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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL P. ZAHALSKY

Appeal 2018-007421
Application 15/158,101[1]
Technology Center 1600

Before FRANCISCO C. PRATS, TAWEN CHANG, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims directed to methods of treating Peyronie's disease. The Examiner rejected the claims for obviousness.

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

We reverse.

[1] Appellant identifies the inventor, Michael P. Zahalsky, as the real party in interest. Br. 3.

STATEMENT OF THE CASE

The sole rejection before us for review is the Examiner's rejection of claims 9 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Williams,[2] Injection,[3] Tunica,[4] and Wegman[5] (Ans. 3–7).

Claim 9, the sole independent claim on appeal, is representative and reads, as follows:

> 9. A method of treating a subject with Peyronie's disease comprising the steps of:
>
> providing a solution of a composition comprising at least one isolated mesenchymal stem cell, at least one component of extracellular matrix, and at least one growth factor; and
>
> injecting the composition within the tunica albuginea of a subject in need of treatment for Peyronie's disease with at least 50 microliter volumes of the composition injected directly into scar tissue or plaque configured as a disorganized collagen structure with irregular vascular structure to induce reorganization of the collagen and induce vasculogenesis, wherein the at least one component of extracellular matrix includes collagenase and collagen.

Br. 18.

DISCUSSION

The Examiner's Rejection

The Examiner cited Williams as describing a method of treating Peyronie's disease, the method involving injecting mesenchymal stem cells

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[2] US 2011/0218396 A1 (published Sept. 8, 2011).
[3] *Peyronie's disease: Diagnostic Work-up and Treatment*, www.urology-textbook.com (2010) (date supplied by Examiner in Notice of References Cited (entered February 23, 2017)).
[4] *Peyronie's disease: Causes and Symptoms*, www.urology-textbook.com (2010) (date supplied by Examiner).
[5] US 6,022,539 (issued Feb. 8, 2000).

as well as a collagen matrix, as recited in claims 9 and 12. Ans. 3–4. The Examiner conceded that Williams did not expressly describe injecting its therapeutic compositions into the tunica albuginea, or the Peyronie's-associated plaque, as recited in claims 9 and 12, but concluded that it would have been obvious to inject Williams's compositions into the site required by the rejected claims in view of Injection and Tunica. *Id.* at 4–5.

The Examiner cited Wegman as evidence that it would have been obvious to inject collagenase alongside Williams's cells and collagen, as recited in Appellant's claims 9 and 12, "since collagenase is well known for treating Peyronie's disease, as evidenced by Wegman." *Id.* at 5. Moreover, the Examiner reasoned, "at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Wegman to include collagenase in the composition of Williams with a reasonable expectation for successfully treating a subject with Peyronie's disease." *Id.* at 5–6.

Analysis

> As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):
>
> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), although the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, *id.* at 415, it also reaffirmed the importance of determining "whether there was an apparent reason to combine the known

elements *in the fashion claimed* by the patent at issue." *Id.* at 418 (emphasis added).

Thus, as the Federal Circuit has since explained, "obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015).

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

We are not persuaded that the preponderance of the evidence supports the Examiner's conclusion of obviousness. In particular, we are not persuaded that the cited references would have suggested including collagenase in Williams's collagen-containing therapeutic compositions.

Claim 9 recites injecting into the tunica albuginea "***a*** solution" that contains at least one isolated mesenchymal stem cell, at least one growth factor, and "at least one component of extracellular matrix . . . wherein the at least one component of extracellular matrix includes collagenase and collagen." Br. 16 (emphasis added). Thus, claim 9 recites a single injected solution that must contain both collagen and collagenase.

As the Examiner found, Williams discloses an injectable tissue or cell transplant that contains corpus cavernosum cells, stromal vascular fraction (SVF) cells, and a biocompatible three-dimensional matrix on which, or in

which, the cells may be disposed. *See* Williams ¶ 31; *see also id.* ¶ 63 (SVF cells include mesenchymal stem cells).

As the Examiner found, and as required by Appellant's claims, Williams discloses that the three-dimensional tissue scaffold used in its methods can be formed of collagen. *See id.* ¶ 200. As the Examiner found, and as required by Appellant's claims, Williams discloses that Peyronie's disease is among the penile defects that may be treated with its cell-containing compositions. *See id.* ¶ 266.

Although Williams does not describe using collagenase to treat Peyronie's disease, Wegman discloses that collagenase administration is effective to treat that disease. *See* Wegman, abstract. In particular, Wegman discloses that, in one patient, three collagenase injections in four days were sufficient to allow rupture of a Peyronie's plaque, with significant plaque softening after the second injection, ultimately resulting in a 60% decrease in penile curvature. *See id.* at 3:35–50. Wegman discloses that "[t]wenty-two patients have been treated under this regimen and all but one have been satisfied." *Id.* at 3:51–52.

We are not persuaded that a skilled artisan, advised by Wegman that collagenase degrades collagen to the degree that Peyronie's plaques are significantly disrupted structurally *in vivo*, would have been motivated to include collagenase in an injected solution that also contained William's collagen-containing three-dimensional tissue scaffold. To the contrary, given Wegman's teaching that collagenase degrades collagen to the degree that Peyronie's plaques are significantly disrupted after injection, a skilled artisan would have reasonably inferred that collagenase would not have been desirable to include in Williams's injected collagen-containing solution. *See*

KSR, 550 U.S. at 418 (noting that "a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.").

The fact that neither Williams nor Wegman expressly teaches that collagenase would act on the collagen present in the injected solution (*see* Ans. 9) does not persuade us that a skilled artisan would have failed to recognize that it would be undesirable to include Wegman's collagenase in Williams's collagen-containing solution, particularly given Wegman's teaching of collagenase's efficacy in degrading Peyronie's plaques *in vivo*. *See id*. at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

Because we are not persuaded, for the reasons discussed, that the combination of Williams and Wegman references would have suggested preparing and injecting a solution having all of the components required by Appellant's claim 9, we reverse the Examiner's obvious rejection of claim 9, as well its dependent claim 12.

SUMMARY

For the reasons discussed, we reverse the Examiner's rejection of claims 9 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Williams, Injection, Tunica, and Wegman.

REVERSED