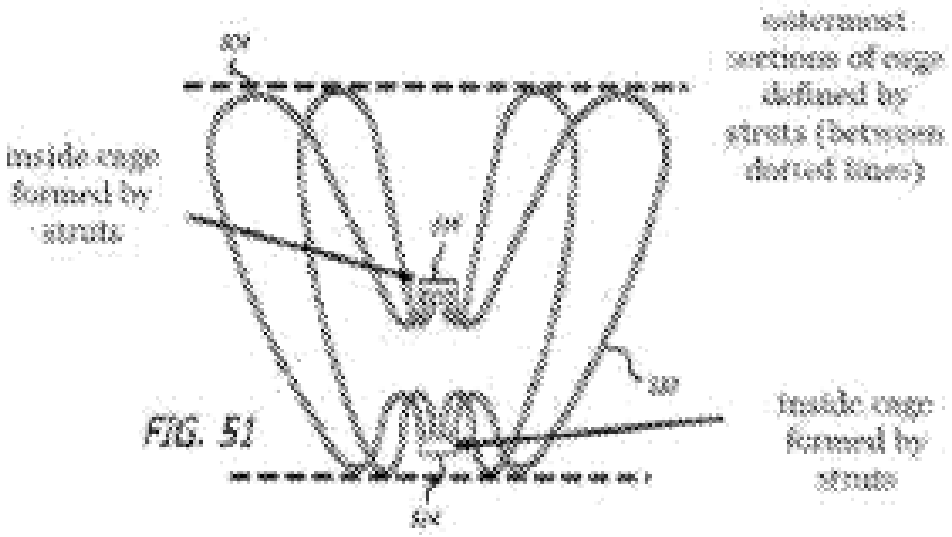
The Examiner finds that Cox teaches, among other things, "an occlusion device . . . having a proximal end (near reference number 504 in Fig. 51) and a distal end (near reference number 506 in Fig. 43)." Final Act. 4. A first Examiner-annotated version of Cox's Figure 51 ("First Annotated Figure 51") is reproduced below.



First Annotated Figure 51

Figure 51 of Cox depicts an elevation view of a laser cut tube that is heat set with first and second ends of the tube axially collapsed towards each other into an everted globe like structure for a device for treatment of a patient's vasculature. Cox ¶¶ 70, 72. The First Annotated Figure 51 includes boxes showing the Examiner-identified "proximal section" and "distal section" of the device.

The Examiner also finds that Cox teaches the device "comprising a cage-like structure." Final Act. 4. In particular, the Examiner finds that "the cage-like structure is deemed to be defined by the outermost sections of the struts as marked by the dashed line in [second] annotated Fig. 51." *Id.* This second Examiner-annotated version of Cox's Figure 51 ("Second Annotated Figure 51") is reproduced below.



Second Annotated Figure 51

The Second Annotated Figure 51 includes dotted lines and an annotation stating "outermost sections of cage defined by struts (between dotted lines)." Final Act. 3. The Second Annotated Figure 51 also includes arrows pointing to first and second hubs/rings 514, 516 and indicates via

annotation that they are both "inside cage formed by struts." *Id.* That is, the Examiner finds that "at least some of the struts are connected to each other at their distal strut ends (at 514) within the cage-like structure." *Id.* at 4.

> The Examiner also finds that Cox teaches
>
> struts (512) . . . having . . . distal strut ends (connected at 514 in Fig. 51) . . . such that the distal ends (the distal ends are deemed to be the s-shaped portions as circled in [first] annotated Fig. 51 . . .) of the struts point in a direction toward the proximal end of the cage-like structure.

Id. at 4. The Examiner takes the position that Cox "show[s] at least a portion of the distal ends of the struts pointing towards the proximal end" and "the claim as presently presented only requires a portion of the distal end of the struts to point in the proximal direction." *Id.* at 4–5. The Examiner asserts that Appellant "has not defined any particular cut off point which defines the distal end, nor has [Appellant] required the entirety of the distal end to be pointing in the proximal direction." *Id.* at 5. The First Annotated Figure 51 includes "small arrows which show at least a portion of the distal ends of the struts pointing towards the proximal end" according to the position taken by the Examiner. Final Act. 4–5.

