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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KENNETH D. CAIN

Appeal 2018-008253
Application 13/570,303
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN,[1] *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

This is a request for rehearing under 37 C.F.R. § 41.79 ("Req. Reh'g") of the Decision on Appeal entered June 17, 2019 ("Dec.").

Appellant[2] contends that the "Board mischaracterized the difference between the disclosure/claims of Cain ['864] and the claims of the present application." Req. Reh'g 3.

We disagree.

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[1] Because of Judge Elizabeth A. LaVier's unavailability, Judge Fredman has replaced Judge LaVier who was on the panel that authorized the original Decision of the Board. *Cf. In re Bose Corp*., 772 F.2d 866, 869 (Fed. Cir. 1985).

[2] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as The Board of Regents of the University of Idaho. Appeal Br. 3.

First, in addressing the obviousness-type double patenting and obviousness rejections, the Decision focused on the differences the Examiner identified between Cain ’864 and the rejected claims. Dec. 3. Appellant has not directed us to where in the Appeal Brief or Reply Brief it was argued that the Examiner had not appreciated the difference between the rejected claims and Cain ’864. It appears that the only difference argued by Appellant in the Appeal Brief is the same difference identified by the Examiner, namely, the lack of disclosure of iron-limited medium by Cain ’864. Appeal Br. 13.

Second, even if the Examiner’s Answer and Decision did not expressly identify all the differences between the claimed subject matter and Cain ’864, Appellant has not provided an explanation as to how this alleged deficiency would change the outcome of the Decision.

Cain ’864 and LaFrentz

Independent claim 4 is directed to a method of reducing morbidity and/or mortality in fish due to disease caused by a bacterium comprising administering “a live attenuated and a virulent derivative strain of the bacterium.” The claim requires “live attenuated and avirulent derivative strain that is administered has been grown, prior to the administering, in or on a medium that is iron-limiting.” In dependent claim 5, “the disease is coldwater disease caused by *Flavobacterium psychrophilum*.”

The Examiner found that it would have been obvious to one of ordinary skill in the art to culture the *Flavobacterium psychrophilum* of Cain ’864 in iron-limited media prior to administration, as required by the rejected claims, based on the teachings in LaFrentz that iron is limited *in*

vivo and that proteins expressed under iron-limiting conditions "'may represent potential vaccine candidate antigens.'" Dec. 3–4.

Appellant contends that the Board erred in determining that the "combination of the Cain ['864] and LaFrentz references would . . . lead one of skill in the art to the present invention." Req. Reh'g 3. Appellant states that the attenuated bacteria of Cain '864 serve as effective vaccines against *Flavobacterium psychrophilum* and include "the virulence determinants and/or protective elements that are necessary to provide this protection." Req. Reh'g 5. For this reason, Appellant states that the skilled worker "would not find it obvious to grow the vaccine of Cain ['864] in the iron-limited media of LaFrentz in order to try to render the vaccine effective, because it already is effective." *Id.*

As indicated by Appellant, Cain '864 discloses that protection against coldwater disease (CWD) can be achieved using attenuated live *Flavobacterium psychrophilum*. Cain '864, col. 3, ll. 29–32. However, the protection is not 100%. Cain '864, col. 13 (Table 3 showing cumulative percent mortality (CPM) and relative percent survival (RPS) after bacteria challenge at the highest value is 40% and 45%, respectively (third row)). Thus, one of ordinary skill in the art seeking to improve the vaccine disclosed by Cain '864 would have had reason to turn to the disclosure by LaFrentz, which teaches that growing *Flavobacterium psychrophilum* under iron-limiting conditions produces unique proteins that may have a role as targets in vaccine development and as "vaccine candidate antigens." LaFrentz 172 (second column, first full paragraph), 175–176, 178. *See also* LaFrentz 179 (last paragraph). As held in *In re Peterson*, 315 F.3d 1325, 1329–30 (Fed. Cir. 2003), there is a "normal desire of scientists or artisans to improve upon what is already generally known." Therefore, although

Cain ’864 teaches that its vaccines are effective, there is still room for improvement in their efficacy (*see* Cain ’864 at column 13 described above) and LaFrentz suggests an approach to do so. Accordingly, we are not persuaded that “the skilled artisan would not find it obvious to grow the vaccine of Cain [’864] in the iron-limited media of LaFrentz in order to try to render the vaccine effective, because it already is effective.” Req. Reh’g 5.

