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MDT_RTGNV/Shumaker & Sieffert P.A.
Attn: IP Legal Department
826 Coal Creek Circle
Louisville, CO 80027

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NELSON, MICHAEL B	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte XIAODONG MA, JUNWEI LI, MIN-SHYAN SHEU, ANASTASIA RIGHTER, and ARIANA GILMORE

Appeal 2019-004523
Application 14/085,127
Technology Center 1700

BEFORE CATHERINE Q. TIMM, LILAN REN, and SHELDON M. MCGEE, *Administrative Patent Judges.*

REN, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1 and 4–14. *See* Final Act. 3. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "Medtronic plc of Dublin, Ireland, which is the ultimate parent entity of Covidien LP, a Delaware limited partnership, having a place of business in Mansfield, MA." Appeal Br. 3.

CLAIMED SUBJECT MATTER

The claims are directed to coated medical devices and "methods for coating medical implants, in embodiments implants made of inert materials such as metals, by immobilizing combinations of silanes on surfaces of the implants." Spec. ¶ 1. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A medical device, comprising:
>
> a substrate, wherein the substrate comprises a material selected from the group consisting of glass, ceramics, and metals, wherein the metal is selected from the group consisting of silver, copper, steel, aluminum, cobalt, chromium, titanium, niobium, tantalum, an alloy of silver, an alloy of copper, an alloy of steel, an alloy of aluminum, an alloy of cobalt, an alloy of chromium, an alloy of titanium, an alloy of niobium, an alloy of tantalum, and combinations thereof;
>
> a silane layer comprising at least one sulfur-functional silane and at least one additional silane, on at least a portion of the substrate;
>
> at least one additional component bound to the silane layer, the at least one additional component selected from the group consisting of monomers, polymers, bioactive agents, and combinations thereof.

Claims Appendix (Appeal Br. 19).

REFERENCES

The prior art references relied upon by the Examiner are:

Name	Reference	Date
Ferrera et al.	US 6,241,691 B1	June 5, 2001
Kyomoto et al.	US 2011/0027757 A1	Feb. 3, 2011
Nakatsuka	JP 2002038105 A	Feb. 6, 2002
Yumoto	H. Yumoto et al. *Anti-inflammatory and protective effects of 2-methacryloyloxyethyl phosphorylcholine polymer on oral epithelial cells* Society for Biomaterials 555–563 (2014)	2014

REJECTION

Claims 1 and 4–14 are rejected under 35 U.S.C. § 103 as being unpatentable over Kyomoto in view of Ferrera and Nakatsuka, with evidence from Yumoto. Final Act. 3.

OPINION

We review the appealed rejections for error based upon the issues identified by Appellant and in light of the arguments and evidence produced thereon. *Cf. Ex parte Frye*, 2010 WL 889747, *4 (BPAI 2010) (precedential) (cited with approval in *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) ("[I]t has long been the Board's practice to require an applicant to identify the alleged error in the examiner's rejections."). After having considered the

evidence presented in this Appeal and each of Appellant's contentions, we are not persuaded that reversible error has been identified, and we affirm the Examiner's § 103 rejection for the reasons expressed in the Final Office Action and the Answer. We add the following primarily for emphasis.

Claim 1[2]

Appellant argues that the Examiner reversibly erred in rejecting claim 1 for failure to provide a rationale to combine the references. Appeal Br. 7. Appellant argues that although Ferrera discloses a nickel-titanium stent with "a strand of radiopaque material, such as platinum or gold" (Ferrera Abstract) and Kyomoto discloses a stent having a titanium substrate (Kyomoto ¶ 69), a skilled artisan would not have "considered the Kyomoto stents to be insufficiently radiopaque" and would not "have looked to Ferrera or considered modifying Kyomoto in view of Ferrera." Appeal Br. 7. Appellant argues that Kyomoto discloses various materials and the skilled artisan "would begin the inquiry with an assessment of whether the listed materials in Kyomoto would provide such functionality rather than move to a secondary reference." *Id.*

We are not persuaded by this argument. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419–20 (2007). As the Examiner points out, Ferrera teaches gold or platinum as two preferred

[2] Appellant does not separately argue the obviousness rejections of claims 4–7 and 10–13. The rejections of these claims stand or fall with the obviousness rejection of claim 1. *See* Appeal Br. 15; *see also* 37 C.F.R. § 41.37(c)(1)(vii).

materials "to provide a radiopaque marker during interventional therapeutic treatment or vascular surgery." Ferrera Abstract (cited in Final Act. 4); *see* Ans. 7. Ferrara discloses these radiopaque materials "dramatically enhance[] the radiopacity of the" cable that forms Ferrara's stent. Ferrara 8:56–57.

