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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TIMOTHY P. HARRAH, JIANMIN LI, and MARK W. BODEN

Appeal 2019-000846
Application 14/315,910
Technology Center 3700

Before JENNIFER D. BAHR, WILLIAM A. CAPP, and LEE L. STEPINA,
Administrative Patent Judges.

BAHR, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision rejecting claims 1–4, 6–9, 11, 12, 14, and 16–21.² We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Boston Scientific Scimed, Inc. Appeal Br. 2.

² Claims 5, 10, and 13 have been withdrawn from consideration, and claim 15 has been canceled. Appeal Br. 4.

CLAIMED SUBJECT MATTER

Appellant's invention is directed to "medical devices, and more particularly to ureteral stents for enhancing patient comfort." Spec. ¶ 2. Claims 1, 14, and 17 are independent. Appeal Br. 16–18. (Claims App.) Claim 14, reproduced below, is illustrative of the claimed subject matter.

14. A medical device, comprising:

an elongate member including at least four support members disposed around a central axis of the elongate member, each of the support members comprising a first material, and a second material, the second material surrounding and contacting an outer circumference of each of the support members, one of the first or second materials comprising a biodegradable or resorbable material or both, and the other of the first or second materials comprising a non-biodegradable material;

wherein at least two of the support members are arranged non-concentrically; and

wherein the medical device is configured to be implanted within a ureter.

EVIDENCE

The prior art relied upon by the Examiner is:

Udipi ³	US 6,918,929 B2	July 19, 2005
Carpenter	US 2008/0288057 A1	Nov. 20, 2008

REJECTIONS

- I. Claim 14 stands rejected under 35 U.S.C. § 112(b) as indefinite.
- II. Claims 1–4, 6–9, 11, 12, 14, 17, 18, and 21 stand rejected under 35 U.S.C. § 102(a)(1) as anticipated by Carpenter.

³ The Examiner and Appellant refer to this reference by the first-named inventor's first name "Kishore." *See, e.g.*, Final Act. 6; Appeal Br. 12.

- III. Claims 1–4, 6–9, 11, 12, 14, and 16–21 stand rejected under 35 U.S.C. § 102(a)(1) as anticipated by Udipi.
- IV. Claims 16 and 20 stand rejected under 35 U.S.C. § 103 as unpatentable over Carpenter.

OPINION

Rejection I—Indefiniteness

Appellant does not contest this rejection. *See* Appeal Br. 8–14. Thus, we summarily sustain the rejection of claim 14 under 35 U.S.C. § 112(b).⁴ *See In re Berger*, 279 F.3d 975, 984, 985 (Fed. Cir. 2002) (holding that the Board did not err in sustaining a rejection under 35 U.S.C. § 112, second paragraph, when the applicant failed to contest the rejection on appeal); Manual of Patent Examining Procedure (MPEP) § 1205.02, 9th ed., Rev. Aug. 2017 (“If a ground of rejection stated by the examiner is not addressed in the appellant’s brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it, unless the examiner subsequently withdrew the rejection in the examiner’s answer.”).

Rejection II—Anticipation by Carpenter

Appellant argues claims 1–4, 6–9, 11, 12, 14, 17, 18, and 21 together in contesting this rejection. *See* Appeal Br. 9–12. We decide the appeal of this rejection on the basis of claim 14, and the remaining claims stand or fall

⁴ Although claims 16 and 21 depend from claim 14 and, thus, would appear to inherit the deficiency of claim 14 identified in the rejection, the Examiner does not include claims 16 and 21 in the rejection. *See* Final Act. 3; *but see* Reply Br. 3 (requesting the Board to affirm “the rejection of claim 14 and its dependent claims under [35 U.S.C. § 112(b)]”).

with claim 14. *See* 37 C.F.R. § 41.37(c)(1)(iv) (permitting the Board to select a single claim to decide the appeal as to a single ground of rejection of a group of claims argued together).

The Examiner finds that Carpenter discloses a medical device as recited in claim 1, comprising, in relevant part, an elongate member (stent 11) including: (1) a plurality of (i.e., at least four) support members (stent struts 10) of a first material (i.e., metal) that is non-biodegradable and (2) a second material (layer 12) surrounding and contacting an outer circumference of each of the support members, wherein the second material is biodegradable or resorbable. Final Act. 5 (citing Carpenter, Fig. 1; ¶¶ 70, 223). The issue raised by Appellant in the Appeal Brief is whether Carpenter discloses that stent struts 10 are made of metal (i.e., non-biodegradable material). *See* Appeal Br. 11.

Appellant contends that paragraph 223 of Carpenter, which the Examiner cites in support of the finding that stent struts 10 are made of metal, “describes a metal stent made of 100% stainless steel,” which is thus “completely non-dissolvable,” while stent 11 of Carpenter’s Figure 1 “is completely dissolvable except for barrier layer 14.” *Id.* Thus, Appellant argues that the embodiment described in Carpenter’s paragraph 223 and the Figure 1 embodiment are “unrelated (and in fact mutually exclusive) embodiments of Carpenter.” *Id.*; *see also* Reply Br. 6 (arguing same).

