

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(2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BERND MEYHACK,
WALTER MARDI and JUTTA HEIM

Appeal No. 94-1775
Application 07/488,513¹

ON BRIEF

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and
MCKELVEY, Senior Administrative Patent Judge.

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, 5
through 16 and 18, all the claims remaining in the application.

¹ Application for patent filed February 27, 1990. According to applicants, this application is a continuation of Application 06/938,102, filed December 4, 1986, now abandoned.

Claims 1, 18, 15 and 16 are illustrative of the subject matter on appeal and read as follows:

1. Method for the production of proteins with hirudin activity comprising culturing under appropriate nutrient conditions yeast cells transformed with a hybrid vector comprising

one to four DNA inserts each comprising a yeast promoter selected from the group consisting of the PHO5 promoter, the GAPDH promoter and a hybrid promoter comprising upstream activation sequences of the PHO5 gene and downstream promoter elements including a functional TATA box of the GAPDH gene,

a DNA segment consisting of a first DNA sequence encoding the PHO5 or invertase signal peptide upstream of and in reading frame with a second DNA sequence coding for mature desulphato-hirudin which DNA segment is under transcriptional control of said yeast promoter, and a DNA sequence containing eukaryotic transcription termination signals,

and a selective gene marker selected from the group consisting of URA1, URA3, ARG4, LEU2, HIS3, HIS4, TRP5 and TRP1, wherein the proteins with hirudin activity are predominantly secreted into the culture medium, and

isolating the proteins with hirudin activity from the culture medium.

18. A method according to claim 1 wherein about 90% or more of the proteins with hirudin activity are secreted into the culture medium.

15. A yeast hybrid vector comprising one to four DNA inserts each comprising a yeast promoter selected from the group consisting of the PHO5 promoter, the GAPDH promoter and a hybrid promoter comprising upstream activation sequences of the PHO5 gene and downstream promoter elements including a functional TATA box of the GAPDH gene, a DNA segment consisting of a first DNA sequence encoding the PHO5 or invertase signal peptide upstream of and in reading frame with a second DNA sequence coding for mature desulphatohirudin which DNA segment is under transcriptional control of said yeast promoter, and a DNA sequence containing eukaryotic transcription termination signals, and a selective gene marker selected from the group consisting of URA1, URA3, ARG4, LEU2, HIS3, HIS4, TRP5 and TRP1.

16. A yeast cell transformed with a hybrid vector comprising one to four DNA inserts each comprising a yeast promoter selected from the group consisting of the PHO5 promoter, the GAPDH promoter and a hybrid promoter comprising upstream activation sequences of the PHO5 gene and downstream promoter elements including a functional TATA box of the GAPDH gene, a DNA segment consisting of a first DNA sequence encoding the PHO5 or invertase signal peptide upstream of and in reading frame with a second DNA sequence coding for mature desulphathohirudin which DNA segment is under transcriptional control of said yeast promoter, and a DNA sequence containing eukaryotic transcription termination signals, and a selective gene marker selected from the group consisting of URA1, URA3, ARG4, LEU2, HIS3, HIS4, TRP5 and TRP1, and mutants thereof.

The references relied upon by the examiner are²:

Derynck et al. (Derynck)	4,742,003	May 3, 1988
Brake et al. ((Brake)	4,752,576	June 21, 1988
Chang et al. (Chang)	5,010,003	Apr. 23, 1991

Eur. Pat. App.(Kramer)	0 124 874	Nov. 14, 1984
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Eur. Pat. App. (Tolstoshev)	0 158 564	Oct. 16, 1985
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Eur. Pat. App. (Tripier)	0 158 986	Oct. 23, 1985
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Edens et al. (Edens), "Synthesis and Processing of the Plant Protein Thaumatin in Yeast", Cell, Vol. 37, pages 629-633 (June 1984).

We make the following patent of record:

Liersch et al. (Liersch)	5,422,249	June 6, 1995
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Claims 1, 5 through 16 and 18 stand rejected under 35 U.S.C. § 103 as unpatentable over Chang in view of any of Brake, Edens, Kramer or Derynck and either of

² Our consideration of the patent documents identified as Tolstoshev and Tripier has been based upon English language translations of the full text documents. Copies of the translations are enclosed with this opinion.

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Tolstoshev or Tripier. In addition, claims 1, 5 through 14 and 18 are provisionally rejected under the judicially created doctrine of obviousness- type double patenting as unpatentable over claim 16 of copending application 07/700,997 in view of Chang and further in view of Brake, Edens, Kramer and Derynck. Finally, claims 1, 5 through 14 and 18 are provisionally rejected under 35 U.S.C. § 103 as obvious over copending application 07/700,997 in view of Chang and further in view of Brake, Edens, Kramer and Derynck.

