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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KIRK JOHNSON, JUAN A. LORENZO, and ROBERT SLAZAS

Appeal 2017-004379
Application 13/798,818
Technology Center 3700

Before ULRIKE W. JENKS, RICHARD J. SMITH, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants[1] submit this appeal under 35 U.S.C. § 134 involving claims to an occlusive device for endovascular treatment of an aneurysm and a method related to use of such a device. The Examiner rejected the claims as indefinite, anticipated, and obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE. A New Ground of Rejection is, however, entered on claims 1 and 16 for obviousness.

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[1] Appellants identify the Real Party in Interest as DePuy Synthes Products, Inc. Br. 1.

STATEMENT OF THE CASE

As background, the Specification explains that a "significant challenge for many current neck-occlusive techniques is to substantially block the aneurysm neck in the parent vessel and yet not impede flow into perforator-type blood vessels, also referred to as small branch vessels." *Id.* ¶ 8. Unintentional blockage of such perforator vessels can cause ischemia and severe damage to the patient. *Id.*

Appellants' "invention relates to implants within body vessels and more particularly to occlusive devices including stents which are irreversibly modified based on localized pressure differentials." Spec. ¶ 2. More specifically, the Specification explains that

> [t]his invention results from the realization that the neck of an aneurysm in a parent vessel can be occluded without also occluding nearby vessels, such as perforator vessels, communicating with the parent vessel by providing a device having frangible material, associated with pores, which irreversibly erodes or ruptures, including deforming, substantially only based on differential pressure and penetrating fluid flow into the perforator vessels. The device effectively senses the presence of an ostium of a perforator vessel and modifies itself to permit flow into the ostium through one or more of the pores, thereby minimizing ischemia, while continuing to substantially block flow into the aneurysm.

Id. ¶ 16; *see also id.* at Fig. 1 (depicting a tubular, stent-like device (10) disposed).

Claims 1–8, 10–20, and 22–26 are on appeal. Claim 1 is illustrative and is reproduced below:

> 1. An occlusive device suitable for endovascular treatment of an aneurysm in a region of a parent vessel in a patient, comprising:
>
> a structure having pre-established pore features and having dimensions suitable for insertion into vasculature of the patient to reach the region of the aneurysm in the parent vessel; and
>
> a frangible material associated with the pore features to generate a first condition for the pore features which initially provides a substantial barrier to flow through the frangible material and, for at least a majority of the pore features, is capable of at least one of localized rupturing and localized eroding, in the presence of a localized pressure differential arising at an ostium of a perforator vessel communicating with the parent vessel to generate, within an acute time period, a second condition for pore features experiencing the localized pressure differential to minimize ischemia downstream of the perforator vessel, the frangible material remaining intact in the presence of a net-zero pressure differential arising at an aneurysm of a vessel, the frangible material includes a non-biodegradable portion and a biodegradable portion.

Br. 8 (Claims App.).

Claim 16 recites a method of treating an aneurysm by selecting, inserting, and positioning the occlusive device having the features substantially as recited in claim 1. Br. 9–10.

The claims stand rejected[2] as follows:

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[2] The Examiner also provisionally rejected the claims for statutory double patenting under § 101 for claiming the same invention. Final Act. 3–6. In the Answer, however, the Examiner indicates that the double patenting rejection "is withdrawn in response to the Terminal Disclaimer." Ans. 2. As a threshold matter, a terminal disclaimer does not overcome a *statutory*, same invention double patenting rejection. MPEP § 804. Nevertheless, because the application (U.S. Appl. No. 13/076,474) is now abandoned, the provisional double patenting rejection is moot.

I. Claims 1–8, 10–20, and 22–26 under 35 U.S.C. § 112, second paragraph, as indefinite.

II. Claims 1–4, 6, 8, 14–18, and 24–26 under 35 U.S.C. § 102(b) as anticipated by Molaei.[3]

III. Claims 5, 7, 19, and 20 under 35 U.S.C. § 103(a) as obvious over Molaei.

IV. Claims 10–13, 22, and 23 under 35 U.S.C. § 103(a) as obvious over Molaei and Boismier.[4]

Appellants indicate that they are aware of no related appeals. Br. 2. The Board, however, notes related Appeal No. 2016-003831 (U.S. Appl. 13/076,474 ("the '474 Application")), which was pending at the time this appeal was filed. The Specification states that the present application claims priority to the '474 Application and that it is incorporated by reference in its entirety. Spec. ¶ 1. The Board has since decided this other appeal, affirming the rejections for obviousness and double patenting. *In re Slazas*, No. 2016-003831 (PTAB Aug. 10, 2017).[5]