In response, the Examiner finds that Carpenter discloses applying coatings containing a bioactive agent to stents in order to treat the vessel and aid in the healing process of the vessel to minimize the potential for restenosis, and that “[a] stainless steel stent is fully capable of having any of the surface coatings (paragraphs 68, 79) designed by Carpenter . . . applied

thereon and used to control the natural cellular response in a vessel in which the stent is implanted.” Ans. 4. Thus, the Examiner takes issue with Appellant’s suggestion that Carpenter does not disclose an embodiment comprising “non-biodegradable support members embedded within a material that is biodegradable or resorbable.” *Id.* The Examiner finds that Carpenter discloses these biodegradable or resorbable “surface coatings can be applied to any stent, and would embed the support members.” *Id.* (citing Carpenter ¶ 279 disclosing a dip coating process that, according to the Examiner, “inherently covers all surfaces when a stent is placed in polymeric coating having the bioactive agent”).

Appellant asserts that the stent of Carpenter’s Figure 1 embodiment “is completely dissolvable except for barrier layer 14,” but does not direct our attention to explicit disclosure in Carpenter that supports this assertion. *See* Appeal Br. 11. Carpenter characterizes Figure 1 as showing “a multilayered polymer-coated stent” and as showing a stent with stent struts and “a multilayered sheath or covering.” Carpenter ¶¶ 31, 69. Carpenter discloses that “[i]n *one embodiment*, the stent structure used in manufacture of the invention multilayered stent as well as the stents comprising a single layer of polymer covering . . . is made of a biodegradable and absorbable material.” *Id.* ¶ 75 (emphasis added). Carpenter also states that in the “multilayered biodegradable stents, the stent structure (i.e., the ‘stent struts’) is *preferably* biodegradable.” *Id.* ¶ 224 (emphasis added). However, Carpenter also discloses that “[t]he stent structure can be formed of any suitable substance, such as is known in the art, that can be processed . . . to contain the porous surface features described herein,” including “a

biocompatible metal, such as stainless steel.” *Id.* ¶ 222; *see also id.* ¶ 223 (disclosing an example of a metal stent structure material).

Appellant does not specifically identify any portion of Carpenter indicating that the disclosure in paragraphs 222 and 223 is not applicable to all stents discussed therein, including the embodiment of Figure 1. Although Carpenter *may* express a preference for a biodegradable stent structure in the multilayered stents, such as the stent of Figure 1, Carpenter discloses that the stent structure can be either metal (i.e., non-biodegradable) or biodegradable. *See* Carpenter ¶¶ 75, 222–24. Thus, Appellant does not apprise us of error in the Examiner’s finding that Carpenter discloses non-biodegradable stent struts 10 in the Figure 1 embodiment.

Appellant presents a new argument in the Reply Brief that was not included in the Appeal Brief. *See* Reply Br. 5. Appellant argues that “Carpenter explicitly states, ‘In coating a porous stent, care must be taken not to occlude pores in the stent structure.’” *Id.* (quoting Carpenter ¶ 220). According to Appellant, because Carpenter (¶ 223) describes stainless steel stents as including pores, coating such metal stents as described by Carpenter, including by dip coating, would not inherently embed the underlying support members as the Examiner states. *Id.* Appellant contends that “Carpenter’s definitions of a coating as **not** including the pores of the underlying stent is an implicit acknowledgement that ‘coating’ and ‘embedding’ are not synonymous.” *Id.* at 6. This argument is untimely, and Appellants do not present any evidence or explanation to show good cause why it should be considered by the Board at this time. *See* 37 C.F.R. § 41.41(b)(2) (“Any argument raised in the reply brief which was not raised in the appeal brief, or is not responsive to an argument raised in the

examiner’s answer . . . will not be considered by the Board for purposes of the present appeal, unless good cause is shown.”). We do note, however, that this line of argument is also unavailing for at least three additional reasons. First, although independent claims 1 and 17 recite that the support members are “embedded within” the biodegradable or resorbable material, independent claim 14, with which Appellant groups claims 1–4, 6–9, 11, 12, 17, 18, and 21 in arguing against this rejection, does not recite that the support members are “embedded within” the biodegradable or resorbable material. *See* Appeal Br. 16–18 (Claims App.). Second, Appellant’s Specification, which uses the word “embedded” only once, does not set forth a definition of the term or otherwise indicate that “embedded” is used in the Specification in a manner other than its ordinary and customary meaning, nor does Appellant elaborate on why Carpenter’s stent struts are not “embedded within” layer 12 shown in Figure 1. In particular, Appellant does not explain, and it is not apparent, why it would be necessary for the layer or coating to occlude the pores in the stent structure for the stent structure to be considered to be “embedded within” the layer or coating material. Third, in describing Figure 1, Carpenter expressly states that the multilayered polymer covering “encapsulates a stent structure.” Carpenter ¶ 69. Appellant does not explain why a stent structure encapsulated in a covering material would not be “embedded within” such covering material. Thus, Appellant’s argument regarding the “embedded within” limitation of claims 1 and 17 fails to identify a distinction between Carpenter and the claimed subject matter.