We vacate the two provisional rejections based upon application 07/700,997. We also vacate the obviousness rejection premised in part upon Chang as it pertains to claims 1 and 5 through 16 and reverse this rejection as it pertains to claim 18. We also make a new ground of rejection under the provisions of 37 CFR § 1.196(b).

PROVISIONAL REJECTIONS

Each of these rejections is premised upon application 07/700,997 which now stands abandoned. However, that application was refiled as application 08/121,974 which issued as U.S. Patent 5,422,249. Since the underlying premise of the two provisional rejections, application 07/700,997 is now abandoned, any issues regarding the patentability of the claims pending in this application on the basis of the claims then pending in that abandoned application are moot. Accordingly, we vacate the two provisional rejections. Upon return of the application, the examiner should consider the `249 patent and determine whether the now issued patent adversely affects the

patentability of any claim pending in this application. If so, the examiner should issue an appropriate Office action setting forth all appropriate rejections.

REJECTION UNDER 35 U.S.C. § 103 PREMISED UPON CHANG

1. Claim 18

Claim 18 is directed to a method for producing proteins with hirudin activity which comprises culturing under appropriate nutrient conditions yeast cells which have been transformed with a specified hybrid vector. In relevant part, claim 18 requires that 90% or more of the proteins with hirudin activity are secreted into the culture medium.

Assuming without deciding that the references relied upon by the examiner would have suggested the construction and use of yeast cells transformed with the hybrid vector required by claim 1 on appeal, the rejection before us still cannot be sustained. According to pages 3-6 of the Examiner's Answer, the examiner's position in regard to the required level of secretion of proteins with hirudin activity is:

[a]ny differences between the amount of protein product secreted using the method of the instant invention, and that of Chang et al. is considered to be expected, since such variability was well known at the time of the invention, as has been pointed out by the applicant in previous arguments and in the Declaration of Dr. Hinnen, submitted 8/9/90, Paper No. 16, and appended to the Brief.

While the record of this application may support the proposition that transformed yeasts will secrete heterologous proteins in a variable amount, that does not in and of itself support the finding which needs to be made under these circumstances, i.e., whether the

prior art relied upon by the examiner would have reasonably suggested that the specific yeast containing the hybrid vector required by claim 18 on appeal secrete 90% or more of the proteins with hirudin activity into the culture medium. At the point where we need a specific, fact supported determination by the examiner, we are only left with a vague conclusion on the part of the examiner.

Obvious determinations must be premised upon a consideration of the “subject matter as a whole.” 35 U.S.C. § 103. Here, the examiner has failed to adequately come to grips with the requirement of claim 18 on appeal that 90% or more of the proteins with hirudin activity produced in that method are secreted into the culture medium. As a consequence, the examiner has failed to properly discharge his initial burden of establishing that the subject matter of claim 18, as a whole, would have been prima facie obvious to one of ordinary skill in the art.

The rejection of claim 18 under 35 U.S.C. § 103 premised upon Chang is reversed.

2. Claims 1 and 5 through 14

Claim 1 differs from claim 18 in that claim 1 requires that “proteins with hirudin activity are predominantly secreted into the culture medium” rather than at a level of 90% or more. Thus, prior to determining whether the subject matter of claim 1 as a whole would have been obvious to one of ordinary skill in the art based upon the applied references, a determination must be made as to what is meant by the requirement of claim 1 that the proteins with hirudin activity are predominantly secreted into the culture medium.

This claim requirement was added by amendment on May 16, 1991 (Paper No. 18). When this amendment was presented, appellants did not specify where in the original disclosure of this application, the amendatory language found written descriptive support or attempt to describe the metes and bounds of the word “predominantly.” In similar fashion, the examiner has not favored the record with his view as to where the original disclosure of the application provides written descriptive support for the newly added language or discussed the metes and bounds of the word “predominantly.”

Assuming again without deciding that the prior art relied upon by the examiner would have suggested the use of yeast cells transformed with the hybrid vector required by claim 1 on appeal to produce proteins with hirudin activity, one is not in a position to make a patentability determination of the subject matter of claim 1 under 35 U.S.C. § 103 as a whole until an understanding is reached as to whether the original disclosure of this application provides written descriptive support of the amendatory language under 35 U.S.C. § 112, first paragraph, and, if so, what the metes and bounds of this amendatory language are. Thus, we are not in a position to render a final decision as to whether the subject matter of claim 1 as a whole would have been obvious to one of ordinary skill in the art. Claims 5 through 14 depend from claim 1 and do not clarify this matter. Accordingly, we vacate the rejection under 35 U.S.C. § 103 premised upon Chang as it pertains to claims 1 and 5 through 14. But see the new grounds of rejections below under the provisions of 37 CFR § 1.196(b).