INDEFINITENESS

The Examiner rejected all the claims on appeal for indefiniteness. Final Act. 7. According to the Examiner, the claim language is amenable to two plausible constructions and, therefore, "the metes and bounds of the

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[3] Molaei et al., US 2006/0259131 A1, published Nov. 16, 2006.
[4] Boismier et al., US 2008/0071348 A1, published Mar. 20, 2008.
[5] The claims in the related appeal appear to have substantially the same scope as the claims here, hence the "same invention" double patenting rejections made in both cases. A different examiner rejected the claims for obviousness over different combinations of art than in this case.

subject matter defined by claims 1 and 16 [and the respective dependent claims] are rendered unclear." *Id.* The Examiner asserts that the "structure" and the "frangible material" recited in claim 1, for example, may be interpreted as two separate elements or as the same thing. *Id.*; Ans. 2–3.

We do not agree with the Examiner's interpretation. As Appellants point out, the "structure" and the "frangible material" are "two different elements of the claim." Br. 5. They may be made of the same or different compounds/substances, but that does not demonstrate indefiniteness. To the contrary, the "structure" defines certain shape and dimensional characteristics of the occlusive device — providing "pre-established pore features" and a size that is suitable for insertion into a patient's vasculature. Br. 8. The "frangible material," on the other hand, defines a further feature of the pores themselves, specifically a material "associated with" the pores that is capable of providing, e.g., localized rupturing or eroding under differential pressure. *Id.* On this record, we conclude that the claims are reasonably clear and definite.

ANTICIPATION

The Examiner has rejected independent claims 1 and 16 (and several dependent claims) as anticipated by Molaei. Final Act. 8–11. The Examiner finds that Molaei's Figure 8 (and features of the device shown in that figure) meets all the limitations of claims 1 and 16. *Id.* at 8–10. Figure 8a of Molaei is reproduced below.

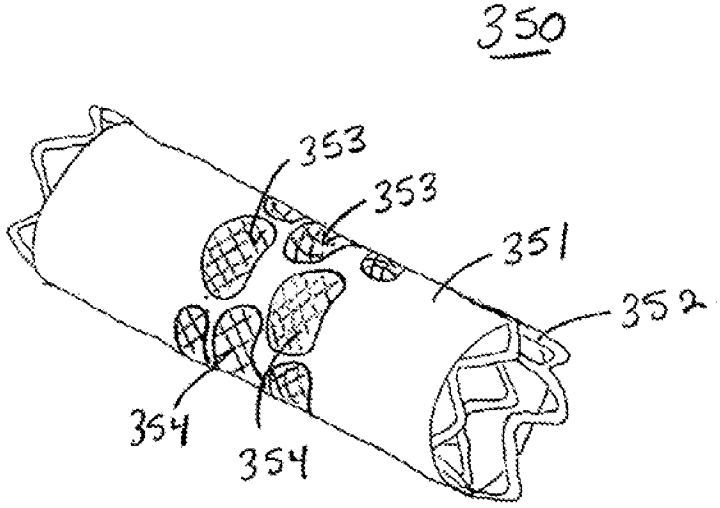

Fig. 8a

Figure 8a of Molaei depicts an endoprosthesis (350) with degradable layers (354). Molaei ¶ 70. Molaei describes that the tubular member (351) includes a plurality of fenestrations (353) that are initially occluded by a degradable layers (354), thus initially obstructing passage between the interior and the exterior of a blood vessel. *Id.* After the endoprosthesis is deployed, "layer **354** degrades and may open fenestrations **353** entirely," such as shown in Molaei's Figure 8b. *Id.*; *see also id.* at Fig. 8b.

According to the Examiner, the embodiment in Molaei's Figure 8 shows a first condition where a frangible material is non-degraded and shows a second condition where the material is fully degraded. Final Act. 8–9. Because the Examiner reasons that "*material degrades in the presence of blood flow, under any pressure differential*," the Examiner finds Molaei's Figure 8 meets the claim requirement that the material is capable of eroding in the presence of a localized pressure differential arising at the ostium of a perforator vessel. *Id.* Regarding the recitation in claim 1 of the frangible

material remaining intact at a net-zero pressure differential arising at an aneurysm of the vessel, the Examiner finds that the frangible material shown in Molaei may remain intact immediately after deployment or without blood flow. *Id.* at 9.

