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Diane Dobrea
100 Pine Street
PO Box 1166
Harrisburg, PA 17108-1166

EXAMINER	
COUGHLIN, DANIEL F	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RYAN K. ROEDER, GABRIEL L. CONVERSE, and STEPHEN M. SMITH

Appeal 2019-002547[1]
Application 14/078,614
Technology Center 1600

Before JOHN E. SCHNEIDER, RYAN H. FLAX, and CYNTHIA M. HARDMAN, *Administrative Patent Judges.*

HARDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims related to a porous reinforced composite scaffold material. The Examiner rejected the claims as obvious under 35 U.S.C. § 103(a) and for obviousness-type double patenting. We heard Appellant's oral argument on March 2, 2020. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real parties in interest as "Inventors/Appellants, Ryan K. ROEDER, Gabriel L. CONVERSE, and Stephen M. SMITH, and Assignee HAPPE Spine, LLC." Appeal Br. 1.

CLAIMED SUBJECT MATTER

Claims 36–47 and 63 are on appeal. Final Act. 2. The claims are directed to a porous reinforced composite scaffold material. Claims 36 and 63 are independent. Claim 36, reproduced below, is illustrative of the claimed subject matter:

> 36. A porous reinforced composite scaffold material, comprising:
>
> a polyaryletherketone polymer, and a plurality of anisometric reinforcement particles comprising calcium phosphate crystals distributed essentially uniformly throughout the polyaryletherketone polymer;
>
> wherein the reinforced composite scaffold material comprises a substantially continuously interconnected plurality of pores that are uniformly distributed throughout the polyaryletherketone polymer, each of the plurality of pores defined by voids interconnected by struts, and having a size within the range from about 10 to 500 μm, and
>
> wherein anisometric reinforcement particles are both embedded within the polyaryletherketone polymer and exposed on the struts within the pore voids, and
>
> wherein the anisometric reinforcement particles are present from about 1 to about 60%, by volume, in the polyaryletherketone polymer, and
>
> wherein the scaffold is formed by mixing particles of the polymer, reinforcement, and a porogen within a fluid to obtain a substantially uniform mixture, removing the fluid, molding the particle mixture at a temperature from between 20 to 400 degrees C, and removing the porogen.

Appeal Br. 11 (Claims Appendix).

REFERENCES

The Examiner relied upon the following prior art references:

Name	Reference	Date
Yuan	US 6,887,408 B2	May 3, 2005
Trieu	US 2002/0115742 A1	Aug. 22, 2002
Roeder	WO 01/54746 A2	Aug. 2, 2001

REJECTIONS

Claims 36–47 and 63 stand rejected under 35 U.S.C. § 103(a) as being obvious over Trieu, Roeder, and Yuan. Final Act. 3.

Claims 36–47 and 63 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1–4, 6–8, 11, 12, 17–19, 21, and 24 of US 7,758,882 in view of Trieu and Yuan. Final Act. 11.

OPINION

Obviousness Over Trieu, Roeder, and Yuan

Examiner's Findings

The Examiner found that Trieu discloses orthopedic compositions that include a homogeneous mixture of a biocompatible polymer such as polyetheretherketone ("PEEK"), and a bioactive particulate ceramic such as hydroxyapatite ("HA"). Final Act. 5. The Examiner found, however, that Trieu discloses neither that the HA is anisometric, nor the process for producing porosity within the matrix. Final Act. 6; Ans. 4.

The Examiner found that Roeder and Yuan overcome these deficiencies in Trieu. Final Act. 6. Specifically, the Examiner found that Roeder discloses composite biomaterials comprising anisometric, crystalline calcium phosphate reinforcement particles, which can be made of HA. Final Act. 6. The Examiner found that Yuan discloses "porous poly(aryl ether

ketone) (PAEK) articles prepared from PAEK/polyimide blends by selective chemical decomposition and subsequent removal of the polyimide phase, wherein the articles exhibit highly interconnected pore structure and a narrow pore size distribution." Final Act. 7. The Examiner stated:

> The art of record, in combination, comes close to meeting all of the limitation[s] of the claimed 'species' of material. For example, the cited references disclose the same PEEK polymer matrix[2] (see Trieu '742), with the same anisometric hydroxyapatite reinforcement particles (Roeder WO '746), wherein the porous matrix of the composite material is prepared by a removing a porogen from a PEEK matrix formed from a blend of polymer and porogen prepared by wet mixing (Yuan '408).

Final Act. 16; *see also id.* 7–8. The Examiner asserted that one of skill in the art would have been motivated to combine these teachings of Trieu, Roeder, and Yuan based on the express teachings of Roeder directed to "the improved structural and mechanical properties of polymer/HA composites wherein the HA is in the form of anisometric crystals, such as in the shape of whiskers (*see* p. 22, ll. 11–15), and by the art-recognized utility of bone morphogenic proteins in the formation on [sic] new bone from implants." Final Act. 8.

