

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANNA BRANDAZZA,
PAOLO SARMIENTOS,
and GAETANO ORSINI

Appeal No. 94-1484
Application 07/536,556¹

ON BRIEF

Before WILLIAM F. SMITH, GRON, and WEIMAR, 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, 2, 4, 5, 7, and 8. Subsequently, claim 1 was canceled and replaced by claim 9.

¹ Application for patent filed July 11, 1990.

Accordingly, claims 2, 4, 5, and 7 through 9 are presented for consideration in this appeal.

Claim 9 is illustrative of the subject matter on appeal and reads as follows:

9. A method for the preparation of non-glycosylated pro-UK, characterized in that non-glycosylated human pro-UK is expressed under the control of the E. coli promoter Ptrp and the Shine-Dalgarno sequence MS-2 by E. coli B wherein the sequence comprising the Shine-Dalgarno sequence MS-2, the ATG start codon and the beginning of the pro-UK gene, flanked upstream by a HindIII site and downstream by a TaqI site is as follows:

HindIII

5N-AGCTTTAATAGACGCCGGCCATTCAAACATGAGGATTACCCATGAGC

3N-AATTATCTGCGGCCGGTAAGTTTGTACTCCTAATGGGTACTCG

TaqI

AATGAACTTCATCAAGTTCCAT-3N

TTACTTGAAGTAGTTCAAGGTAGC-5N

and said HindIII site is downstream of the promoter Ptrp.

The references relied upon by the examiner are²:

² In addition, the examiner cites a reference to Kane (Kane et al., "Formation of Recombinant Protein Inclusion Bodies in Escherichia coli, TIBTECH, vol. 6, pp. 95-101 (1988)) at page 2 of the Examiner's Answer. However, the examiner does not rely upon Kane in the statement of the rejection. Rather, the examiner cites Kane at page 9 of the Examiner's Answer "for evidentiary purposes only." As pointed out by the court in In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970), "[w]here (continued...)

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Remaut et al. (Remaut), "Inducible High Level Synthesis of Mature Human Fibroblast Interferon in Escherichia coli", Nucleic Acids Research, vol. 11, no. 14, pp. 4677-4688, (1983)

Holmes et al. (Holmes), "Cloning and Expression of the Gene for Pro-urokinase in Escherichia coli," Biotechnology, vol. 3, no. 10, pp. 323-29 (1985)

Renhof et al. (Renhof), "Synthesis and Functional Activity of Translation Initiation Regions in mRNA," FEBS, vol. 185, no. 2, pp. 277-81 (1985)

Hibino et al. (Hibino), "Enhanced Expression of Human Pro-urokinase cDNA in Escherichia coli." Agric. Biol. Chem., vol. 52, no. 2, pp. 329-336 (1988)

Claims 2, 4, 5, and 7 through 9 stand rejected under 35 U.S.C. § 103 as unpatentable over Holmes in view of Hibino, Remaut, and Renhof. We reverse.

Discussion

By its terms, 35 U.S.C. § 103 requires that obviousness of claimed subject matter be determined on the basis of the "subject matter as a whole." Claim 9 on appeal requires the use of a specific strain of microorganism, E. coli B. The examiner has not explained where or how any of the four references relied upon, individually or in combination, teach or suggest the use of E. coli B. Appellants argue this point at

²(...continued)

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." Accordingly, we have not considered Kane in deciding the issues presented.

page 4 of the Appeal Brief (“the cited references do not disclose or suggest the strain E. coli B”).

Where as here, the examiner’s patentability determination under 35 U.S.C. § 103 has been based on less than the “subject matter as a whole,” the rejection is legally flawed and cannot be sustained. We recognize that the examiner belatedly attempted to rectify this error at page 5 of the Examiner’s Answer where, in responding to appellants’ arguments, the examiner stated that “Appellants have acknowledged, and it has been argued by the examiner, that E. coli B strains . . . are known and available to the public” We first note that the examiner has not relied upon any evidence in stating the rejection in support of the statement. Second, assuming *arguendo*, that E. coli B strains were known at the time of the present invention, that knowledge does not necessarily mean that the use of those strains would have been considered obvious by one of ordinary skill in the art in the manner required by the claims on appeal.

The rejection under 35 U.S.C. § 103 is reversed.

Other Issues

As set forth above, our decision in this appeal has centered upon the failure of the examiner to properly account for that portion of the claimed subject matter directed

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to the use of E. coli B. Appellants argued that the use of this particular strain is significant in the present invention. See, e.g., the first full paragraph of page 5 of the Appeal Brief. As stated at page 20 of the specification:

The choice of the host strain is also a critical step in the development of an efficient method of production. It is, in fact, known that insertion of the same expression plasmid in different strains can lead to very different expression efficiencies (Harris T.J.R. and Emtage J.S. Microbiological Sciences, 3, p. 28-31, 1986).

The Harris reference has not been made of record by either appellants or the examiner.

Furthermore, the specification indicates at page 21 that:

For instance, fermentations at high biomass may dramatically be influenced by the type of host. The present inventors as well as other groups of researchers have consistently found that E. coli strains of the type B can be grown more easily than, e.g., K-12 strains. Insertion of the same expression plasmids, pFC16 or pFC44, in K-12 strains such as C600 generates recombinant strains, which cannot grow, in fermentators, as efficiently as the recombinant B strains. In other words, yields of recombinant non-glycosylated pro-UK are higher from B strains, when using the same expression plasmids.

Appellants have not made of record any further information regarding the work of the “other groups of researchers” who found that E. coli B can consistently be grown more easily than other E. coli strains.

Upon return of the application, appellants and the examiner should take a step back and re-evaluate the record, paying special attention to that aspect of the claimed invention which involves the use of E. coli B. If the work of the “other groups of

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researchers” acknowledged by appellants at page 21 of the specification is prior art, it would appear to be relevant in determining the patentability of the subject matter on appeal.

The decision of the examiner is reversed.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Teddy S. Gron)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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