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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTOPHER J. REUTER,
STEVEN J. MACKENZIE, LAUREN G. DANIELSON, and
VINCENT SCUILLA[1]

Appeal 2018-000260
Application 14/211,078
Technology Center 1600

Before DONALD E. ADAMS, TAWEN CHANG, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method of inhibiting gram negative microorganisms, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

According to the Specification, pathogenic microorganisms, such as *Vibrio* species that are pathogenic to fish and shellfish, cause major losses in

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[1] Appellants identify the Real Party in Interest as Osprey Biotechnics, Inc. (Appeal Br. 3.)

aquaculture farming. (Spec. ¶ 6.) "Thus, it is important to provide new and effective [bacterial] strains that have antibacterial activity against specific disease-causing microbes affecting the aquaculture industry." (*Id.*)

"*Bacillus amyloliquefaciens* is a gram-positive non-pathogenic soil bacterium" that is "known for its ability to degrade proteins extracellularly." (*Id.* ¶ 3.) The Specification states that a novel strain of *Bacillus amyloliquefaciens* has been identified and isolated and further states that the strain is "characterized by its ability to inhibit the growth and/or activity of gram negative microorganisms, such as . . . *Vibrio* . . . ." (*Id.* ¶ 7.)

Claims 15, 21, and 22 are on appeal. Claim 15 is illustrative and reproduced below:

> 15. A method of inhibiting gram negative microorganisms, comprising:
>
> adding to a material contaminated with a pathogenic gram negative microorganism an amount of *Bacillus amyloliquefaciens* strain OBT712 as deposited with the American Type Culture Collection under accession number PTA-122189 that produces enzymes, metabolites or antibiotics that inhibit growth of gram negative pathogenic microorganisms that is effective to inhibit the gram negative microorganism, wherein the *Bacillus amyloliquefaciens* strain OBT712 is applied to containments in which shrimp or fish are farmed to reduce incidents of *Vibrio,* wherein the *Bacillus amyloliquefaciens* strain OBT712 is added in a live vegetative state.

(Appeal Br. 11 (Claims App.).)

The Examiner rejects claims 15, 21, and 22 under 35 U.S.C. § 103 as being unpatentable over Villamar[2] and Terhune.[3] (Ans. 5.)

The Examiner rejects claim 22 under 35 U.S.C. § 103 as being unpatentable over Terhune and Harel.[4] (Ans. 2.)

DISCUSSION

Issue

The Examiner has rejected claims 15, 21, and 22 as obvious over Villamar and Terhune and rejected claim 22 as obvious over Terhune and Harel. The same issues are dispositive for both rejections; we therefore discuss them together.

The Examiner finds that Villamar suggests all of the limitations of the claims except that it does not expressly disclose the specific *Bacillus* species or strain recited in the claims. (Ans. 5–8.) However, the Examiner finds that Terhune teaches treating or preventing diseases caused by pathogenic bacteria or fungi by administering *Bacillus* strains to an environment such as a pond or to aquatic animals such as farmed fish and crustaceans (e.g., shrimp). (*Id.* at 8.) The Examiner further finds that Terhune teaches that suitable strains for its invention include *Bacillus amyloliquefaciens* strains AP79 (NRRL B-50741), AP143 (NRRL B-50742), AP193L (NRRL B-50743), and AP254L (NRRL B-50745), which exhibit "antibiotic activity in various bacterial pathogens of aquatic animals such as farmed fish and crustaceans (e.g.[,] shrimp)." (*Id.* at 8–9.) The Examiner finds that the *B.*

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[2] Villamar et al., US 2004/0009160 A1, published Jan. 15, 2004 (hereinafter "Villamar").
[3] Terhune et al., US 2012/0328572 A1, published Dec. 27, 2012 (hereinafter "Terhune").
[4] Harel, WO 03/103692 A1, published Dec. 18, 2003.

amyloliquefaciens strains disclosed in Terhune "each appear to be identical to the presently claimed OBT712 strain based on the fact that the microorganisms of Terhune are of the same species and have the same property of inhibiting the growth of *Vibrio*." (*Id.* at 9.)