As to the occlusion device being "for an atrial appendage," the Examiner takes the position that "this is a recitation of intended use" and "[a] recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *Id.* at 4. The Examiner also takes the position that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim" and "[i]n the instant case, the structure of Cox is capable of being placed in any vascular abnormality including an atrial appendage." *Id.*

As to "a filter membrane affixed at the proximal end of the device" as claimed, the Examiner finds that Cox teaches a filter membrane at what the Examiner has identified as the distal end of the device. *Id.* at 5 (citing Cox Fig. 43). The Examiner finds that other embodiments of Cox teach a filter membrane at what the Examiner has identified as the proximal end of the device. *Id.* (citing Cox Figs. 20, 25–27). The Examiner concludes that it would have been obvious to place the filter on either end of the device as is known in the art as evidenced by Cox itself and which is a mere rearrangement of parts and/or reversal of the essential working parts of a device. *Id.* (citing *In re Japikse*, 181 F.2d 1019 (CCPA 1954) and *In re Einstein*, 46 F.2d 373 (CCPA 1931)). The Examiner further finds that "Cox teaches having the filter located at either end of the device depending upon where the device is to be placed in the body" and concludes it would have been obvious "to have the filter membrane be located at whatever portion of the device was best so as to optimize the device to accommodate variations in patient anatomy so as to better treat the particular location where the device will be deployed." *Id.* at 6.

Appellant first argues that:

> Cox teaches that the end of the device of Figs. 43 or 51 near first ring or hub 514 [and having the smaller diameter] is a proximal end and, correspondingly the end of the device near second ring or hub 516 [and having the larger diameter] [is] to be considered the distal end of the device 500.

Appeal Br. 10. Appellant asserts that "this clear error in the identification of the elements of Cox has led the Examiner to annotate Fig. 51 of Cox as having an enlarged proximal end and a smaller distal end which is the reverse of the teaching of Cox." Reply Br. 3. Appellant supports its argument with reference to Cox's delivery system for device 500, in which

the delivery system includes actuator 112 and a release mechanism 114 disposed on the distal end of actuator 112, such that end 508 of device 500 in contact with release mechanism 114 must be the proximal end. Appeal Br. 9–10 (citing Cox Fig. 44, ¶ 143); *see also* Cox ¶ 210 (stating that "release mechanism 114 . . . releasably secures a distal end of the actuator member 112 to the device 500" and "detachment mechanism 114, or portion thereof, may be secured within the lumen of the first ring 514") and Cox ¶ 73 (stating that "FIG. 52 [which includes a portion of ring/hub 514] is an enlarged view of a proximal portion of a strut element of the heat set support structure of FIG. 51").

Appellant's Specification states that "the term 'proximal' refers to those parts of the device which, when following a delivery catheter or delivery instrument during regular percutaneous delivery, are closer to an end of the catheter or instrument that is configured for manipulation by the user." Spec. 6:4–6. The Specification further states that "the term 'distal' is used to refer to those parts of the device that are more distant from the end of the catheter or instrument that is configured for manipulation by the user and/or that are inserted further into the body of a patient." *Id.* at 6:7–9.

We agree with Appellant that in accordance with how Cox discloses delivery of device 500 (*see, e.g.*, Cox Fig. 44), the end with ring/hub 514 is the proximal end and the end with ring/hub 516 is the distal end. The Examiner, however, responds that (i) "the claims are directed only to 'an occlusion device,'" (ii) "Appellant has not claimed a delivery device," and (iii) "[t]he Cox reference teaches all of the structures in the relative orientation as claimed." Ans. 3. We find the Examiner to have the better position. That a certain end of the claimed occlusion device is deemed a proximal end and that an opposing end is deemed a distal end does not

impose any structural limitations on the occlusion device itself as claimed, but rather simply reflects how the occlusion device would be oriented relative to a delivery instrument when placed within a human body—i.e., is a recitation with respect to the manner in which the claimed occlusion device is intended to be employed. The particular manner in which a device or article is intended to be employed, however, cannot be relied on to distinguish structure from the prior art. *See, e.g.*, *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

With respect to the structure of the proximal and distal ends, the claim recites that the proximal section defines a first maximum diameter, the distal second defines a second maximum diameter less than the first maximum diameter, and there is an intermediate section between the proximal and distal sections that tapers from the first maximum diameter to the second maximum diameter. Appeal Br. 19 (Claims App.). The Examiner has shown how Cox's occlusion device meets these structural limitations. The Examiner also found that Cox's occlusion device is capable of being oriented during delivery with the larger diameter end being closer to the delivery instrument and the smaller diameter end being more distant from the delivery instrument. *See* Ans. 3 (the Examiner stating that "[t]here are no structures in the device of Cox which would prevent the device from being deployed with the larger diameter end at the proximal side of the device (closest to the surgeon) and the smaller diameter end at the distal side"). Appellant has not rebutted this finding. Whether Cox's occlusion device actually is employed in such a manner is immaterial to whether Cox's occlusion device is capable of being so employed. A device of the prior art meets a functionally-defined limitation if it is capable of the recited function, and the prior art reference need not envision the device actually being used

to perform the claimed function. *See Schreiber*, 128 F.3d at 1477. Any difference between the claimed occlusion device and Cox's occlusion device is in its use, not its structure. Thus, we are not persuaded of error in the Examiner's finding that Cox teaches an occlusion device with a proximal section defining a first maximum diameter, a distal section defining a second maximum diameter less than the first maximum diameter, and an intermediate section between the proximal section and the distal section which tapers from the first maximum diameter to the second maximum diameter, as claimed.

