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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* CLAUS HARDER, MARC KUTTLER,  
BODO GEROLD and HEINZ MUELLER

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Appeal 2011-005923  
Application 11/221,344  
Technology Center 1700

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Before CHARLES F. WARREN, LINDA M. GAUDETTE, and  
KAREN M. HASTINGS, *Administrative Patent Judges*.

WARREN, *Administrative Patent Judge*.

DECISION ON APPEAL

Applicants appeal to the Board from the final rejection of claims 1-6, 9 and 12-24. We have jurisdiction. 35 U.S.C. §§ 6 and 134(a) (2002); 37 C.F.R. § 41.31(a) (2010).

Claims 1 and 21 illustrate Appellants' invention of an endoprosthesis, such as a stent (Spec. ¶ 0001), comprising a carrier structure which includes at least one component comprising a biocompatible, biodegradable magnesium alloy, and are representative of the claims on appeal:

1. An endoprosthesis comprising a carrier structure which includes at least one component comprising a biocompatible, biodegradable magnesium alloy of the following composition:

Rare earth metals: between at least about 2.0 and about 5.0% by weight, with neodymium between about 1.5 and about 3.0% by weight;

Yttrium: between about 3.5% and about 4.5% by weight;

Zirconium: between about 0.3% and about 1.0% by weight;

Balance: between 0 and about 0.5% by weight;

wherein the balance comprises any element other than rare earth metals, yttrium, zirconium and magnesium, and

magnesium occupies the proportion by weight that remains to 100% by weight in the alloy;

and wherein the composition comprises < 0.03% by weight of copper, < 0.005% by weight of nickel, < 0.03% by weight of mercury, and < 0.03% by weight of cadmium.

21. An endoprosthesis comprising a carrier structure which includes at least one component comprising a biocompatible, biodegradable magnesium alloy of the following composition:

Rare earth metals: between about 2.0 and about 5.0% by weight, with neodymium between about 1.5 and about 3.0% by weight and further including scandium;

Yttrium: between about 3.5% and about 4.5% by weight;

Zirconium: between about 0.3% and about 1.0% by weight;

Balance: between 0 and about 0.5% by weight;

wherein the balance comprises any element other than rare earth metals, yttrium, zirconium and magnesium, and

magnesium occupies the proportion by weight that remains to 100% by weight in the alloy.

Appellants request review of the grounds of rejection under 35 U.S.C. § 103(a) advanced on appeal by the Examiner: claims 1-6, 9 and 12-20 over

Harder ‘793 (EP 1 419 793 A1<sup>1</sup>), Kaese ‘293 (EP 1, 338 293 A1<sup>2</sup>), Tikhova (UK 1 378 281), and Morgan;<sup>3</sup> and claims 21-24 over Harder ‘793, Kaese ‘293, Tikhova, Morgan and Smola.<sup>4</sup> Br. 12; Ans. 4, 5.

We affirm the Primary Examiner’s decision that the appealed claims are unpatentable in view of the applied references.

However, we designate our affirmance of the grounds of rejection as involving new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (2010) because our affirmance is based on a different interpretation of the language of the appealed claims and thus our rationale for applying Harder ‘107 and Tikhova to independent claims 1 and 19 and claims dependent on claim 1, and Harder ‘107, Tikhova and Smola to claim 21 and claims dependent thereon is different than stated by the Examiner and considered by Appellants. We further need not consider Kaese ‘172 and Morgan with respect to either ground of rejection. *See, e.g., In re Stepan Co.*, 660 F.3d 1341, 1346 (Fed. Cir. 2011); *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011).

## OPINION

### A.

We interpret the language of claims 1, 19 and 21 by giving the terms

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<sup>1</sup> We refer to Harder ‘107 (US 2006/0246107 A1) relied on by the Examiner as a translation of Harder ‘793, which Appellants do not contest.

<sup>2</sup> We refer to Kaese ‘172 (US 6,854,172 B2) relied on by the Examiner as a translation of Kaese ‘293, which Appellants do not contest.

<sup>3</sup> J.E. Morgan, B.L. Mordike, *Development of Creep Resistant Magnesium Rare Earth Alloys*, 2 Strength Met. Alloys 643-8 (1983).