For the above reasons, Appellant does not apprise us of error in the rejection of claim 14 as anticipated by Carpenter. Accordingly, we sustain

the rejection of claim 14, as well as claims 1–4, 6–9, 11, 12, 17, 18, and 21, which fall with claim 14, as anticipated by Carpenter.

Rejection III—Anticipation by Udipi

The Examiner finds that Udipi discloses a medical device as recited in claims 1 and 17 comprising, in pertinent part, an elongate member (stent 120) including a plurality of support members (metal stent framework 226) embedded within a biodegradable or resorbable material (coating 222).

Final Act. 6, 8 (citing Udipi, Figs. 1–2; 5:50–60; 6:5–20; 7:8–15)

The Examiner finds that Udipi discloses a medical device as recited in claim 14, comprising, in relevant part, an elongate member (stent 120) including: (1) at least four support members (metal stent framework 226) comprising a first material that is non-biodegradable and (2) a second material (coating 222) that is biodegradable or resorbable surrounding and contacting an outer circumference of each of the support members. Final Act. 8 (citing Udipi, Figs. 1–2; 5:50–60, 6:5–20; 7:8–15).

Appellant argues that Udipi “fails to teach or suggest a plurality of support members embedded within such a material (as recited in claims 1 and 17), or at least four support members surrounded by such a material (as recited in independent claim 14).” Appeal Br. 13. Rather, Appellant contends, Udipi “simply discloses a stent . . . made of a single material, and which may include a coating around individual struts of the framework.” *Id.*

Appellant’s arguments do not persuasively identify a distinction between the claimed subject matter and Udipi’s stent. Although Udipi’s stent framework 226 may be a unitary structure, the framework does, as Appellant acknowledges (*id.*), comprise a plurality of individual struts of the

framework, which can be seen in cross-section in Figure 2 of Udipi. We discern no error in the Examiner considering each of these struts to be a support member as called for in claims 1, 14, and 17. Further, Udipi's stent framework 226 is coated with drug-polymer coating 222, thereby embedding the struts within the coating material, such that the struts are surrounded by the coating material. Notably, claims 1, 14, and 17 do not require that the second material (the biodegradable or resorbable material) comprise a single, unitary, monolithic body that surrounds the support members and embeds the plurality of support members within such a body.

Appellant asserts "that 'coating' and 'embedding' are not synonymous." Reply Br. 7. Appellant does not make this argument in the Appeal Brief, and, thus, the argument is untimely. *See* 37 C.F.R. § 41.41(b)(2). Further, as discussed above in regard to the rejection based on Carpenter, Appellant does not sufficiently elaborate on how the term "embedded" distinguishes over Udipi's stent framework struts being coated with drug-polymer coating 222. *See* Reply Br. 7.

For the above reasons, Appellant does not apprise us of error in the rejection of independent claims 1, 14, and 17 as anticipated by Udipi. Accordingly, we sustain the rejection of claims 1, 14, and 17, as well as their dependent claims 2-4, 6-9, 11, 12, 16, and 18-21, for which Appellant does not present any separate arguments, as anticipated by Udipi. *See* Appeal Br. 13.

Rejection IV—Obviousness

Aside from relying on the arguments presented for independent claims 14 and 17, from which claims 16 and 20 depend, and baldly disagreeing with

the Examiner's taking of Official Notice, Appellant does not present any substantive arguments contesting the rejection of claims 16 and 20 as unpatentable over Carpenter. *See* Appeal Br. 13–14. For the reasons discussed above, Appellant's arguments do not apprise us of error in the rejection of claims 14 and 17 and, likewise, fail to apprise us of error in the rejection of claims 16 and 20, which we, thus, sustain.

DECISION

The Examiner's decision rejecting claims 1–4, 6–9, 11, 12, 14, and 16–21 is AFFIRMED.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
14	§ 112(b)	14	
1–4, 6–9, 11, 12, 14, 17, 18, 21	§ 102(a)(1) Carpenter	1–4, 6–9, 11, 12, 14, 17, 18, 21	
1–4, 6–9, 11, 12, 14, 16–21	§ 102(a)(1) Udipi	1–4, 6–9, 11, 12, 14, 16–21	
16, 20	§ 103 Carpenter	16, 20	
Overall Outcome		1–4, 6–9, 11, 12, 14, 16–21	

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