Appellants contend that the "degradable layer 354 [of Molaei] will degrade regardless of pressure differential as admitted by the Examiner," and thus "Molaei fails to anticipate the present invention" because claim 1 requires the frangible material be capable of localized eroding/rupturing at a differential pressure at an ostium of a perforator vessel, while remaining intact at a net-zero pressure differential arising at an aneurysm of the vessel. Br. 5–6.

> [U]nless a [prior art] reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008).

We are unpersuaded the Examiner has shown by a preponderance of the evidence that the embodiment cited in Molaei meets all the limitations of claims 1 and 16. It is not clear, nor is it necessarily the case, that the degradable layer (354) covering the fenestrations (353) in Molaei's Figure 8 would exhibit the characteristics of the frangible material recited in the claims — remaining intact at the site of an aneurysm but selectively rupturing or eroding at the site of openings to perforator vessels based on a differential pressure. Other teachings and embodiments in Molaei (discussed below) suggest modifications that would appear to provide these

features, but the Examiner has not adequately cited to them. To the extent that picking from among distinct teachings in Molaei is appropriate, such picking and choosing invokes the issue of obviousness, not anticipation. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) ("[P]icking and choosing may be entirely proper in the making of a 103, obviousness rejection . . . but it has no place in the making of a 102, anticipation rejection").

For the reasons above, we reverse the rejection of claims 1 and 16 (and the respective dependent claims) as anticipated by Molaei.

OBVIOUSNESS

The Examiner rejected dependent claims 5, 7, 19, and 20 as obvious over Molaei, and claims 10–13, 22, and 23 as obvious over Molaei and Boismier. Final Act. 12–14. Those rejections, however, rely on the same limited teachings cited and unpersuasive analysis related to Molaei discussed above concerning the anticipation of independent claims 1 and 16. For that reason, we also reverse the rejections for obviousness on appeal.

NEW GROUND OF REJECTION

As explained further below, we enter a New Ground of Rejection of claims 1 and 16 under 35 U.S.C. § 103(a) as obvious over Molaei (or Molaei combined with Boismier).[6]

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[6] Should there be further prosecution, we leave to the Examiner to determine whether to reject any of other claims based on the combined art cited here or found in the related appeal discussed above. *See* 37 C.F.R. § 41.50(b); s*ee also* Manual of Patent Examining Procedure (MPEP) § 1213.02. Under 37 C.F.R. § 41.50(b), the Board may, in its decision, make a new rejection of one or more of any of the claims pending in the case. Because the authority

Molaei teaches an endoprosthesis that modifies the amount of velocity of blood passing between a primary vessel and an aneurysm in that vessel. Molaei ¶ 32, Figs. 1a, 1b. According to Molaei, such a prosthesis

> can be deployed to divert, reduce or block blood flow between vessel **26** and aneurysm **25**. The endoprosthesis can also reduce blood flow between vessel **26** and a feeder vessel **27**. If so deployed, prosthesis **100** may sufficiently reduce blood flow to allow clotting or other healing processes to take place within aneurysm **25** and/or opening **29**. . . . Prosthesis **100** can also (or alternatively) allow blood to pass between vessel **26** containing the prosthesis and adjacent vessels, e.g., feeder vessel **27**, while still providing reduced flow with respect to the aneurysm.

Id. In other words, Molaei teaches that it may be desirable to design an endoprosthesis that blocks (or substantially blocks) flow to an aneurysm while allowing some flow from the vessel through the device and into feeder (i.e., perforator) vessels.

Molaei goes even further in this regard. In embodiments, Molaei discloses that portions of the endoprosthesis (e.g., a center portion 326 as shown in Fig. 7b) may be structured to limit or prevent flow to an aneurysm, but allow flow to feeder vessels. Molaei ¶ 65 (also noting that the center portion may itself include fenestrations), Figs. 7a, 7b. According to Molaei, in embodiments, "[o]ver time following deployment, e.g., weeks, months, or even several years, center portion **326** degrades." *Id.* ¶ 66. Moreover, Molaei discloses that "[i]n other embodiments, center portion **326** includes a

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under 37 C.F.R. § 41.50(b) is discretionary, no inference should be drawn from the decision to exercise that discretion with respect to some but not all of the claims on appeal.

biodegradable portion and another portion, which is either not biodegradable or has a significantly different degradation lifetime." *Id.* ¶ 67. For example, Molaei teaches that

> [a] first portion . . . has a short degradation lifetime and is oriented to face feeder **27**. A second portion . . . has a longer degradation lifetime as is oriented to face aneurysm **25**. Accordingly, prosthesis **325** can provide both rapid reestablishment of flow between a vessel weakened by an aneurysm and a [feeder] vessel branching therefrom and long-term flow reduction with respect to the aneurysm itself.