<sup>4</sup> B. Smola, I. Stulíková, F. von Buch, B.L. Mordike, *Structural aspects of high performance Mg alloys design*, Materials Science & Engineering A324 (2002) 113-117.

thereof the broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *See, e.g., In re Suitco Surface, Inc.*, 603 F.3d 1255, 1259-60 (Fed. Cir. 2010); *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1256 (Fed. Cir. 2007); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004); *In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).

The language of claim 1 specifies an endoprosthesis, such as a stent, which comprises at least a carrier structure that includes at least any component comprising at least any magnesium alloy that is biocompatible and biodegradable and contains, in percent by weight of the element, about 2.0 to about 5.0% of any “rare earth metal” as defined in the Specification, with at least neodymium present between about 1.5 and about 3.0%, such that if neodymium is the sole rare earth metal, it is present between about 2.0 and about 3.0% (Spec. ¶ 0014); between about 3.5% and about 4.5% of Yttrium; between about 0.3% and about 1.0% of zirconium; and the remainder up to 100% of magnesium. Spec. ¶¶ 0013, 0026, 0036.

Thus, where neodymium is the only rare earth element, the encompassed alloys range from an alloy containing about 2.0% neodymium, about 3.5% yttrium, about 0.3% zirconium, and about 94.2% magnesium, to an alloy containing about 3.0% neodymium, about 4.5% yttrium, about 1.0% zirconium, and about 91.5% magnesium. If other rare earth elements are present, the amount of neodymium can be 1.5%, and the other rare earth elements can be present from 0.5 to 3.5% depending on the amount of neodymium, and the amount of magnesium is adjusted accordingly.

We determine that the “balance” of any element(s) other than rare earth metals, yttrium, zirconium and magnesium can be “0” but can range up

to about 0.5%, with the amount of the “balance” element(s) reducing the amount of magnesium accordingly. Appellants disclose that the “balance” elements can be “impurities caused by the magnesium alloy production process” which are to be “avoided,” as well as any element(s) which affect mechanical and biocompatibility properties. Spec. ¶¶ 0015-0017, 0019; dependent claims 5, 14.

With respect to the “impurity” elements, according to Appellants the “proportions by mass of one, more or all of” such elements as disclosed can be present when the “balance” amount is greater than “0,” and the amount of the “impurity” if present is the “<” range specified for the elements copper, nickel, mercury and cadmium in claim 1, and the elements aluminum, silver, chromium and beryllium, as specified in dependent claims 6, 9, 12 and 13, respectively. Spec. ¶¶ 0015-0017. However, we fail to find any disclosure in the Specification that the magnesium alloy produced by any process would necessarily include any or all of the impurity elements copper, nickel, mercury and cadmium specified in claim 1, and optionally further include the impurity elements copper, nickel, mercury and cadmium in claims 6, 9, 12 and 13. Spec. ¶¶ 0015-0017, 0027, 0036. Thus, in light of the Specification, we determine that the “<” range specified for each of the optional impurity elements is 0 to the specified upper limit. For example, we interpret the limitation “< 0.03% by weight of copper” to encompass the range of 0 to less than 0.03% by weight of copper.

We note that we fail to find in the language of claim 1 or in the disclosure in the Specification any basis for Appellants’ contention that “the alloy in the claimed stent contains no more than about 88 percent magnesium and the total of the magnesium, rare earth metals, yttrium and

zirconium components in the alloy are no more than 90 percent by weight.” Response filed February 4, 2008. Indeed, the plain language of claim 1 encompasses magnesium alloys that contain more than 88% by weight of magnesium and require that the specified elements and “balance” constitute 100% by weight of the magnesium alloys.

Method claim 19 specifies that the endoprosthesis is made by a method comprising at least the step of extruding the same magnesium alloy specified in claim 1.

The language of claim 21 specifies a magnesium alloy that differs from that of claim 1 in the further limitation “and further including scandium” in the limitation on rare earth metals, and in the absence of the limitations on impurity elements. We find that “scandium” is included in the definition of “rare earth metal,” but the amount of scandium is not specified per se in claim 21 or in the Specification. Spec. ¶ 0012, 0014, 0026, 0036. Thus, we determine that the amount of scandium present in the magnesium alloys encompassed by claim 21 ranges from a mere presence up to about 3.5% by weight depending on the amount of neodymium and other “rare earth metals” present.

#### B.

We find that Harder ‘107 would have described to one of ordinary skill in the art an endoprosthesis, such as a stent, which comprises at least a carrier structure that includes at least any component comprising at least any magnesium alloy that is biocompatible and biodegradable, and includes one or more of the elements neodymium, yttrium and zirconium. Harder ‘107 ¶¶ 0020-0022, 0032-0038, 0045, 0058-0059, 0063-0070. Harder ‘107 would have described magnesium alloys having the composition, in % by weight:

1.5 to 4.4% by weight “rare earths (without yttrium),” 3.7 to 5.5% yttrium, balance <1%, magnesium >90%; and preferably magnesium alloys having the composition, in % by weight: 1.8 to 2.7% neodymium, 3.7 to 5.5% yttrium, 0.2 to 1.2% zirconium, with magnesium balance to 100%.

Harder ‘107 ¶¶ 0033-0038. Harder ‘107 would have described a commercially available magnesium alloy WE43 that has good workability and is biocompatible and biodegradable. Harder ‘107 ¶ 0038. Harder ‘107 would have described stent 10 comprising a magnesium alloy WE43 having the composition, in % by weight: 2.2% neodymium, 4.1% yttrium, 0.53% zirconium, balance <0.4%, and magnesium balance to 100%. Harder ‘107 ¶¶ 0060-0061, 0063-0069, Fig. 1.

We determine that one of ordinary skill in the art would have reasonably inferred that the thin support portions 14 and connecting legs 16 of stent 10 are formed at least in part by extruding the commercially available magnesium alloy WE43.<sup>5</sup> Harder ‘107 ¶¶ 0060-0061, Figs. 1, 2.

We further determine that while Harder ‘107 would not have disclosed each of the “rare earths” elements, one of ordinary skill in the art would have reasonably inferred that the term “rare earths” reasonably includes the elements yttrium and scandium as was well known.<sup>6</sup>

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<sup>5</sup> It is well settled that a reference stands for all of the specific teachings thereof as well as the inferences one of ordinary skill in this art would have reasonably been expected to draw therefrom, *see In re Fritch*, 972 F.2d 1260, 1264-65 (Fed. Cir. 1992); *In re Preda*, 401 F.2d 825, 826 (CCPA 1968), presuming skill on the part of this person. *In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985).

<sup>6</sup> *See, e.g., Lanthanides*, 14 *Kirk-Othmer Encyclopedia of Chemical Technology* 1091 (4th ed., John Wiley & Sons. 1995) (“The rare earths comprise lanthanides, yttrium, . . . and scandium.”).

We find that Harder '107 would not have disclosed that magnesium alloys can include impurity elements caused by processing, but as we found, one of ordinary skill in the art would have reasonably worked the magnesium alloys taught by Harder '107 to form stents. Harder '107 ¶¶ 0033-0038, 0060-0061, 0063-0068, Figs. 1, 2.

We find that Tikhova would have disclosed to one of ordinary skill in the art that in a magnesium alloy containing rare earths and zirconium, the combination of neodymium, yttrium and zinc provides high creep resistance and strength, and zirconium contributes to mechanical and casting properties. Tikhova 1:43-60. Tikhova would have described an alloy containing, in percent by weight of the element, 0.5 to 4.0% neodymium, 0.8 to 6.0% yttrium, 0.31 to 1.1% zirconium, 0.1 to 2.2% zinc, up to 0.05% copper, up to 0.2 manganese, and balance magnesium. Tikhova 1:43-48.

We find that Smola would have disclosed to one of ordinary skill in the art that the inclusion of small amounts of scandium and manganese in magnesium alloys containing rare earths, including yttrium, has a beneficial effect on creep behavior. Smola abstract, 114-15, 115, 116. Smola would have disclosed that magnesium forms intermetallic phases with scandium, and manganese is a grain refiner in magnesium alloys and forms similar intermediate phases with most rare earths as does magnesium. Smola 114-115. In magnesium alloys containing yttrium, the stability of the manganese-scandium phase is controlled by the amount of manganese, reducing the amount of “expensive” scandium in the magnesium alloys containing rare earths, scandium and manganese. Smola 115.

C.

