

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HERINDER K. LONIAL, SATWANT K. NARULA and PAUL J. ZAVODNY

Appeal No. 95-0420
Application 07/959,509¹

ON BRIEF

Before WINTERS, WILLIAM F. SMITH and OWENS Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 17, which are all of the claims pending in the application.

Claims 1 and 17, which are illustrative of the subject matter on appeal, read as

¹Application for patent filed October 9, 1992. According to appellants, this application is a continuation of application 07/616,621, filed November 21, 1990, now abandoned.

follows:

1. A human cell line which has been stably transformed by a recombinant vector comprising a reporter gene operatively linked to a promoter that has a nucleotide sequence corresponding to the sequence of a human HLA-DR" gene and is delimited at the 5' end by a nucleotide residue corresponding to one of residues -1300 to -136 and at the 3' end by a residue corresponding to about residue +32, both delimiting nucleotide residues being numbered from the site of transcription initiation of the human HLA-DR" gene, expression of which reporter gene can be induced by human IFN-(. (emphasis added)

17. Plasmid pHL-cll-h/gGH.

In setting forth the prior art rejection under 35 USC § 103, the examiner relies on the following references:

Selden et al., "Human Growth Hormone as a Reporter Gene in Regulation Studies Employing Transient Gene Expression", *Molecular and Cellular Biology*, Vol. 6, No. 9, pp. 3173-3179 (Sep. 1986). (Selden)

Tsang et al., "Mutational Analysis of the DRA Promoter: *cis*-Acting Sequences and *trans*-Acting Factors", *Molecular and Cellular Biology*, Vol. 10, No. 2, pp. 711-719 (Feb. 1990). (Tsang)

The issue presented for review is whether the examiner erred in rejecting claims 1 through 17 under 35 USC § 103 as unpatentable over the combined disclosures of Selden and Tsang.

On consideration of the record, including Appellants' main Brief, the Reply Brief and

the supplemental Reply Brief, and the Examiner's Answer and supplemental Answer, we reverse the examiner's rejection under 35 USC § 103.

DISCUSSION

First, in presenting their case before the Board, Appellants group and argue claim 17 separately. See the main Brief, pages 3, 12 and 13. The examiner, however, does not focus separately on claim 17. The examiner does not explain how or why a person having ordinary skill in the art, armed with disclosures of Selden and Tsang, would have arrived at the plasmid defined in this claim. Therefore, the examiner has not established a *prima facie* case of unpatentability of claim 17, and the rejection of this claim on prior art grounds is reversed.

Second, in claims 1 through 16, Appellants recite a human cell line which has been stably transformed by a recombinant vector. Manifestly, the combined disclosures of Selden and Tsang are insufficient to support a conclusion of obviousness of claims containing that limitation. As acknowledged by the examiner in the supplemental Answer, page 2, second paragraph, "[t]he rejection does not supply a reference teaching stably transfected cells". (emphasis added). Where, as here, the combined disclosures of Selden and Tsang do not reach the claimed subject matter as a whole,

including the requirement of a human cell line that has been stably transformed by a

recombinant vector, the stated rejection under 35 USC § 103 cannot stand. The rejection of claims 1 through 16 under 35 USC § 103 as unpatentable over the combined disclosures of Selden and Tsang is reversed.

We are mindful that the examiner cites three new references in the Examiner's Answer;² that the examiner discusses one of these references in the Examiner's Answer, page 5, and all of those references in the supplemental Answer, paragraph bridging pages 2 and 3; and that the examiner further refers to an acknowledgment made in Appellants' Reply Brief (supplemental Answer, page 3, lines 1 through 4). The new references and the acknowledgment, however, are not included in the statement of rejection under 35 USC § 103. As stated in In re Hoch, 428 F.2d 1341, 1342 n3, 166 USPQ 406, 407 n3 (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.

We shall not pass on the merits of the unstated rejection which the examiner belatedly attempts to bring through the "back door", based on the combined disclosures of

Selden, Tsang, Wurm, MacDonald, and Smith, and an acknowledgment found in

² These new references are: (a) Wurm, "Integration, Amplification and Stability of Plasmid Sequences in CHO Cell Cultures", *Biologicals*, Vol. 18, pp. 159-164, (1990); (b) Macdonald, "Development of New Cell Lines for Animal Cell Biotechnology", *Biotechnology*, Vol. 10, No. 2, pp. 155-178, (1990); and (c) Smith et al., U.S. Patent No. 5,223,421 Jun. 29, 1993.

Appellants' Reply Brief. Rather, we restrict our review to the stated rejection of record, based on the combined disclosures of Selden and Tsang. That rejection falls short of the mark in view of the claim limitation requiring a human cell line which has been "stably transformed" by a recombinant vector, and that rejection is reversed.

Third, we refer to the Zavodny Declaration executed March 25, 1993, filed under the provisions of 37 CFR 1.132. The Zavodny Declaration and its attachments constitute objective evidence of non-obviousness, relied on by Appellants to rebut any inference of obviousness which may be established by the cited prior art. As correctly pointed out by Appellants, however, the examiner does not come to grips with this rebuttal evidence. See the main Brief, page 11; and the Reply Brief, page 3. Having reviewed the Examiner's Answer and the supplemental Answer, we find no indication that the examiner stepped back and reevaluated patentability in light of the objective evidence set forth in the Zavodny declaration. In and of itself, this constitutes reversible error. As stated in In re Hedges 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986),

If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed. [citations omitted].

This the examiner did not do.

The rejection of claims 1 through 17 under 35 USC § 103 as unpatentable over the

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combined disclosures of Selden and Tsang is reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
WILLIAM F. SMITH)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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TERRY J. OWENS)	
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