The Examiner concludes that it would have been obvious to a skilled artisan to combine Villamar and Terhune to arrive at the claimed invention, with a reasonable expectation of success, by using dried vegetative cells of *Bacillus amyloliquefaciens*, as taught by Terhune, when practicing Villamar's method of inhibiting *Vibrio* in order to prevent diseases in aquatic species. (*Id.* at 9–10.) The Examiner finds that it would have been obvious to use *B. amyloliquefaciens* cells in Villamar's method, with a reasonable expectation of success, because Villamar teaches "selecting the *Bacillus* of [its] invention on the basis of producing antibiotic to inhibit or kill pathogenic bacteria such as *Vibrio*," and Terhune's *B. amyloliquefaciens* strains are expected to exhibit antibiotic activity against *Vibrio*. (*Id.*)

With respect to claim 22, the Examiner also finds that Terhune teaches all of the limitations of the claim, except that it does not "expressly disclose providing any one of their *B. amyloliquefaciens* strains to rotifers that become food for the shrimp or fish." (Ans. 3.) The Examiner finds, however, that Harel teaches a method of delivering live, bioactive probionts or prebionts to fish and crustaceans, comprising feeding to such fish and crustaceans zooplankton comprising the probiont or prebionts. (*Id.*) The Examiner also finds that Harel teaches that the zooplankton can be rotifers and that the probiotics or prebiotics may be *Bacillus*. (*Id.* at 4.)

The Examiner concludes that it would have been obvious to a skilled artisan to combine Terhune and Harel to arrive at the invention

of claim 22, with a reasonable expectation of success, by providing the *B. amyloliquefaciens* strains disclosed in Terhune to fish and shrimp through rotifers (i.e., by feeding the strains to rotifers and then feeding the rotifers to shrimp and fish). (*Id.* at 4.) The Examiner finds that

> [t]here would have been a reasonable expectation of success in treating or preventing disease in the aquatic animals by *Vibrio* via this modification since Harel indicates that its technique is suitable for delivering probionts such as *Bacillus* sp. while maintaining the probionts' viability and/or bioactivity, [as] well as being suitable for improving the survival rate of breeding larvae and juvenile fish.

(*Id.*)

For both rejections, Appellants contend that the cited prior art combinations do not suggest the claimed methods because the claimed OBT712 strain is not anticipated by Terhune. (Appeal Br. 7–8.)

The issue with respect to this rejection is whether the cited prior art combinations suggest the use of the claimed OBT712 strain.

Analysis

We agree with the Examiner that claims 15, 21, and 22 are obvious over Villamar and Terhune and claim 22 is obvious over Terhune and Harel. Only those arguments timely made by Appellants in the briefs have been considered; arguments not so presented are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.").

Appellants' sole argument in the Appeal Brief as to both rejections rests on a comparison of Figure 1 of Appellants' application, which shows

the 16S rDNA sequence for the claimed OBT712 strain, and Terhune's SEQ ID NO:2, which is a partial sequence of the 16S rDNA of the *B. amyloliquefaciens* strain Chilli-1. (Appeal Br. 7–8.) Appellants contend that, because the comparison shows that the sequences are not identical, the claims are not obvious over the combinations of Terhune and Villamar or Harel. (*Id.*)

We do not find this argument persuasive. As the Examiner points out in the Answer, Terhune does not teach that *Bacillus* species useful in its invention must include a sequence identical to SEQ ID NO:2. (Ans. 11.) Instead, Terhune teaches that "[t]he disclosed compositions and methods may include or utilize *B. amyloliquefaciens* or a *Bacillus* species that is closely related to *B. amyloliquefaciens*," wherein the latter is defined as "a species comprising a 16S rDNA sequence comprising SEQ ID NO:2 or comprising a 16S rDNA sequence having at least about 90% . . . sequence identity to SEQ ID NO: 2." (Terhune ¶ 21.) In short, Terhune suggests a genus of *Bacillus* would be useful in its method of treating or preventing disease in fishes or crustaceans so long as it belongs to the *B. amyloliquefaciens* species or comprises a 16S rDNA sequence having at least about 90% sequence identity to SEQ ID NO:2. We find that OBT712 is a strain of *B. amyloliquefaciens* within the genus of *B. amyloliquefaciens* that Terhune suggests would be useful in its method for the reasons that follow.