We determine that one of ordinary skill in the art routinely following

the teachings of Harder ‘107 would have reasonably arrived at a stent which comprises at least a carrier structure that includes a magnesium alloy which contains rare earths, such as neodymium, as well as yttrium, zirconium, a balance of other elements, and magnesium in amounts that at least overlap with the amounts of these elements in the magnesium alloys included in the stents encompassed by claim 1, as we interpreted this claim above. Harder ‘107 ¶¶ 0033-0038. The amounts of the elements in the magnesium alloys described by Harder ‘107 also at least overlap with the amounts of the elements in the magnesium alloys in the stents encompassed by dependent claims 2-13 and 15-18. and in the stents prepared in the method of claim 19. *See, e.g., In re Harris*, 409 F.3d 1339, 1341-44 (Fed. Cir. 2005); *In re Peterson*, 315 F.3d 1325, 1329-30 (Fed. Cir. 2003).

Indeed, we find that stent 10 prepared with the magnesium alloy WE43 described by Harder ‘107 is encompassed by claims 1, 2, 4-13 and 15-19. Harder ‘107 ¶¶ 0063-0068. Accordingly while the ground of rejection of claims 1, 2, 4-13 and 15-19 over Harder ‘107 is under § 103(a), the evidence of a lack of novelty of the claimed stents is “the *ultimate* obviousness,” and thus, to the extent that Harder ‘107 anticipates the claimed processes encompassed by claims 1, 2, 4-13 and 15-19, the case of obviousness is not rebuttable by evidence. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991); *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982) (“[L]ack of novelty is the ultimate of obviousness. . . . That the rejection is here described as one under § 103 is not controlling, for it is not in this case rebuttable by evidence. Here we have the *ultimate* obviousness – lack of novelty. To recognize that fact is not to replace the rejection with a new one based on anticipation.”).

With respect to claim 14, Harder '107 does not specifically disclose that the magnesium alloys used to form the stents can contain zinc in “balance” in claim 1 on which claim 14 depends. However, we determine that one of ordinary skill in the art would have reasonably used zinc in the magnesium alloys of Harder '107 in the reasonable expectation of improving the creep resistance and strength of the magnesium alloys as shown by Tikhova in magnesium alloys containing amounts of neodymium, yttrium, zirconium, balance, and magnesium which overlap with the amounts of these elements in the magnesium alloys of Harder '107.

We point out that Harder '107 discloses a “balance” of other ingredients for the described magnesium alloys which corresponds to the “balance” in claim 1. While Harder '107 does not disclose that the “balance” includes impurities from the magnesium alloy production process as specified in claims 1, 5, 6, 9, 12 and 13, such impurities, if present, would be inherent in the magnesium alloys described by Harder '107. The properties of biocompatibility and biodegradability as well as mechanical integrity, the latter specified in claim 18, would also be inherent in the magnesium alloys described by Harder '107 and Tikhova. Indeed, the claimed stents and those of Harder '107 and Tikhova are the same or similar in design and prepared from the same and similar magnesium alloys having the same and overlapping amounts of elements, and thus the claimed stents and those of the references reasonably appear to be identical or substantially identical. Spec. Figs. 1, 2; Harder '107 Figs. 1, 2. *See, e.g., In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”).

With respect to method claim 19, we determine that one of ordinary skill in the art would have reasonably inferred from Harder '107 that stent 10 was formed at least in part by extruding the commercially available magnesium alloy WE43, which alloy falls within the magnesium alloys specified in claim 19 as we interpreted this claim above.

Accordingly, we are of the view that the endoprosthesis or stents prepared with magnesium alloys encompassed by claims 1-6, 9 and 12-20 would have been prima facie obvious to one of ordinary skill in the art over Harder '107 alone and as combined with Tikhova.

We further determine that one of ordinary skill in the art routinely following the teachings of Harder '107 and Smola would have reasonably arrived at a stent which comprises at least a carrier structure that includes a magnesium alloy which contains rare earths, such as neodymium and scandium, as well as yttrium, zirconium, a balance of other elements, and magnesium in amounts that at least overlap with the amounts of these elements in the magnesium alloys included in the stents encompassed by claim 21, as we interpreted this claim above. Harder '107 ¶¶ 0033-0038, 0063-0068; Tikhova 1:43-48; Smola abstract, 114-15, 115, 116.

