The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JONATHAN H. DINSMORE and JUDSON RATLIFF

Appeal No. 1999-1256
Application 08/333,076

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

REQUEST FOR REHEARING

Appellants request rehearing and reconsideration of the board's decision entered July 30, 2001, wherein the examiner's rejection of claims 31 and 32 under 35 U.S.C. § 112, first paragraph, was affirmed.

In effect, Appellants assert that the board applied the wrong legal standard in reviewing the rejection for nonenablement. See page 2, first full paragraph ("Applicants, however, in order to provide an enabling disclosure, need not demonstrate how embryonic stem cells can be made to differentiate into every desirable cell type."); id., last paragraph ("[O]ne need not show the culturing of embryonic stem cells in the

differentiation culture medium in the presence of every agent which promotes differentiation of the embryonic stem cells into every desired cell type."); and page 3 ("[I]t is not necessary that Applicants culture embryonic stem cells in the presence of every agent and every medium which would promote differentiation of the embryonic stem cells into every desired cell type.").

Appellants analogize the instant claims to an invention "directed to the culture conditions for expression of recombinant protein in a certain cell." Page 2, second full paragraph. They argue that, in such a case, "the inventor need not enable one skilled in the art to express a wide variety of proteins in order to be entitled to coverage of the inventive culture conditions for expression." Id.

To the extent that Appellants urge that the board applied an incorrect standard of enablement to the claims on appeal, we disagree. The appropriate legal standard for determining enablement was discussed and applied on pages 7-8 of the decision entered July 30, 2001, which states:

> The specification discloses no agents that promote differentiation of embryonic stem cells into cell types other than neuronal cells and muscle cells. In addition, the specification states that the prior art does not disclose any agents that promote differentiation of embryonic stem cells into a particular cell type. See page 2 ("Differentiation of stem cells into a homogeneous population, however, has not been achieved.").
>
> Thus, the specification lacks working examples or detailed guidance concerning the range of differentiation-promoting agents encompassed; the scope of the claims encompasses using any differentiation promoting agent to produce any type of cell; the prior art provides no guidance regarding producing a specific cell type from embryonic stem cells; and neither the prior art nor the specification provides any basis on which to predict what type of cell will result from treatment with a given agent.

> Thus, on this record, it appears that the full scope of claims 31 and 32 could only be practiced by those skilled in the art who carried out the very considerable experimentation necessary to identify agents that promote differentiation of embryonic stem cells into each of the different types of possible differentiated cells.
>
> Therefore, based on the factors set out in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), and despite the high level of skill in the art, we conclude that practicing the full scope of claims 31 and 32 would require undue experimentation. We therefore affirm the rejection of claims 31 and 32 under 35 U.S.C. § 112, first paragraph.

Thus, as the decision itself makes clear, we applied the standard of enablement set out in In re Wands and agreed with the examiner's conclusion that undue experimentation would have been required to practice the full scope of claims 31 and 32. The Wands factors are an appropriate framework for analyzing enablement. See, e.g., Enzo Biochem Inc. v. Calgene Inc., 188 F.3d 1362, __, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999).

As for Appellants' "analogous example," we disagree that the instant claims are analogous to an invention "directed to culture conditions for expression of recombinant protein in a certain cell." Such conditions would be expected to be similar regardless of the specific heterologous protein being expressed by the cell. In the instant claims, by contrast, the particular agent that is added to the differentiation culture medium determines what type of cells the embryonic stem cells differentiate into: different agents would be required to induce the embryonic stem cells to differentiate into each type of differentiated cell (muscle cells, nerve cells, hematopoietic cells, skin cells, islet cells, liver cells, etc.). Appellants' example is therefore unhelpful to their case.

We have carefully reviewed the original opinion in light of Appellants' request, but we find no point of law or fact which we overlooked or misapprehended in arriving at our decision. To the extent it is relevant, Appellants' request amounts to a reargument of points already considered by the board. For the reasons discussed in the decision of July 30, 2001, we decline to reverse the examiner's rejection of claims 31 and 32 on the basis of nonenablement.

Appellants' request has been granted to the extent that the decision has been reconsidered, but such request is denied with respect to making any modifications to the decision affirming the examiner's rejection under 35 U.S.C. § 112, first paragraph.

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

REHEARING DENIED

William F. Smith Administrative Patent Judge	))))) BOARD OF PATENT
Donald E. Adams Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
Eric Grimes Administrative Patent Judge	)))

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