With respect to the claim limitation reciting a pore size "within the range of about 10 to 500 μm," the Examiner acknowledged that Yuan discloses porous PAEK materials with smaller pore sizes (including below 0.25 μm), but argued that "the reference explicitly teaches that there are a number of factors affecting pore size, such as polyimide selection, blend processing conditions, and PAEK/polyimide blend ratio such that, for

[2] We note that the appealed claims recite the polymer PAEK, which is taught in Yuan, rather than PEEK. *See* Appeal Br. 11–13 (Claims Appendix).

example, low PAEK/polyimide ratios favor increased bulk porosity and increased pore diameter." Final Act. 15. The Examiner asserted that "modification of these parameters consistent with the teachings of Yuan '408 to produce porous PAEK/PEEK materials with pore sizes reading on the claimed range would amount to nothing more than optimization of a result-effective variable, the exercise of which is well with[in] the expertise of one of ordinary skill in the appropriate art." *Id.*

With respect to the limitation in claim 36 directed to the anisometric reinforcement particles being "exposed on the struts within the pore voids,"[3] the Examiner conceded that the cited references do not explicitly teach this limitation. Final Act. 9. The Examiner stated, however, that "composite particles prepared according to the teachings of the cited art, with high porosity and at a volume loading of the reinforcement particles as high as 60% in a PAEK thermoplastic polymer, would necessarily read on this limitation." *Id.* The Examiner further elaborated that "given teachings of the cited reference directed to the substantially uniform mixture of polymer, leachate, and calcium phosphate particles, the remaining solid polymeric material within the porous polymer matrix would necessarily display at least a portion of the calcium phosphate particles on the surfaces of the 'struts,' thus meeting this limitation." Final Act. 13.

[3] Discussion herein relating to this limitation of claim 36 also applies to the similar limitation of claim 63 reciting that the anisometric reinforcement particles "extend from a strut surface into a pore void." Appeal Br. 13 (Claims Appendix).

The Examiner construed the claims as product-by-process claims, and accorded the process limitations recited in claims 36 and 63 no patentable weight. Final Act. 9.

Analysis

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We conclude that the Examiner has not satisfied this burden.

Appellant argues that the Examiner has not established a prima facie case of obviousness because the cited combination of prior art fails to disclose the claimed pore size range ("from about 10 to 500 μm"). Appeal Br. 3–4. We agree. Yuan is directed to porous PAEK articles, which can be used as membranes for fluid separations such as microfiltration, ultrafiltration, and nanofiltration. Yuan Abstract. Yuan teaches that "[t]he porous PAEK articles of this invention are characterized by a narrow pore size distribution and frequently exhibit small average pore sizes. The average pore diameter can be below 1 micrometer, and frequently is below 0.25 micrometer." Yuan 12:10–15. As noted above, the Examiner concedes that Yuan discloses pore sizes smaller than those claimed, but asserts that pore size is a result effective variable, which a person of ordinary skill in the art would have optimized. Final Act. 15; Ans. 13.

While we agree that pore size appears to be a result effective variable, the Examiner has not established that in performing routine optimization of pore size, a person of ordinary skill in the art would have had a reasonable expectation of arriving at the claimed pore size range of about 10 to 500 μm (or, for that matter, motivation to do so). "The reasonable expectation of

success requirement refers to the likelihood of success in combining references *to meet the limitations of the claimed invention*." *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (emphasis added). The Examiner lists a number of variables that affect pore size, "such as polyimide selection, blend processing conditions, and PAEK/polyimide blend ratio." Final Act. 15. The Examiner, however, has provided no persuasive rationale as to how a person of ordinary skill in the art would have optimized these variables to the claimed range, or why they would have been motivated to do so, particularly where Yuan discloses PAEK articles having pore sizes at least an order of magnitude smaller.

Appellant additionally argues that the Examiner erred by relying on inherency with respect to the claim limitations requiring the anisometric reinforcement particles being "exposed on the struts within the pore voids" (claim 36), or "extend[ing] from a strut surface into a pore void" (claim 63). Appeal Br. 5. We agree. The record does not reflect persuasive reasoning why this feature would be inherent in the proposed prior art combination.

The Examiner reasoned that "composite particles prepared according to the teachings of the cited art, with high porosity and at a volume loading of the reinforcement particles as high as 60% in a PAEK thermoplastic polymer, would necessarily" result in anisometric reinforcement particles "exposed on the struts within the pore voids." Final Act. 9. The Examiner further stated:

> [G]iven teachings of the cited reference directed to the substantially uniform mixture of polymer, leachate, and calcium phosphate particles, the remaining solid polymeric material within the porous polymer matrix would necessarily display at least a portion of the calcium phosphate particles on the surfaces of the "struts," thus meeting this limitation.

