

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JAMES M. PETITTE,
CATHERINE A. RICKS, and
SALLY E. SPENCE

Appeal No. 1999-1223
Application No. 08/446,021

ON BRIEF

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

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 32. Subsequent thereto, claim 26 was cancelled leaving claims 1 through 25 and 27 through 32 for our consideration.

Claims 1, 12, and 22, the independent claims pending in the application are representative of the subject matter on appeal and read as follows:

1. A method of altering the phenotype of a bird, comprising introducing avian somatic tissue-specific stem cells into an egg containing a bird during in ovo incubation, said cells containing and capable of expressing at least one DNA molecule in an amount effective to cause a change in the phenotype of the bird.

12. A method of altering the phenotype of a bird comprising introducing avian embryo cells into the air cell of an egg containing a bird during in ovo incubation, said embryo cells containing and capable of expressing at least one DNA molecule in an amount effective to cause a change in the phenotype of the bird.

22. A method of altering the phenotype of a bird comprising introducing avian somatic tissue-specific stem cells to the air cell of an egg containing a bird during in ovo incubation, the avian somatic tissue-specific stem cells containing and capable of expressing at least one DNA molecule in an amount effective to cause a change in the phenotype of the bird.

Claims 1 through 25 and 27 through 32 stand rejected under 35 U.S.C. § 112, first paragraph (enablement). The examiner states at page 2 of the Examiner's Answer that "[n]o new prior art has been applied in this examiner's answer." However, in expressing the rejection on pages 2-7 of the Examiner's Answer, the examiner relies upon references identified as Shuman, Salser, and Brazolot. A review of the Final Rejection reveals that the examiner did not rely upon these or any other references in support of the enablement rejection. Thus, the examiner's statement that she does not rely upon any new references in support of the rejection is incorrect. As set forth in In re Hoch, 428 F.2d 1341, 1342 n. 3, 166 USPQ 406, 407 n. 3 (CCPA 1970), "Where a reference is relied on to support a rejection, whether or not in a 'minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection." The propriety of the examiner relying upon new references in support of a rejection in the Examiner's Answer is not apparent. Under these circumstances, we will review the examiner's rejection as set forth in the Examiner's Answer to the extent it does not rely upon the new evidence. On this basis, we reverse the rejection.

Discussion

This board serves as a board of review, not a de novo examination tribunal. 35 U.S.C. § 6(b). The manner in which appellants and the examiner have presented the issues in this appeal makes review of the issues difficult. The only Office action on the merits issued by the examiner prior to the appeal proceeding was a first Office action final rejection. As indicated above, the enablement rejection set forth therein did not rely upon any evidence in support of the examiner's conclusions. Appellants' response to the final Office action was to merely cancel claim 26. Appellants did not present substantive arguments in response to the examiner's rejection. Rather, this appeal proceeding was instituted.

Appellants' Brief on appeal was accompanied by six documents attached as Exhibits A-F. It does not appear that appellants relied upon this evidence previously in this application. In submitting the new evidence with the Appeal Brief, appellants did not comply with the provisions of 37 CFR § 1.195. Rather than enforce the provisions of that rule, the examiner accepted the Appeal Brief and filed her Answer in which she also relied upon new evidence for the first time. Furthermore, the substance of the rejection in the Answer is substantially different from the rejection expressed in the final Office action. Appellants did not respond to the examiner's new position by way of Reply Brief.

Thus, as the record now stands, we have before us for review two completely new positions taken by appellants and the examiner without benefit of a reasoned exchange of views as to the strengths and weaknesses of the respective cases. While we have the benefit of the examiner's views in regard to the new evidence presented by

appellants in this appeal proceeding, we do not have the benefit of appellants' views in regard to the new evidence the examiner relies upon. This is another reason why it is appropriate to consider the examiner's position sans the new evidence.

As seen from the claims reproduced above, the subject matter on appeal involves altering the phenotype of a bird by introducing specified cells into an egg containing a bird during in ovo incubation. The specified cells contain and must be capable of expressing at least one DNA molecule in an amount effective to cause a change in the phenotype of the bird. As stated on page 7 of the Appeal Brief:

The Examiner acknowledges that Appellants have established the ability of such cells to migrate to the avian embryo and persist in the hatched chick. As stated in the Final Office Action of 4 September 1996 (at page 4): "the transformed cells would need to reach their target, which the applicant has shown the instant method to achieve"; and "(t)he problem is not cells reaching their targets".