Id. Molaei further teaches that markers may be included on the prosthesis/stent that aid with positioning of the prosthesis with respect to the aneurysm and feeder vessels. *Id.* Hence, the skilled person would understand that Molaei suggests that certain portions of the endoprosthesis facing an aneurysm may be tailored to biodegrade slowly (or not at all) while other portions adjacent feeder vessels are designed to degrade rapidly to reestablish flow between the vessel and the feeders.

In other embodiments, including the one relied upon by the Examiner, Molaei describes an endoprosthesis that includes a plurality of circumferential fenestrations (i.e., pore features) that are covered by degradable layers. *Id.* ¶ 70. Molaei discloses that the degradable layers may degrade upon deployment in the vessel to open the fenestrations. *Id.* And, like other embodiments, Molaei teaches that markers may be included to indicate the orientation of the fenestrations relative to an aneurysm or feeder vessels. *Id.* ¶ 71.

Molaei teaches that several biodegradable polymers may be used with its embodiments. Among those polymers, Molaei identifies polyglycolic

acid and polycaprolactone. *Id.* ¶ 47. Molaei also teaches, in embodiments, that the polymers may be provided in coatings of various thicknesses, e.g., 35 μm. *Id.* ¶ 69; *see also id.* ¶ 61 (describing use of polymer bands having a thickness of "about 50% of a . . . thin film [less than about 50 μm (¶ 8)]," hence about 25 μm or less). Molaei teaches that polymers may be selected based on the mechanical or chemical properties desired. *Id.* ¶¶ 41–42.

Based on the foregoing, it would have been obvious to design an occlusive device like one shown in Molaei's Figure 8, which includes several fenestrations (pores) along its length. It would have further been obvious to design or modify the degradable polymer layer associated with those fenestrations so that some portions (those facing feeder vessels) of the polymer will rupture or erode rapidly, while other portions (those facing an aneurysm) will erode slowly, or not bioerode at all. The skilled person would have been motivated to make this modification with a reasonable expectation of success based on the express teachings of Molaei, which describe the advantages of including a material that erodes in a differential pattern. *See*, *e.g.*, *id.* ¶¶ 32, 65–67. And this would involve little more than either substituting or slightly modifying the biodegradable layers in one embodiment for another. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.").

As noted above, Molaei also discloses that the biodegradable polymers may include polyglycolic acid or polycaprolactone. Appellants' Specification and claims use the same polymers for forming the recited "frangible material." *See* Spec. ¶ 18; Br. 8 (pending claim 4). As evidenced

by Boismier, it was known in the art that polyglycolic acid (PGA) bioerodes quickly and polycaprolactone more slowly. Boismier ¶¶ 8, 65. Molaei also suggests thicknesses for its polymer layers (e.g., 35 μm) that squarely falls within the range of acceptable thicknesses for the frangible material described and claimed by Appellants. Spec. ¶ 18; Br. 9 (pending claim 6 (reciting a range of 10–500 microns)).

We thus find, under these circumstances, that Molaei teaches or suggests a substantially identical device and method compared to what is claimed. Absent persuasive evidence to the contrary, a device constructed by following Molaei's teachings would include the claimed "frangible material" and would be expected to exhibit the selective rupturing or eroding at the different pressures recited in the claim. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).[7]

For the reasons above, we conclude claims 1 and 16 would have been obvious over Molaei (or Molaei in combination with Boismier).

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[7] To the extent Appellants' argument (Br. 5) suggests that the phrase "the frangible material remaining intact in the presence of a net-zero pressure differential arising at an aneurysm of a vessel" requires absolutely no erosion of the material at that site or that the material remain intact permanently, we are not persuaded that this is the broadest reasonable interpretation of the claims. To the contrary, the Specification states that the device "substantially block[s] flow into the aneurysm" and further indicates that preferably the frangible material provides a flow barrier at the neck of the aneurysm for eight to twelve weeks. Spec. ¶¶ 16, 37.

SUMMARY

We reverse the rejections for indefiniteness, anticipation, and obviousness on appeal. We enter a New Ground of Rejection of claims 1 and 16 under 35 U.S.C. § 103.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

> When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground 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. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing.* Request that the proceeding be reheard under §41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the MANUAL OF PATENT EXAMINING PROCEDURE § 1214.01 (9th Ed., Rev. 07.2015, Nov. 2015).

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).

REVERSED; 37 C.F.R. § 41.50(b)