Appellant next argues that Cox fails to teach "at least some of the struts are connected to each other at their distal strut ends within the cage-like structure," as claimed. Appeal Br. 10. In particular, Appellant argues that even if the distal strut ends may be "within the outer periphery of the cage," this is not equivalent to the claimed limitation. *Id.* Appellant argues that "neither first ring or hub 514 nor second ring or hub 516 is disclosed as residing 'within' the cage-like structure," but rather "rings or hubs 514, 516 of Cox are located external to the cage-like structure and within proximal and distal dimples which are conditioned to form as the device is released from a delivery system." *Id.* In other words, Appellant argues that rings or hubs 514, 516 are "outside of the volume defined by the struts 512 in Fig. 51" and instead are "within the volume external to the cage-like structure defined by the struts 512 in Fig. 51." *Id.* at 11–12. Appellant further argues that the Examiner "errs in attempting to substitute an unsupported definition of 'within' amounting to 'between the extreme longitudinal extents of the deployed device' for 'within the volume defined by the cage structure,' where 'within' (adv.) is used in the sense of 'in or into the interior : inside." *Id.* at 12. Appellant additionally argues that "one

of ordinary skill in the art would understand the latter definition to be more in keeping with the instant specification and figures." *Id.*

The Examiner does not disagree with Appellant's proffered definition of "within" as meaning "in or into the interior: inside." Ans. 4. But the Examiner responds that in order to understand what is "in or into the interior: inside" of the cage-like structure, "the outer boundary of the 'cage-like structure' must be known." *Id.* The Examiner asserts that in the absence of any explanation in the claims of what is the outer boundary of the cage-like structure, apart from indicating that it is "formed of struts with proximal and distal ends," "all the space that is contained within the outer peripheries of the struts is deemed to be 'within' the cage-like structure." *Id.* at 4–5.

We agree with the Examiner that in the absence of further limiting language in the claim, or of a clear indication in the Specification that "within" specifically refers to being within a "volume" of the cage-like structure, the Examiner's position in which the Examiner shows how rings/hubs 514, 516 of Cox are within or inside of an outer periphery of the cage-like structure is sufficient to show that Cox teaches "struts . . . connected to each other at their distal strut ends within the cage-like structure," as claimed.

Appellant next argues that Cox fails to teach that "the distal ends of the struts point in a direction towards the proximal end of the cage-like structure" as recited in claim 1 in that the distal ends point in a distal direction. Appeal Br. 13, 14 (underlining omitted). Appellant's argument does not respond with sufficient particularity to the position taken by the Examiner in the Final Action in which the Examiner is specifically pointing to portions of the s-shaped portions of the struts as identified in the First

Annotated Figure 51 to meet the claim limitations. Accordingly, we do not find this argument persuasive of error.

Appellant next argues that "Cox does not . . . teach an occlusion device for an atrial appendage and does not mention an atrial appendage." Appeal Br. 14. Appellant further argues that "[w]hile a suitably dimensioned device of Fig. 43 of Cox may physically be positioned within an atrial appendage, if so positioned it would no longer work for its intended purpose of providing an intrasaccular device for treatment of a berry type aneurysm." *Id.* at 15. In addition, Appellant argues that:

> [t]he Examiner's proposed positioning of the device of Fig. 43 of Cox within a left atrial appendage does not inherently occlude the ostium of the left atrial appendage and it is not clear that it would be retained within the left atrial appendage upon implantation, both of which would be required for the device to serve the intended purpose of a device of Cox.

Id. at 16.

The Examiner responds that the statement of the device being "for an atrial appendage" "is in the preamble of the claim and does not impart structure or limit the structure of the claimed invention." Ans. 5. The Examiner asserts that the preamble is "merely a recitation of intended use." *Id.* at 6. Moreover, the Examiner asserts that there is support for the device of Cox being able to be placed in any vascular abnormality in that Cox explicitly states "'embodiments of devices and methods herein are directed to blocking a flow of fluid through a tubular vessel or into a small interior chamber of a saccular cavity within a mammalian body'" and "an atrial appendage can reasonably be interpreted as a subset of 'saccular cavities' and within the scope of the teachings of Cox." *Id.* (quoting Cox ¶ 2). We agree with the Examiner that the recitation of "for an atrial appendage" is

merely an intended use and lacks patentable weight. Regardless, and even if that recitation carries patentable weight, the device of Cox would be capable of being placed in an atrial appendage, which is all that would be required in that the claim recites no particular functionality of the device upon its placement in the atrial appendage. Appellant appears to concede that "a suitably dimensioned device of Fig. 43 of Cox may physically be positioned within an atrial appendage." Appeal Br. 15.

