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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CORY CHRISTENSEN and BONNIE HUND

Appeal 2019-002834
Application 14/273,492
Technology Center 1600

Before ULRIKE W. JENKS, TIMOTHY G. MAJORS, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellant[1] submits this appeal under 35 U.S.C. § 134(a) involving claims to a transgenic plant cell having an increased level of cold tolerance. 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 Ceres, Inc. as the real party in interest. App. Br. 2. Herein, we refer to the Final Action mailed January 25, 2018 ("Final Act."); Appellant's Appeal Brief filed September 25, 2018 ("App. Br."); Appellant's Response to Notification of Non-Compliant Appeal Brief filed October 15, 2018 ("Response"); Examiner's Answer mailed December 28, 2018 ("Ans."); and Appellant's Reply Brief filed February 27, 2019 ("Reply Br.").

STATEMENT OF THE CASE

Claims 15–22 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 15 is independent and representative of the claims on appeal. It reads as follows:

> 15. A plant cell comprising an exogenous nucleic acid said exogenous nucleic acid comprising a regulatory region operably linked to a nucleotide sequence encoding a polypeptide, wherein said polypeptide has 90% or greater sequence identity to the amino acid sequence of SEQ ID NO:2 and wherein a plant produced from said plant cell has an increased level of cold tolerance as compared to the corresponding level of cold tolerance of a control plant that does not comprise said nucleic acid.

Response 2.

Appellant seeks review of the following rejections:

I. Claims 15–17, 19, and 22 under 35 U.S.C. § 102 as anticipated by Churchman,[2] and

II. Claims 15–22 under 35 U.S.C. § 103 as unpatentable over Churchman in view of Alexandrov[3] and Peres[4].

App. Br. 3–9.

The issue for each rejection is: Does the preponderance of evidence of record support Examiner's conclusion that the cited prior art anticipates or renders obvious Appellant's claims?

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[2] Michelle L. Churchman et al., *SIAMESE, a Plant-Specific Cell Cycle Regulator, Controls Endoreplication Onset in Arabidopsis Thaliana*, 18 THE PLANT CELL 3145–57 (2006) ("Churchman").
[3] US 2006/0057724 A1; published March 16, 2006 ("Alexandrov").
[4] Adrian Peres et al., *Novel Plant-specific Cyclin-dependent Kinase Inhibitors Induced by Biotic and Abiotic Stresses*, 282 J. BIO. CHEM. 25588–96 (2007) ("Peres").

Analysis

Rejection I: Anticipation by Churchman

Examiner finds that Churchman discloses leaf cells transformed to express a polypeptide "that shares 98.4% identity with instant SEQ ID NO: 2." Final Act. 3 (emphasis omitted). While Churchman makes no mention of cold tolerance, Examiner determines that its transformed plant cells would necessarily exhibit the increased level of cold tolerance recited in claim 15 and therefore Churchman anticipates that claim. *See id.* at 8.

Appellant argues that the record does not support Examiner's finding that increased cold tolerance is inherent in Churchman's transformed plant cells. In particular, Appellant urges the transformation disclosed in Churchman may or may not result in a plant having increased cold tolerance as recited in claim 15, but that a limitation must necessarily be present for it be deemed inherent to the prior art. *See* App. Br. 6–7. Appellant relies on the Declaration of Dr. Roger Pennell dated March 7, 2017 ("Pennell Decl.") as evidence that "not all transgenic plants [expressing a polypeptide with the recited sequence identity] necessarily exhibit increased growth under cold-stress condition as compared to control plants." App. Br. 7. The Pennell Declaration points to the results in Example 3 of the Specification showing that out of six events in which plants were successfully transformed to express SEQ ID NO:2 only seedlings from two of those events exhibited increased cold tolerance relative to the control in the inventors' assay. *Id.* (citing Pennell Decl. ¶ 17). According to Dr. Pennell:

> This is often observed when creating transgenic plants. . . . Although plant transformation is often routine, the phenotypes of individual transformation events harboring identical transgenes are not uniform. For transgenes that impart a

> phenotype, it is typical to find that more than half of the successfully transformed plants actually exhibit phenotypes that are indistinguishable from controls. Interestingly, transformed plants that do not exhibit a phenotype are nevertheless often likely to express the transgene because they were marker-selected for vector integration in transcriptionally active regions of the chromatin. Some of the causes for this phenomenon are dosage effects, threshold mechanism, differential tissue expression, genetic background dependence, transgene silencing, disruption of endogenous genes by transgene insertion, and paramutation. Thus, any one or a combination of multiple mechanisms may explain why expression of a transgene by a transformation event is not accompanied by the phenotype, and, even if the transgene is expressed, there is no guarantee that the transformation event exhibits the phenotype.

Pannell Decl. ¶ 18.