A comparison of the 16S rDNA in Figure 1 of the Specification and Terhune's SEQ ID NO:2 shows that, out of the 525 overlapping nucleotides between the 16S rDNA sequence of the claimed OBT712 strain and SEQ ID NO:2, only eight nucleotides are different. Thus, the sequence identity of

OBT712 to SEQ ID NO:2 is at least about 90% identical. Moreover, the claim indicates that OBT712 is a *B. amyloliquefaciens* strain.

Given that the claims explicitly recite OBT712 strain as a *B. amyloliquefaciens* strain and given the substantial similarity between (a) the 16S rDNA sequence for the claimed OBT712 strain as shown in Figure 1 and (b) Terhune's SEQ ID NO:2, we find that the Examiner has established a prima facie case that Terhune suggests that the OBT712 strain when added to a material contaminated with *Vibrio* would result in inhibition of those gram negative microorganisms as required by the claims. This is true even if OBT712 is a previously unknown strain of *B. amyloliquefaciens*. *Compare In re Kaufmann*, 451 F.2d 1096, 1098 (CCPA 1971) (affirming rejection of claims to a process for producing a compound using *Proteus* OX-19, a particular penicillin acylase-producing strain of a *Proteus* species, where the prior art generally discloses producing the same compound using penicillin acylase-producing strains of several genera, including the genus *Proteus*) *with In re Pleuddemann*, 910 F.2d 823, 826–828 (Fed. Cir. 1990) (reversing an obviousness rejection where the prior art did not make it obvious to use a new compound because the functioning of the new compound was not suggested by the prior art).

Appellants have not persuasively identified any error by the Examiner or otherwise persuasively rebutted the prima facie case.[5] An earlier

[5] Both Figure 1 of the Specification and Terhune's SEQ ID NO:2 appear to only be partial sequences. (Spec. ¶ 9 (describing Figure 1 as the "relevant" sequence for *B. amyloliquefaciens* strain OBT712); Terhune ¶ 21 (stating that SEQ ID NO:2 is a "partial" sequence of *B. amyloliquefaciens* strain Chilli-1 16S rDNA).) Thus, each contains nucleotide sequences before or after the overlapping portion that do not appear in the other. We also acknowledge that Terhune describes specific methods for determining

disclosure of a genus does not necessarily prevent patenting a species member of the genus, for instance if the species exhibits unexpected results. *Abbvie Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366, 1380 (Fed. Cir. 2014). However, Appellants have not presented any evidence of unexpected results.

In the Reply Brief, Appellants contend that "[t]he Examiner's argument [in the Answer] is inconsistent with the Examiner's previously stated rationale for the rejection." (Reply Br. 2–3.) However, this contention relates to a petitionable matter and not to an appealable matter. *See* MPEP § 1002.02(c)(6).

Finally, Appellants argue in the Reply Brief that, putting aside the comparison of Specification's Figure 1 and Terhune's SEQ ID NO:2, there is simply insufficient basis for concluding that any of the AP79, AP143, AP193L or AP254L strains is identical to the OBT712 strain recited in the claims. (Reply Br. 3–5.) We are not persuaded for the same reasons already discussed: Terhune's teaching is not limited to the four *B. amyloliquefaciens* strains explicitly recited. Rather, as discussed above, Terhune teaches that its methods may use *B. amyloliquefaciens* generally or a *Bacillus* species that is closely related to *B. amyloliquefaciens*. (Terhune

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"percentage sequence identity" rather than simply comparing them side by side. (Terhune ¶¶ 23–24.) However, in light of the substantial similarity of the overlapping portion of the two sequences discussed above, we find that the Examiner has met the burden of presenting a prima facie case of unpatentability. *Cf. In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where . . . the claimed and prior art products are identical or substantially identical . . . 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.")

¶ 21.) Thus, the fact that the claimed OBT712 strain is not identical to one of AP79, AP143, AP193L, or AP254L does not suffice to show that the claims are not obvious.

Accordingly, we affirm the Examiner's rejections of claims 15, 21, and 22 as obvious over Villamar and Terhune and claim 22 as obvious over Terhune and Harel.

SUMMARY

For the reasons above, we affirm the Examiner's rejection of claims 15, 21, and 22.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED