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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHARLES H. CRAIG, HERBERT R. RADISCH JR.,
THOMAS A. TROZERA, DAVID M. KNAPP, TIMOTHY S. GIRTON,
and JONATHAN S. STINSON

Appeal 2014-003692¹
Application 12/955,522²
Technology Center 3700

Before JENNIFER D. BAHR, STEFAN STAICOVICI, and
KEN B. BARRETT, *Administrative Patent Judges*.

STAICOVICI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

¹ The instant appeal is related to Appeal Nos. 2007-2379 (10/112,391, mailed Jan. 31, 2008), 2008-2994 (10/103,411, mailed Jan. 15, 2009), 2010-006353 (10/103,411, mailed June 16, 2011), and 2010-007318 (10/112,391, mailed Sept. 28, 2010).

² According to Appellants, the real party in interest is Boston Scientific Scimed, Inc. Appeal Br. 1 (filed July 29, 2013).

Charles H. Craig et al. (Appellants) appeal under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1–3, 5–10, and 19–26.³ We have jurisdiction over this appeal under 35 U.S.C. § 6(b).

SUMMARY OF DECISION

We AFFIRM.

INVENTION

Appellants' invention relates to an intravascular stent manufactured from a radiopaque alloy. Spec. 1, ll. 16–18.

Claims 1 and 22 are independent. Claim 22 is illustrative of the claimed invention and reads as follows:

22. An intravascular stent consisting of an alloy comprising about 11 to about 18 wt.% chromium, about 5 to about 12 wt.% nickel, at least about 15 wt.% iron, and about 5 to about 50 wt.% platinum, the stent having a generally tubular structure defined by a plurality of interconnected struts having interstitial spaces therebetween, the stent being expandable from a first position, sized for insertion into a vessel, to a second position, where at least a portion of said stent is in contact with a vessel wall of the vessel.

³ Claims 4 and 11–18 are canceled. Appellants' Amendment 2–3 (filed Dec. 20, 2012).

REJECTIONS

The following rejections are before us for review:

- I. The Examiner rejected claims 1, 3, 6, 19–22, and 24 under 35 U.S.C. § 103(a) as being unpatentable over Dang (US 6,471,721 B1, iss. Oct. 29, 2002), Nishikawa (JP 55-131157, pub. Oct. 11, 1980)⁴, and with evidentiary support from Tu (US 6,077,298, iss. June 20, 2000) and Fischell (US 5,607,442, iss. Mar. 4, 1997).
- II. The Examiner rejected claims 7, 8, 10, 25, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Dang, Nishikawa, with evidentiary support from Tu and Fischell, and Cox (US 6,273,911 B1, iss. Aug. 14, 2001).
- III. The Examiner rejected claims 2, 5, 9, and 23 under 35 U.S.C. § 103(a) as being unpatentable over Dang, Nishikawa, with evidentiary support from Tu and Fischell, Cox, and Del Corso (US 4,891,080, iss. Jan. 2, 1990).⁵

⁴ We derive our understanding of this reference from the English language translation. All references to the text of this document are to portions of the translation.

⁵ Although the Examiner fails to mention Fischell in Rejections II and III, as claims 7, 8, 10, 25, and 26 of Rejection II and claims 2, 5, 9, and 23 of Rejection III depend directly or indirectly from independent claims 1 and 22, we consider the omission a typographical error.