Upon considering the record as a whole, we are persuaded by Appellant's argument. Claim 15 recites both a structural requirement (i.e., that the cell has exogenous nucleic acid comprising a regulatory region operably linked to a nucleotide sequence encoding a polypeptide with 90% or greater sequence identity to SEQ ID NO:2) and a functional requirement (i.e., that a plant produced from the cell has increased cold tolerance relative to a control). Examiner has presented sufficient evidence of structural similarity between the cells in Churchman that have been transformed to express SMR3 to demonstrate that this functional requirement may be inherent to that reference. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) ("[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing they are not."). However, the evidence in the Pennell Declaration is sufficient to meet Appellant's burden to demonstrate that the

claimed increase in cold tolerance is not necessarily present in Churchman's transformed cells. That declaration explains that both generally, and in the specific instance of claimed transformation, only around 50% of successful transformation events result in the claimed phenotype.

Examiner states that the "only connection to the cold tolerance phenotype that the Appellant has provided is the overexpression of the polypeptide (as further supported by their own data which only distinguishes the plants based on successful transform[ation] and overexpression of SEQ ID NO:2)." Ans. 17–18. We disagree. Examples 2 and 3 in the Specification describe functional assays used to distinguish between successfully transformed cells that produce plants with increased cold tolerance and successfully transformed cells that do not. *See* Spec. ¶¶ 183–200. And the results in Example 3 support that most of the time a successful transformation did not result in progeny with increased cold tolerance. *Id.* ¶¶ 198–200. Thus, based on the record before us, Appellant has shown that increased cold tolerance is not an inherent feature of cells that have been successfully transformed to overexpress a peptide with 90% or greater identity to SEQ ID NO:2. For this reason, Examiner's rejection is not supported by the preponderance of the evidence.

Rejection II: Obviousness Over Churchman, Alexandrov, and Peres

Examiner relies on the same inherency finding concerning Churchman for the obviousness rejection. *See* Final Act. 10. In addition, Examiner finds that Alexandrov teaches that transformation of plant cells with a sequence that "shares **100%** identity" with SEQ ID NO:2 "is useful 'for making plants with increased biomass and foliage.'" *Id.* at 11 (quoting Alexandrov, Sequence Listing for SEQ ID NO:1751). Examiner further

finds that Peres teaches that SMR3 "expression is upregulated during abiotic stress conditions – including in response to heat stress, hypoxia, osmotic stress, salt stress, and UV-B." *Id.* (citing Peres 25594 (Fig. 7)). Examiner determines these teachings would motivate a skilled artisan "to produce transgenic plants and plant cell expressing" SEQ ID NO:2 and "assay the transformed plants under abiotic stress conditions" to identify those with increased cold tolerance. *Id.* at 12.

Appellant argues that the obviousness rejection should be reversed because none of the cited references "are asserted to teach increased level of cold tolerance." App. Br. 9. As before, Appellant urges that increased cold tolerance is not an inherent feature of plant cells that have been transformed to overexpress the claimed peptide. *See id.* at 9–12. Regarding Peres, Appellant contends it "merely suggests upregulation of SMR3 . . . during abiotic stress conditions" not that "SMR3 is upregulated during cold stress" specifically or that "expressing of SMR3 increases the level of cold tolerance." Reply Br. 11; *see also* App. Br. 15. Therefore, asserts Appellant, Peres does not evidence a motivation to assay plants produced from cells transformed according to the teachings in the other references for increased cold tolerance, nor does it provide a reasonable expectation of success in doing so. *Id.*

Upon considering the record as a whole, we are persuaded by Appellant's arguments. Like Churchman, neither Alexandrov, nor Peres, suggests any correlation between the sequences the rejection is based upon and cold tolerance. Alexandrov teaches that SEQ ID NO:1751 is useful for making: (1) "lethal plants for genetic confinement systems," (2) "plants with increased biomass and foliage," and (3) "smaller plants." Alexandrov,

Sequence Listing for SEQ ID NO: 1751. Peres teaches that a structurally similar protein, SMR3, is upregulated in response to some types of stress and not in response to others. *See* Peres 25594 (Fig. 7). But Peres does not report whether SMR3 is upregulated in response to cold stress. Even if it did, Examiner has not sufficiently articulated why that teaching would motivate a skilled artisan to assay plants transformed to overexpress SMR3 for increased cold tolerance.

As explained above, the Pennell Declaration evidences that cells successfully transformed to overexpress SEQ ID NO: 2 must be assayed to identify those giving rise to progeny with increased cold tolerance. Thus, while the evidence of record supports Examiner's finding that one would be motivated to make the claimed transformation (e.g., to increase biomass or foliage as taught in Alexandrov), it does not demonstrate that one of ordinary skill in the art would reasonably expect that transformation to successfully produce progeny with increased cold tolerance as claimed. Accordingly, we reverse.

DECISION SUMMARY

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
15–17, 19, 22	102	Churchman		15–17, 19, 22
15–22	103	Churchman, Alexandrov, Peres		15–22

REVERSED