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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHELE VIOLA MANUEL, HARPREET SINGH BRAR,
IDA E. SVENSSON BERGLUND, MALISA SARNTINORANONT,
and BENJAMIN G. KESELOWSKY¹

Appeal 2019-003912
Application 15/366,263
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and
JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies University of Florida Research Foundation, Inc. as the real party-in-interest. App. Br. 3.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–19 as unpatentable under 35 U.S.C. § 103(a) over the combination of Yang et al. (US 2010/0075162 A1, March 25, 2010) (“Yang”), Rathenow et al. (US 2005/0079200 A1, April 14, 2005) (“Rathenow”), and Boyden et al. (US 2010/0262239 A1, October 14, 2010) (“Boyden”).

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a non-toxic, bioresorbable alloy for use in implants that incorporates magnesium, calcium, and strontium.
Abstr.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

1. A bioresorbable, non-toxic, osteogenic magnesium alloy, said alloy comprising, by weight percentage:

0.3 to 10 percent calcium;

0.3 to 10 percent strontium; and

80 to 99.4 percent magnesium.

App. Br. 14.

ISSUES AND ANALYSIS

We agree with, and expressly adopt, the Examiner’s findings, reasoning, and conclusion that the claims are obvious over the prior art. We address below the arguments raised by Appellant.

Issue 1

Appellant argues that the claimed alloy would not have been “obvious to try” in view of the “broad genus” of alloys taught by the prior art. App. Br. 5–6.

Analysis

The Examiner finds Yang teaches “an implant consisting of a biodegradable magnesium-based alloy” with “excellent strength and interfacial strength to an osseous tissue.” Final Act. 5 (citing Yang Abstr.). The Examiner finds the biodegradable magnesium alloy is represented by the formula $Mg_aCa_bX_c$, wherein X is selected from a group of thirteen elements including strontium (Sr). *Id.* (citing Yang ¶ 10, claims 1–3). The Examiner finds Yang teaches the following molar ratios a, b, and c for each component: 50–100% Mg, 0–40% Ca, and 0–40% Sr. *Id.* The Examiner determines “it would have been obvious to one of ordinary skill in the art at the time of the invention to select any point within the ranges taught by Yang” to form the claimed biodegradable magnesium-based alloy with a reasonable expectation of success. *Id.* at 6.

Appellant argues the “fact that the claimed subgenus is encompassed by the broad genus of Yang is not sufficient by itself to establish *a prima facie* case of obviousness.” App. Br. 5 (citing *In re Baird*, 16 F.3d 380, 382

(Fed. Cir. 1994)). Appellant contends that “the Examiner is alleging that it would be obvious to try every combination of metal and molar ratio until one arrived at the claimed alloy.” *Id.*

Appellant argues further that “a claimed invention is not obvious to try when the prior art discloses ‘a broad selection of choices for further investigation.’” App. Br. 7 (citing *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1356 (Fed. Cir. 2013)). Appellant argues that “Yang’s formula covers over a billion combinations of alloys and their respective molar ratios” and Yang provides no guidance on how to narrow the broad genus to achieve the claimed combination. *Id.* Appellant argues that Yang teaches that component X is an impurity, and is included as a substitute for lower purity magnesium to decrease manufacturing costs, but not to create an alloy with improved properties. *See id.* at 7–8 (citing Yang ¶¶ 11, 49). Appellant argues, therefore, that Yang does not provide guidance “for selecting any of the various Xs having various values of ‘c,’ much less providing guidance for selecting Sr in particular for use in the alloy, or use of Sr at the percentage recited in claim 1.” *Id.* at 8.

We are not persuaded. The facts of the present appeal are distinguishable from those presented before our reviewing court in *Leo*. In *Leo*, our reviewing court determined that “[b]ecause the problem was not known, the possible approaches to solving the problem were not known or finite, and the solution was not predictable, it would not have been obvious for a person of ordinary skill to make the claimed invention.” 726 F.3d at 1356–1357. Particularly, the court found that:

While the record shows that ... the prior art indicated that both vitamin D analogs and corticosteroids were effective treatments

for psoriasis ... that same prior art gave no direction as to which of the many possible combination choices were likely to be successful. Instead, the prior art consistently taught away from combining vitamin D analogs and corticosteroids.

Id. at 1357.