This argument is not persuasive also because it lacks evidentiary support. "Attorneys' argument is no substitute for evidence." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989). As the Examiner points out, Appellant's argument that metals used in Kyomoto are sufficiently radiopaque is unsupported by evidence. Ans. 7. Appellant does not address the lack of evidentiary support. *See* Reply Br. 2–16. The argument is, therefore, unpersuasive of error in the Examiner's finding that it would have been "advantageous to include a radiopaque metal like gold in the stent substrate in order to allow the stent to be tracked via the [radiopaque] marker properties of the gold." Final Act. 4.

Appellant next argues that because Kyomoto states that "[i]t is essential to use . . . metal capable of forming a hydroxyl group on a surface of the metal by surface treatment" (Kyomoto ¶ 69), the Examiner fails to explain why the skilled artisan "would have considered 'gold with the titanium,' as a viable substrate material that contacts the binder layer." Appeal Br. 8–9.

This argument is not persuasive. The Examiner explains that Ferrera describes the advantages of including gold in a stent and accordingly finds that "the substrate that results from the combination of Kyomoto and Ferrera would still include exposed titanium portions and therefore would still include the hydroxyl groups for bonding with the silane layer." Ans. 9. "[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." *KSR*, 550 U.S. at 417. In this case, the Examiner explains that the gold and titanium in the proposed combination each improves the stent as taught by the prior art. *See id.* Appellant's additional argument that a skilled artisan would not have had a reason to consider further modification based on Kyomoto and Ferrera (Reply Br. 8) – even if supported by evidence – does not identify error in the Examiner's conclusion that it is within the ordinary skill to apply the prior art teachings.

Appellant next argues that a skilled artisan would not have combined Nakatsuka with Kyomoto because "Nakatsuka is directed to solving a different problem than the problem addressed in Kyomoto." Appeal Br. 14. According to Appellant, "Nakatsuka describes formulation used as dental adhesives" which "is not described in the context of improving the adhesion of silane binders in general." *Id.* at 13–14 (emphases omitted).

To the extent that Appellant's argument is that Nakatsuka is non-analogous art, the correct focus of the analogous art test is not whether the prior art references are analogous to each other, but whether the references are analogous art to the claimed subject matter. *In re Kahn*, 441 F.3d 977, 986–7 (Fed. Cir. 2006). Therefore, Appellant's argument is unpersuasive because it does not apply the correct legal standard. Moreover, Appellant's argument does not identify error in the Examiner's finding that the silane in Kyomoto and Nakatsuka are similar in chemical structure. *Compare* Ans. 7–8, *with* Reply Br. 13.

Appellant's argument about the predictability of success is also unpersuasive. *See* Appeal Br. 14 (arguing, for example, that "Nakatsuka fails

to disclose or suggest that such adhesives would improve adhesion of the phosphorylcholine biocompatible layer of Kyomoto or provide an explanation as to why one of ordinary skill in the art would have considered the Nakatsuka dental adhesives relevant for such purposes"). First and foremost, all of the features of one reference need not be bodily incorporated into the other reference and the skilled artisan is not compelled to blindly follow the teaching of one prior art reference over the other without the exercise of independent judgment. *See Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984). Moreover, the Examiner finds that all the recited structural components are known in the art and each such component serves its known purpose in arriving at the recited apparatus. *See KSR*, 550 U.S. 398, 416 (2007). "Obviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988).

The rejection of claim 1—and, the rejection of claims 4–7 and 10–13 that depend from claim 1—is sustained for no reversible error has been identified.

Claims 8 & 9

Appellant argues claims 8 and 9 as a group. These claims recite various compositions of the "at least one additional component bound to the silane layer." *See* Appeal Br. 15. The dispositive limitation is "wherein the at least one additional component bound to the silane layer is selected from . . . phosphorylcholiness" as recited in claim 8. *See id.* at 20.

Appellant argues that the Examiner reversibly erred in failing to explain that the combined structure would have "sufficient compatibility

with the outer biocompatible coating of phosphorylcholine described in Kyomoto." Appeal Br. 15. We are not persuaded by this argument. As noted *supra*, "[o]bviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d at 903–04. The claim language at issue does not require a particular level of biocompatibility and Appellant does not structurally distinguish the prior art. The rejection is therefore sustained.

Claim 14

Claim 14 depends from claim 1 and additionally recites "wherein the medical device comprises a stent."

Appellant argues that the Examiner reversibly erred because the prior art stents have "different constructions, components, and functionality." Appeal Br. 16. Appellant argues that the prior art references show "conflicting stent structures" and the Examiner fails to explain how a modification would have been made. *Id.*

As noted *supra*, all of the features of one reference need not be bodily incorporated into the other reference. *Lear Siegler*, 733 F.2d at 889. The claim language of claim 14 requires no more than "a stent" which is undisputedly taught in the prior art. The rejection of claim 14 is sustained.

CONCLUSION

The Examiner's rejection is affirmed.

More specifically,

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 4–14	103	Kyomoto, Ferrera, Nakatsuka, Yumoto	1, 4–14	
Overall Outcome:			1, 4–14	

TIME PERIOD FOR RESPONSE

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