Appellant next argues that:

> the Examiner's proposed modifications of Cox, the exchange of the proximal end of the device for the distal end of the device within the aneurysm would place the defect spanning structure membrane, mesh or microfiber matrix deep within the aneurysm and would fail to substantially block flow into the defect 106 at the mouth thereof or otherwise isolate the vascular defect 106 when the device 500 is deployed in an expanded state. Similarly, relocating the defect spanning structure from the small diameter proximal end as disclosed by Cox to the large distal end would also fail to substantially block flow into the defect 106 at the mouth thereof or otherwise isolate the vascular defect 106 when the device 500 is deployed in an expanded state. Both of the proposed modifications to Cox would alter the principle of operation of the device[,] rendering the resulting device unsuited for its intended purpose.

Appeal Br. 16–17.

We do not find these arguments persuasive. The Examiner has explained adequately that having the filter at one end or at the other end of the device would be dependent on where the device is to be placed in the body, and also that Cox itself discloses that a filter can be on either end of its devices depending on the location and orientation of the particular device. Final Act. 5–6; Ans. 3–4 (citing Cox ¶¶ 176, 201–209, Figs. 20, 25–27). Appellant has not provided any factual evidence or persuasive technical

reasoning to explain why ensuring that the defect spanning structure is at the end of the device that is located at the mouth of the defect, depending upon how the device is intended to be delivered and employed within the human body, would have been beyond the level of ordinary skill in the art or unpredictable to a person of ordinary skill in the art. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). We agree with the Examiner one of ordinary skill in the art would recognize that the device of Cox could have the defect spanning structure at different ends of an occlusion device depending upon how and where the occlusion device was going to be placed in the human body. Final Act. 5.

For the foregoing reasons, Appellant does not apprise us of error in the Examiner's determination that Cox renders obvious the subject matter of independent claim 1. Accordingly, we sustain the rejection of claim 1, and claims 2–5, 7–14, 16, 18, and 19 falling therewith, under 35 U.S.C. § 103 as unpatentable over Cox.

Rejection II

Claim 15 recites that "the distal strut ends in part or completely differ in wall thickness and/or a strut width from the other struts of the cage-like structure." Appeal Br. 21 (Claims App.). The Examiner determines that Cox does not explicitly teach this feature, although the Examiner notes that Cox teaches that the struts may have a variety of cross-sections. Final Act. 11 (citing Cox ¶ 126). The Examiner turns to Ferrera, finding that "Ferrara teaches an implantable cage device in which the struts have varying thicknesses." *Id.* (citing Ferrera ¶¶ 41, 246, 285). The Examiner also finds that "Ferrera teaches that varying the thickness of the struts allows the device to be more flexible overall, as well as allowing the device to bend in

more directions without breaking." *Id.* at 11–12 (citing Ferrera ¶ 285). The Examiner concludes that it would have been obvious "to modify the device as taught by Cox to include varying strut thickness as taught by Ferrera at the distal strut ends so as to impart additional flexibility to the device ensuring that it is sufficiently flexible to fill the desired space." *Id.* at 12.

Appellant argues that the Examiner's stated reasoning "does not appear to address a disclosed deficiency of the device of Cox which is not disclosed as requiring flexibility or bending" and that "there appears to be no expressed motivation for one of ordinary skill in the art to modify the structure of Cox to address a problem which does not appear explicitly to be present in the devices of Cox." Appeal Br. 17–18. To the extent that Appellant is insisting on an explicit teaching, suggestion, or motivation in Cox for the Examiner's proposed modification, such an argument has been foreclosed by the Supreme Court. *KSR*, 550 U.S. at 419 (stating that a rigid insistence on teaching, suggestion, or motivation is incompatible with its precedent concerning obviousness). Rather, the Court requires that we look to whether the Examiner has provided "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) (cited with approval in *KSR*, 550 U.S. at 418). Here, where Cox has a device with arched struts with a "reverse bend at each end" (Cox ¶ 203, Fig. 43), the Examiner has adequately explained why Ferrera's teachings of varying strut thickness for flexibility and/or bending are relevant to Cox. Moreover, it is not necessary for a determination of obviousness that the reference to be modified recognize or acknowledge a deficiency with its own design in order to provide a motivation to modify or improve it. *See KSR*, 550 U.S. at 417 ("[I]f a technique has been used to improve one device, and a person of

ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

For the foregoing reasons, Appellant does not apprise us of error in the Examiner's determination that the combination of Cox and Ferrera renders obvious the subject matter of dependent claim 15. Accordingly, we sustain the rejection of claim 15 under 35 U.S.C. § 103 as unpatentable over Cox and Ferrera.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–5, 7–14, 16, 18, 19	103	Cox	1–5, 7–14, 16, 18, 19	
15	103	Cox, Ferrera	15	
Overall Outcome			1–5, 7–16, 18, 19	

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