In contrast to the unknown combination at issue in *Leo*, Yang teaches a: “biodegradable magnesium-based alloy” with “excellent strength,” “represented by Formula MgCaX” wherein X is an element “that is added on manufacturing an implant in the related art.” Yang ¶¶ 8, 10. Yang teaches X is one of thirteen specific elements, including strontium. *Id.* Contrary to Appellant’s argument, Yang provides specific guidance that the choice of alloy is one that is suitable for a biodegradable implant having a controlled biodegradation rate and excellent strength. Accordingly, the Examiner has identified detailed methodology for practicing the invention as well as evidence suggesting that the proposed modification would be successful. *See In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (“[T]he record shows that a skilled artisan would have had a resoundingly ‘reasonable expectation of success’ in deriving the claimed invention in light of the teachings of the prior art”).

With respect to Appellant’s argument regarding the molar ratios of each component of the alloy, our reviewing court has stated that “[a] *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art.” *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). Moreover, if “the claimed ranges are completely encompassed by the prior art, the conclusion is even more compelling than in cases of mere overlap.” *Id.* at 1330. Yang teaches a

biodegradable alloy for use in a surgical implant with molar ratios of 50–100% Mg, 0–40% Ca, and 0–40% Sr that encompass the ranges recited in the claims. Therefore, we agree with the Examiner that claim 1 is prima facie obvious over the prior art and we turn to Appellant’s evidence of unexpected properties. “[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious.” *Id.*

Issue 2

Appellant argues the claimed alloys have superior and unexpected properties. Reply Br. 3.

Analysis

Appellant contends that the claimed ternary alloys of magnesium, calcium, and strontium “have improved degradation and compressive strength as compared to other magnesium alloys.” App. Br. 9. Appellant argues that Examples 1–9 of the Specification demonstrate improved degradation rate and improved compressive strength of ternary alloys compared to binary Mg-Ca alloys with similar calcium content. *Id.* (citing Spec. ¶¶ 47–56). Appellant argues that the “findings were not predictable and are in fact unexpected” in view of Yang’s conclusion that “strontium was just another impurity like iron and nickel, which increase corrosion and decrease strength.” Reply Br. 4.

The Examiner responds that Yang teaches ternary alloys as claimed, and not the binary alloys distinguished by Appellant’s examples. *See* Ans. 6. The Examiner finds Yang teaches an implant with an easily controlled

biodegradation rate and excellent strength. *Id.* The Examiner determines that “the instant claims would have been obvious with the expected benefit of providing an implant in wherein the biodegradation rate can be easily controlled as well as have excellent strength and interfacial strength to an osseous tissue.” *Id.* at 7.

We are not persuaded by Appellant’s evidence of allegedly unexpected results. “When unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.” *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). Appellant has not provided any evidence directly comparing the claimed alloys to the prior art, and particularly to the ternary alloys taught by Yang, to demonstrate that the superior properties argued by Appellant are, indeed, unexpected.

Just as importantly, Appellant has not shown that the allegedly unexpected properties that Appellant claims are not inherently present in the alloys of Yang. Appellant argues that certain alloys within the claimed range have different properties compared to others outside of that range. However:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. ... Whether the rejection is based on “inherency” under 35 U.S.C. § 102, on “prima facie obviousness” under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO’s inability to

manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (C.C.P.A. 1977). Appellant has not demonstrated that the alloys of Yang do not possess these allegedly unexpected properties, and does not, therefore, overcome the Examiner's *prima facie* conclusion of obviousness.

Finally, Appellant argues that the claimed alloys possess “a significantly improved degradation rate” and an “improved compressive strength,” compared to related alloys outside the claimed range. In addition to our reasons explained *supra*, i.e., that Appellant has not compared the results to the closest prior art or shown that the alleged superior results are not inherent to the alloys of Yang, unexpected results that are probative of nonobviousness are those that are: “different in kind and not merely in degree from the results of the prior art.” *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (citation omitted). Appellant does not adduce any evidence of record to persuade us that the differences between the properties of the claimed alloys and those of the alloys taught by Yang are differences in kind, rather than merely of degree.

We are consequently not persuaded that the Examiner erred in concluding the claims are obvious over combined cited prior art and we affirm the Examiner's rejection of the claims.

CONCLUSION

The rejection of claims 1–19 as unpatentable under 35 U.S.C. § 103(a) is affirmed.

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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).

AFFIRMED

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1-19	103(a)	Yang, Rathenow, Boyden	1-19	