Final Act. 13; *see also* Ans. 5. Thus, the Examiner cites several factors that purportedly result in anisometric reinforcement particles that are exposed on the struts within the pore voids, i.e., high porosity, volume loading of the reinforcement particles as high as 60% in a PAEK thermoplastic polymer, and a substantially uniform mixture of polymer, leachate, and calcium phosphate particles. The Examiner, however, has not provided any persuasive technical reasoning as to why these factors would necessarily result in exposed anisometric reinforcement particles.

Moreover, Appellant persuasively argues that it has "rebutted any purported basis in fact or technical reasoning for the inherency argument." Appeal Br. 5. Appellant argues that contrary to the Examiner's assertion, high porosity will not necessarily cause reinforcements to be exposed. Specifically, Appellant argues that Holy[4] "discloses scaffolds having about 56 vol% calcium phosphate reinforcements in a scaffold having 81-91% porosity," yet "the calcium phosphate reinforcements were shown to be encapsulated and not exposed." Appeal Br. 6; *see also* Third Roeder Declaration[5] ¶ 14(a). Appellant also argues that a volume loading of the reinforcement particles as high as 60% will not necessarily cause reinforcements to be exposed. Appeal Br. 5–6. Relying on the Third Roeder Declaration, Appellant explains that:

> the maximum packing factor for reinforcements in a polymer matrix, which is the point beyond which contained reinforcements would necessarily be exposed, is not affected by percentage porosity of the scaffold, and [] the maximum packing factor for non-spherical fibers is between 78.5 vol%

[4] Holy et al., US 2003/0008395 A1, published Jan. 9, 2003 ("Holy").
[5] Declaration Under 37 CFR § 1.132 by Ryan K. Roeder, dated September 27, 2017 ("Third Roeder Declaration").

> and 90.7 vol% (considerably higher than the loadings of 1 to about 60% recited in claims 36 and 63).

Appeal Br. 6; *see also* Third Roeder Declaration ¶¶ 10–15.

The Examiner did not persuasively respond to these assertions in the Final Action or the Answer. The Examiner noted that Appellant disputes inherency by relying on the "extent of porosity (as supported by hypothetical 'schematics')" and the "loading of reinforcement particles (*cf*. maximum packing factor)," and by citation to prior art (Ans. 6), but on this record, the Examiner did not persuasively address the substance of Appellant's arguments. The Examiner also generically noted that the conclusions Appellant draws from the data presented in the declarations are "flawed," but again, the record before us does not reflect the reasons why the Examiner believes the conclusions in the Third Roeder Declaration are flawed. Ans. 6.

The Examiner asserts that Appellant "incorrectly interprets (or over-interprets) [Holy] as teaching that the reinforcement particles are completely entrapped within the polymeric component of the matrix and, therefore, cannot be exposed within the pores of the matrix." Ans. 10. The relevant portion of Holy states: "Calcium phosphate crystals were trapped in the resulting scaffolds." Holy ¶ 112. The Examiner suggests that by this statement, Holy is merely conveying that the calcium phosphate crystals were "not washed from the matrix" in the same way Holy's sacrificial porogen particles are washed from the matrix. Ans. 12 (citing Holy ¶ 76, which states: "[T]he precipitated polymer does not form a coating that intimately envelops the [porogen] particles.").

We disagree with the Examiner's interpretation of Holy. Holy indicates that the calcium phosphate reinforcement crystals were added as a

means "to enhance the osteogenic and mechanical properties of the scaffold." Holy ¶ 112. As such, there is no reason why a person of ordinary skill in the art would have expected that these crystals would have been washed from the matrix during the preparation process. The better reading is to take Holy's statement at face value—the calcium phosphate crystals were trapped *in* the resulting scaffolds—i.e., not exposed in the pore voids. This reading of Holy is consistent with Dr. Roeder's testimony, which states: "Holy neither shows nor suggests that the trapped reinforcement particles are exposed on any surface of the scaffold." Second Roeder Declaration[6] ¶ 22. Accordingly, the Examiner has not persuasively established that Holy's solution process results in porous scaffold having reinforcements that are exposed in the pore voids.

Appellant further cites the Fifth Roeder Declaration,[7] which discusses preparation of a scaffold prepared according to a process that "approximat[ed] the Yuan melt mixing process." Appeal Br. 6. According to Appellant, the "resulting scaffold had HA whisker reinforcements embedded within the PAEK polymer with negligible exposure." *Id.* We are not persuaded by this experimental evidence. Yuan discloses both a wet-mixing process (or "solution [wet] process"), and a melt-mixing process. Yuan 10:16–37. The Examiner's rejection is based on Yuan's wet mixing process. *See* Final Act. 16 (citing wet mixing process), *id.* at 18–19 (stating that Yuan "discloses a wet mixing process that is substantially the same as

[6] Declaration Under 37 CFR § 1.132 by, dated September 5, 2017 ("Second Roeder Declaration").
[7] Declaration Under 37 CFR § 1.132 by, dated March 2, 2018 ("Fifth Roeder Declaration").

the process disclosed and claimed by Applicants"); Ans. 8 (citing wet mixing process). Because the basis for the rejection relied on Yuan's solution [wet] process, we find the experimental work conducted on the melt-mixing process to be of little probative value to the question of whether the Examiner's asserted prior art combination inherently results in the exposure of the reinforcement particles in the pore struts.