ANALYSIS

Rejection I

The Examiner finds that Dang discloses, *inter alia*, a 316L stainless steel intravascular stent including an expandable tubular body of interconnected struts with interstices therebetween. Final Act. 2–3 (citing Dang, Fig. 4) (transmitted Feb. 15, 2013). The Examiner further finds that because Dang discloses that “conventional metal stents are insufficiently radiopaque for fluoroscopic visualization,” Dang includes “radiopaque materials into grooves of a conventional stainless steel stent.” *Id.* at 3 (citing Dang, col. 1, ll. 42–67, col. 2, ll. 1–58, and col. 5, ll. 6–64). However, the Examiner finds that Dang’s stent material does not have the composition of each of independent claims 1 and 22. *Id.* Nonetheless, the Examiner finds that Nishikawa discloses a sweat and/or seawater corrosion resistant 316L stainless steel-platinum alloy having the composition of independent claims 1 and 22. *Id.* at 3–4. The Examiner further notes Tu’s disclosure of “vascular stents . . . formed from a biocompatible alloy of stainless steel and platinum” and Fischell’s disclosure that “[e]lectrolytic corrosion of metals is also a well known problem for implantable metals in the bloodstream.” *Id.* at 3. Thus, in view of the disclosures of Tu and Fischell, the Examiner concludes that it would have been obvious for a person of ordinary skill in the art to use the corrosion resistant 316L stainless steel-platinum alloy of Nishikawa to make the stent of Dang to “provide[] *improved radiopacity* and *improved corrosion resistance* as desired by stent manufacturers.” *Id.* at 4.

Appellants argue that because “Dang . . . discloses a composite body portion,” the stent of Dang does not “consist[] of a single alloy,” as per

independent claim 22, or include a “body portion that consists of a single alloy,” as per independent claim 1.⁶ Appeal Br. 3. Appellants also maintain that Nishikawa’s plated wristwatch band, like Dang, is a composite structure. *Id.* at 4; *see also* Nishikawa 2. Appellants further argue that based on the disclosures of Nishikawa, Tu, and Fischell, “[o]ne having ordinary skill in the art would not have had any reason to modify Dang’s stent to include only the claimed metal,” and thus “consist of a single alloy.” *Id.* at 3–4.⁷ Thus, according to Appellants, the Examiner’s “modification of Dang’s stent to use Nishikawa’s alloy alone, eliminating Dang’s radiopaque material, represents a wholesale redesign of Dang’s stent” and thus, it “would change the principle of operation of” Dang’s stent. *Id.* at 5.

We appreciate that the stent of Dang is not manufactured from a single alloy, as called for by independent claims 1 and 22, and that Nishikawa discusses plating the disclosed alloy relied upon by the Examiner. However, obviousness does not require that all of the features of the secondary reference be bodily incorporated into the primary reference. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). In this case, we do not agree with Appellants that a person of ordinary skill in the art would not have been prompted to modify Dang’s stent with Nishikawa’s alloy, as the Examiner proposes. An improvement that is nothing more than the predictable use of prior art elements according to their established functions is likely to be

⁶ The transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520 (CCPA 1931).

⁷ According to Appellants, (1) Tu discloses a stainless steel-platinum alloy for making stents (*see* col. 3, ll. 21–24); and (2) Fischell discloses a gold plated stainless steel stent (*see* col. 2, ll. 61–67).

obvious. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007). Here, the Examiner's modification is an improvement to the stent of Dang to use the alloy of Nishikawa to lead to a predictable result, namely, to provide improved radiopacity and corrosion resistance. *See* Final Act. 4. This modification is well within the skill of one having ordinary skill in this art. *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.”). Given that: (1) Dang discloses using platinum as a radiopaque material in combination with a 316L stainless steel stent; (2) Nishikawa discloses a 316L stainless steel-platinum alloy that provides improved electrolytic corrosion resistance when compared to a 316L stainless steel material; (3) Tu discloses that stainless steel-platinum alloys can be used to manufacture a stent; and (4) Fischell discloses that electrolytic corrosion of metals is a well-known problem for implantable metals in the bloodstream, the Examiner's reasoning has rational underpinnings. *See* Dang, col. 5, ll. 17–19 and 38–44; Nishikawa, p. 2; Tu, col. 3, ll. 21–24, and Fischell, col. 2, ll. 54–67.