We determined above that Harder '107 would have disclosed magnesium alloys encompassed by claim 1 to one of ordinary skill in the art, which alloys differ from the magnesium alloys specified in claim 21 in that Harder '107 does not specifically disclose that the "rare earths" which can be used in the magnesium alloys disclosed therein include scandium. We further determined that one of ordinary skill in the art would have reasonably inferred that the term "rare earths" in Harder '107 includes all rare earth elements which were known to include yttrium and scandium. We

determine that one of ordinary skill in the art would have reasonably used scandium and manganese in the magnesium alloys of Harder '107 as taught by Smola in rare earth containing magnesium alloys in the reasonable expectation that the scandium and manganese would improve the creep resistance of the magnesium alloys, and that the presence of manganese would reduce the amount of scandium necessary to achieve the improvement.

The properties of biocompatibility and biodegradability as well as mechanical integrity, the latter in claims 22 and 23, would be inherent in the magnesium alloys described by Harder '107 and Smola. Indeed, the claimed stents and those of Harder '107 and Smola are the same or similar in design and prepared from the same and similar magnesium alloys having the same and overlapping amounts of elements, and thus reasonably appear to be identical or substantially identical. Spec. Figs. 1, 2; Harder '107 Figs. 1, 2. *See, e.g., In re Spada*, 911 F.2d at 708.

Accordingly, we are of the view that the endoprosthesis or stents prepared with magnesium alloys encompassed by claims 21-24 would have been prima facie obvious to one of ordinary skill in the art over the combined teachings of Harder '107 and Smola.

D.

We have considered Appellants' arguments in the Brief as they pertain to the new grounds of rejection. We are not persuaded by Appellants' contention that one of ordinary skill in the art would not have combined Harder '107 and Tikhova because there would have been no reasonable expectation that the magnesium alloys would be biocompatible and biodegradable. Br. 17-18. Indeed, Harder '107 would have disclosed

that the magnesium alloys include a “balance” of unspecified elements, and Tikhova’s magnesium alloys containing the same elements in overlapping amounts as the alloys of Harder ‘107, include zinc in amounts which overlap with the “balance” in the alloys of Harder ‘107. We further are unconvinced by Appellants’ contention that one of ordinary skill in the art would not have combined Harder ‘107 and Tikhova because Tikhova teaches that the magnesium alloys are used at temperatures well above the “physiological temperature.” Br. 18-19. We determine that one of ordinary skill in the art would have considered the performance of the magnesium alloys at the temperature range(s) employed in methods of forming the stent, which is not argued by Appellants.

We are also not persuaded by Appellants’ contentions with respect to Appellant Harder’s testimonial evidence in the Declaration Under 37 C.F.R. § 1.132, filed October 13, 2009 (Harder Declaration). Br. 19-20. Indeed, Harder ‘107 discloses that magnesium alloys having neodymium, yttrium, zirconium, “balance” and magnesium encompassed by claims 1, 19 and 21 can be used for stents. Harder ‘107, e.g., ¶ 0046. Thus, contrary to Appellants’ contentions, one of ordinary skill in the art would have had a reasonable expectation of success in using the magnesium alloys of Harder ‘107 alone and as further combined with each of Tikhova and Smola in forming stents. Br. 21-24. We note that contrary to Appellants’ contentions, one of ordinary skill in the art routinely following the combined teachings of Harder ‘107 and Smola would have used scandium in the low amounts taught by Smola as a “rare earth” in the magnesium alloys of Harder ‘107. Br. 21-22.

Accordingly, having reconsidered Appellants’ arguments, including

consideration of the evidence in the Harder Declaration in light of Appellants' arguments in the Brief, as they pertain to the new ground of rejection which we have entered above, we remain of the opinion that the claimed invention is prima facie obvious over Harder '107 alone and as combined with each of Tikhova and Smola as we have applied these references to appealed claims 1-6, 9 and 12-24. Thus, the burden of going forward with respect to these grounds of rejection remains with Appellants.

The Primary Examiner's decision is affirmed, and we have entered new grounds of rejection pursuant to our authority under 37 C.F.R. § 41.50(b) (2010).

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (2010).

37 C.F.R. § 41.50(b) provides "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 C.F.R. § 41.50(b) also provides that 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 proceedings will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the application be reheard under § 41.52 by the Board upon the same record. . . .

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).

Appeal 2011-005923  
Application 11/221,344

AFFIRMED  
37 C.F.R. § 41.50(b)

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