Finally, we note that the Examiner has recognized that "there are a number of interrelated process parameters that bear on the resulting composite material, and that can play a part in the resultant structure as claimed." Ans. 8. On this record, the Examiner has neither persuasively delineated the process parameters that necessarily result in exposure of the anisometric reinforcement particles on the pore struts, nor established that Yuan's process specifies such parameters.

There is a "high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Par Pharm. Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014). On this record, we conclude that Examiner has not established that the prior art combination would necessarily result in a porous composite scaffold material wherein the anisometric reinforcement particles are "exposed on the struts within the pore voids" (claim 36), or "extend from a strut surface into a pore void" (claim 63), or that such exposed reinforcements would be the natural result of the combination of elements explicitly disclosed by the proposed prior art combination.

Appellant next asserts that the Examiner erred in failing to accord patentable weight to the process limitations of claims 36 and 63. Appeal Br. 7. Appellant asserts that the process steps impart structural features to the claimed scaffolds that patentably distinguish them from the asserted prior art combination. Appeal Br. 8.

Generally, process limitations in a product-by-process claim are given little if any weight in determining patentability. *In re Nordt Devel. Co.*, 881 F.3d 1371, 1374 (Fed. Cir. 2018). "If the process limitation connotes specific structure and may be considered a structural limitation, however, that structure should be considered." *Id.*

Here, Appellant has offered sufficient evidence that the claimed process steps result in a scaffold that structurally differs from the scaffolds identified in the prior art. Dr. Roeder testified that the claimed process produces scaffolds having reinforcements that are exposed in the strut voids, whereas prior art processes resulted in scaffolds having reinforcements that are encapsulated in the polymer, and do not extend into the strut voids. *See* Fifth Roeder Decl. ¶ 12; Second Roeder Decl. ¶¶ 17, 22, 24. As discussed above, the Examiner concedes that the cited combination of art does not expressly disclose a scaffold or material having reinforcements exposed in the strut voids (Final Act. 9), and has not demonstrated that the prior art materials inherently have such exposed reinforcements. As such, on this record, the Examiner has not established that the claimed product is the same as the prior art products made by different processes. Under these circumstances, the process limitations should be given patentable weight. The Examiner has not shown that such process steps are disclosed in the prior art of record.

Appellant also asserted unexpected results. Appeal Br. 9. Because we conclude the Examiner did not establish a prima facie case of obviousness, we decline to reach Appellant's arguments regarding unexpected results.

Obviousness-Type Double Patenting

The Examiner asserted that claims 1–4, 6–8, 11, 12, 17–19, 21, and 24 of US 7,758,882 ("the '882 Patent") are directed to a composite biomaterial comprising, among other things, a thermoplastic polymer and anisometric calcium phosphate reinforcement particles. Final Act. 11–12. The Examiner acknowledged that the claims of the '882 Patent do not expressly disclose or teach, among other things, pores with diameters ranging from about 10 to 500 μm, or that the anisometric calcium phosphate particles are exposed on the struts within the pore voids. Final Act. 13. The Examiner asserted that the "teachings of Trieu '742 *and* Yuan '408 . . . remedy those deficiencies." Final Act. 13. The Examiner also again relied on inherency to meet the "exposed on the struts" limitation. Final Act. 13.

For the same reasons discussed above, we conclude that the Examiner has not established a prima face case that the combination of the '882 Patent, Trieu, and Yuan meets at least the claim limitation of a pore size "within the range from about 10 to 500 μm," or that the limitations "exposed on the struts within the pore voids" or "extend from a strut surface into a pore void" are inherent in the cited combination. Accordingly, we reverse the nonstatutory obviousness-type double patenting rejection.

CONCLUSION

We reverse the rejection of claims 36–47 and 63 under 35 U.S.C. § 103 as being unpatentable over Trieu, Roeder, and Yuan.

We reverse the rejection of claims 36–47 and 63 on the ground of nonstatutory obviousness-type double patenting over the claims of US 7,758,882, Trieu, and Yuan.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
36–47, 63	103	Trieu, Roeder, Yuan		36–47, 63
36–47, 63		Obviousness-type double patenting over US 7,758,882, Trieu, Yuan		36–47, 63
Overall Outcome:				36–47, 63

REVERSED