The examiner agrees stating in the paragraph bridging pages 9-10 of the Examiner's

Answer:

The examiner has even stated that the disclosed method (example 3 and onward) shows retention of hematopoietic stem cells in hatchlings injected at an embryonic stage with stem cells. However, the mere retention of the cells does not imbue a useful phenotypic change to the bird. Such a phenotype change does not need to be commercially successful or therapeutically effective for enablement. However, the method must be shown to be predictable that the change will benefit the art. This is the purpose of patents. Inventions that are of no use are not patentable, they are not enable [sic] as to how to use. This is the status of the instant invention.

We believe the examiner's position is aptly summarized at page 11 of the Examiner's Answer where she states "[t]hus as the specification fails to provide sufficient guidance as to DNA sequences, promoters, and routes of delivery and

dosage regimes to embryonic birds in ovo to produce a useful phenotypic change in birds, the claims are not enabled."

Appellants argue that the working examples of this application teach a method of delivering heterologous cells to an avian embryo where the cells persist in the hatched chick. Appellants argue that that chick containing heterologous cells represents a chick having a changed phenotype. The examiner disagrees stating at page 11 of the Examiner's Answer the fact that the hatched chick contains the heterologous cells "does not indicate that the method results in [a] useful phenotypic change to the bird." From this, it appears the examiner agrees that the hatched chicks described in the working examples do have an altered phenotype, just that the altered phenotype is not "useful."

Since the Examiner's Answer represents a new position taken by the examiner, it is difficult for us to fully understand the examiner's insistence that appellants demonstrate "a useful phenotypic change in birds." The specification states at page 6:

As used herein, an altered "phenotype" of a bird is intended to encompass a sustained alteration in the cellular biochemistry of a bird by the expression of a foreign DNA molecule within the tissues of the bird, which alteration results in a change in one or more physical characteristics of the bird. Thus an altered phenotype can be a change in size, appearance, endocrine response growth rate, immune response to specific antigens, metabolic rate, feed consumption and efficiency, gender, and the like.

Contrary to the examiner's insistence, the hatched chicks of the working examples appear to be as "useful" as any other chick would be. We believe that the examiner's real concern is that the hatched chicks do not meet the above referenced specification

definition of "altered phenotype," i.e., "a sustained alteration in the cellular biochemistry . . . by the expression of a foreign DNA molecule within the tissues of the bird."

If that is in fact the examiner's concern, the examiner has not set forth a rejection based upon the relevant legal principles and performed the fact-finding needed to support such a conclusion. As set forth in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996)

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

Clearly, to make a case of undue experimentation, the examiner needs to make a more detailed analysis taking into account the scope of the claims, the state of the prior art, and relevant evidence which is properly applied in support of the conclusions reached.

What is not helpful is the examiner's insistence that birds produced by the claimed method be "useful." As argued by appellants, the examiner's insistence in this regard bespeaks more of a utility rejection under 35 U.S.C. § 101 than an enablement rejection.

Furthermore, to the extent the examiner may be concerned that the claims embrace possible inoperative embodiments, we point out Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude . . . possible inoperative substances . . ." In re Dinh-Nguyen, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1973). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

To summarize, the claims on appeal only require the method result in a bird which has a changed phenotype. There is no requirement that the change in phenotype be "useful" as apparently the examiner is demanding. The change in phenotype may indeed be considered frivolous by many, yet the resulting bird will still be "useful." Again, it may be the examiner's concern that undue experimentation would be required to practice the invention as to any specific embodiment or that a substantial number of embodiments embraced by the claims on appeal are not enabled without undue experimentation. If so, she has not made that case.

The decision of the examiner is reversed.

REVERSED

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

Appeal No. 1999-1223
Application No. 08/446,021

Page 9

Kenneth D. Sibley
P.O. Box 37428
Raleigh, NC 27627

dem