3. Claims 15 and 16

We vacate the prior art rejection as it pertains to these claims since we have no analysis from the examiner in support of his conclusion that these two claims are unpatentable. Claim 15 is directed to a yeast hybrid vector having specified DNA sequences and claim 16 is directed to a yeast cell transformed with a hybrid vector containing specified DNA sequences. These claims have not been separately discussed by the examiner and appellants in this appeal. While these claims do not explicitly require that the yeast hybrid vector or the yeast cell transformed with the hybrid vector must function upon use to secrete proteins with hirudin activity into the culture medium in any particular amount, their patentability must be determined with that property in mind. As set forth in In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963), "a compound and all of its properties are inseparable; they are one and the same thing."

In our view, the same concept applies to composition of matter claims 15 and 16. Until appellants and the examiner have separately addressed the merits of the patentability of these claims, taking into account the properties possessed by the yeast hybrid vector and transformed yeast cell, we are not in a position to render a final decision on the patentability of these claims. It may be that yeast hybrid vectors according to claim 15 on appeal and transformed yeast cells according to claim 16 on appeal possess the property of expressing proteins with hirudin activity over a wide range of values. Some values within that range may reasonably be concluded to have been expected based upon

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a consideration of the prior art. Other values within that range may be considered to have been unexpected based upon a consideration of the same prior art. If the examiner and appellants determine that to be the situation, cases such as In re Muchmore, 433 F.2d 824, 826, 167 USPQ 681, 683 (CCPA 1970) in which the court held that claims which read on both obvious and unobvious subject matter are obvious under 35 U.S.C. § 103 need to be considered. This analysis needs to be made by the examiner and appellants in the first instance and should not be made by this board in a vacuum. By statute, this board acts as a board of review.

35 U.S.C. § 7 (“The [board] shall . . . review adverse decisions of examiners upon applications for patents . . .”).

Upon return of the application, the examiner should consider the patentability of claims 15 and 16 apart from the method claims pending in this application. If the examiner determines that claims 15 and 16 are unpatentable, he should issue an appropriate Office action so that appellants will have a full and fair opportunity to respond to the newly stated position.

NEW GROUNDS OF REJECTION UNDER 37 CFR § 1.196(B)

Under the provisions of 37 CFR § 1.196(b), we make the following new grounds of rejection.

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Claims 1 and 5 through 14 are rejected under 35 U.S.C. § 112, first paragraph, as lacking written descriptive support in the original disclosure of this application and 35 U.S.C. § 112, second paragraph, as being indefinite.

As set forth above, claim 1 was amended during prosecution of this application to require that the proteins with hirudin activity are “predominantly” secreted into the culture medium. The specification of this application consists of 117 pages. Appellants did not point out where the original disclosure of this application provided the written descriptive support required under 35 U.S.C. § 112, first paragraph. Our review of the matter, hampered as it was by the lack of guidance from appellants, did not reveal any portion of the specification which can reasonably be said to provide the requisite written descriptive support for the amendatory language.

An integral part of the analysis to determine whether the original disclosure of this application provides written descriptive support for the questioned amendatory language is a determination of the metes and bounds of the word “predominantly.” If one does not know what to look for, one will never know whether they found it. As the record now stands, the written descriptive support for and the metes and bounds of the questioned term cannot be readily ascertained.³

³ Issues such as those raised in this new ground of rejection would be avoided in the most part if examiners would enforce the requirements of 37 CFR § 1.75(d)(1) when amendments are submitted during the prosecution of an application. If upon receipt of the amendment filed May 16, 1991, in this application, the examiner had required appellants to state for the record where the amended claim language finds “clear support or

TIME PERIOD FOR RESPONSE

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)).

37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

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

REVERSED-IN-PART
VACATED-IN-PART
37 CFR § 1.196(b)

antecedent basis in the description," these issues would have been resolved at an earlier point in time.

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SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
)	
FRED E. MCKELVEY, Senior)	
Administrative Patent Judge)	

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Michael W. Glynn
CIBA-GEIGY Corp.
Patent Department
520 White Plains Road
P. O. Box 2005
Tarrytown, N Y 10591-9005