Furthermore, even though we appreciate Appellants' position that there is no support in either Tu or Fischell to replace a composite material structure, such as Dang's stent, with a single alloy, as taught by Nishikawa (*see* Reply Br. 1–2 (filed Feb. 5, 2014)), we note that The Supreme Court has rejected the rigid requirement that the rationale for the proposed combination come from within the references. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Here, in view of Tu's disclosure that

stainless steel-platinum alloys can be used to manufacture a stent and Fischell's disclosure that electrolytic corrosion of metals is a well-known problem for implantable metals in the bloodstream, the Examiner's modification is merely the use of Nishikawa's stainless steel-platinum alloy to make the stent of Dang. *See* Final Act. 4. The Examiner is correct in that such a modification provides improved corrosion resistance, while also providing radiopaque properties. *See* Ans. 8.

We also do not agree with Appellants that the Examiner's modification "would change the principle of operation of" Dang's stent. *See* Appeal Br. 5. Rather, we agree with the Examiner that the modification "results in a stent that remains suitable for implantation and addresses the issue of increasing radiopacity with platinum as desired in Dang, and further provides enhanced corrosion resistance." Ans. 8. We further agree with the Examiner that a person of ordinary skill in the art "would look to the specific alloys taught in Nishikawa because they would be expected to be biocompatible (as evidenced by Fischell) and provide enhanced radiopacity as desired in each of Dang and Tu." *Id.* (emphasis omitted).

Lastly, Appellants reference our Decision in related Appeal No. 2010-007318 (hereafter "Decision") and state that "[t]he BPAI never ruled that one having ordinary skill in the art would have found it obvious to eliminate Dang's radiopaque material" and further request that we "evaluate the pending claims with fresh eyes." Appeal Br. 5. Appellants note that in contrast to the claims presented in related Appeal No. 2010-007318, "the pending claims exclude the possibility of a device having Dang's composite structure." Reply Br. 1.

We do not agree with Appellants' assessment because we stated in our Decision that, "when the platinum-alloyed 316L stainless steel material of Nishikawa is used to make the *stent of Dang* . . . both corrosion resistance and radiopaque properties of the stent are improved." Decision 6 (emphasis added). Hence, as we refer to the "stent of Dang," we are referring to the entire stent, which includes both 316L stainless steel body 11 and platinum strips 13. As such, in contrast to Appellants' position, we did take into consideration in our Decision that the Examiner's modification replaces Dang's 316L stainless steel body 11 and platinum strips 13 with Nishikawa's stainless steel-platinum alloy. Nonetheless, even assuming *arguendo* that we were to accept Appellants' assertions, we are not persuaded because we agree with the Examiner that the "claim language 'consisting of' does not differentiate the claimed invention from the [combined] teachings of Dang, Nishikawa, Tu, and Fischell." Ans. 7. The Examiner's stated rejection sets forth that "the separate platinum layer and stainless steel layer [of Dang's stent] would be eliminated and replaced with [Nishikawa's] single material (an alloy of the stainless steel and platinum) to address the problems [of radiopacity and corrosion] noted in the prior art." *Id.* It is quite clear that when the platinum-alloyed 316L stainless steel material of Nishikawa is used to make the stent of Dang, as the Examiner proposes, the resulting stent does not require platinum strips 13 because the alloy already includes platinum for providing radiopaque properties.

In conclusion, for the foregoing reasons, we sustain the rejection under 35 U.S.C. § 103(a) of claims 1, 3, 6, 19–22, and 24 as unpatentable over Dang, Nishikawa, and with evidentiary support from Tu and Fischell.

Rejections II and III

As to the remaining rejections, Appellants rely on the same arguments presented *supra*. See Appeal Br. 5–6. Accordingly, for the same reasons as discussed above, we sustain the rejection under 35 U.S.C. § 103(a) of claims 7, 8, 10, 25, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Dang, Nishikawa, with evidentiary support from Tu and Fischell, and Cox. We also sustain the rejection of claims 2, 5, 9, and 23 as being unpatentable over Dang, Nishikawa, with evidentiary support from Tu and Fischell, Cox, and Del Corso.

SUMMARY

The Examiner’s decision to reject claims 1–3, 5–10, and 19–26 is affirmed.

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

AFFIRMED