Appellant also contends that the rejection is based on “impermissible hindsight” because Cain ’864 teaches that its vaccine is “effective” and “definitely must contain the necessary protective elements to confer protection,” and thus there would be no reason to turn to LaFrentz. Req. Reh’g 6–7; *see id.* at 4 (Appellant contends that “[i]t is only through the impermissible use of hindsight that the Board, and the Examiner, have concluded that the present claims are obvious in view of the cited prior art”). This argument does not persuade us that we erred in the Decision. Appellant admits:

> The secondary LaFrentz reference discloses that whole cell bacterial vaccines grown in standard iron-rich media do not work because they lack the necessary protective elements to confer protection. LaFrentz also discloses that bacteria grown in iron-limited media produce several proteins at higher levels than are produced when the bacteria are grown in iron-rich media. LaFrentz concludes that it might be worthwhile to test some of these proteins to see if they could be used as isolated protein vaccines.

Req. Reh’g 6.

Thus, one of ordinary skill in the art would have had reason to determine whether culturing the bacteria in iron-limited media, which Appellant admits produce proteins under these conditions that “might be

worthwhile to test . . . to see if they could be used as isolated protein vaccines," enhanced vaccine efficacy. An explicit suggestion to modify the prior art is unnecessary to establish obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). As held by the U.S. Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007):

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Appellant further argues that "the Board has mis-comprehended Appellant's Brief on Appeal and Appellant's Reply Brief." Req. Reh'g 9. Appellant asserts that it "never stated during the prosecution, or during this appeal, that it should make little or no difference whether the bacteria cells were grown in iron-limited media prior to administration." Req. Reh'g 9.

In the Decision, it was stated:

> Appellant also argues that the Examiner's logic that it would have been obvious to culture the bacteria in iron-poor media is incorrect. Appeal Br. 15–16. *Appellant contends it "should make little or no difference" whether the bacteria were cultured in iron-limited media prior to administration because* "after being administered, the bacteria would necessarily grow in an iron-limited medium, and therefore, after growing for a time within the iron-poor environment within the fish, they would produce a similar protein expression pattern as would bacteria that were grown in iron-limited media before administration to a fish." *Id.* at 16. Appellant argues that, in contrast, the '303 Application discloses "the unexpected discovery" that the attenuated bacteria grown in iron-limited media enhanced vaccine effectiveness as compared to a vaccine already shown to be effective. *Id.*

Dec. 6 (emphasis added).

In other words, Appellant was arguing that it would not have been expected that growing the bacteria in an iron limited medium prior to administration would have enhanced vaccine efficacy *because* when the bacterial cells were introduced into the fish, they would then be grown in the iron-poor fish environment. Appellant now asserts that the Board misconstrued what they said. This is incorrect. In the Appeal Brief, Appellant stated:

> If the Examiner's logic were correct, then, because the environment within a host fish is naturally iron-poor due to the presence of iron-binding proteins within the host fish, *it should make little or no difference whether or not bacteria* to be used as a vaccine *were grown in iron-poor media or iron-rich media prior to being administered* to the fish. This is because, after being administered, the bacteria would necessarily grow in an iron-limited medium, and therefore, after growing for a time within the iron-poor environment within the fish, they would produce a similar protein expression pattern as would bacteria that were grown in iron-limited media before administration to a fish.

(Appeal Br. 16 (emphasis added).)

The Examiner's "logic," according to Appellant, is that a host fish has an iron-poor environment. Appeal Br. 15. Indeed, LaFrentz makes such a statement: "[I]ron is limited *in vivo* due to host production of iron-binding proteins." LaFrentz 172 (first column). Appellant is arguing that "growing" the bacteria in a fish after immunization would provide an iron-poor environment, making the claimed prior iron-limited culturing step unnecessary. We understood that this argument had to do with lack of motivation to combine the publications, i.e., if iron is limited in the fish, then once the fish had been immunized with the bacteria, the bacteria would

experience an iron-limited environment, making any prior culturing in an iron-limited media superfluous. We considered this argument, but found it unpersuasive. Dec. 6–7. Appellant has not identified a defect in our response to the arguments set forth in the Decision.

Conclusion

Appellant's Request for Rehearing is granted to the extent that we have reconsidered our Decision in light of the arguments in Appellant's Request. Appellant's Request is denied to the extent that we do not modify the outcome of the Decision.

DENIED