

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 50

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHAN A. VAN DEN BERG, ALBERT J.J. VAN OOYEN, KRIJN RIETVELD,
CORNELIS P. HOLLENBERG, SUNIL DAS and ALBERT DE LEEUW

Appeal No. 95-0083
Application 07/711,556¹

ON BRIEF

Before STONER, Chief Administrative Patent Judge and
WINTERS and WILLIAM F. SMITH, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed May 29, 1991. According to appellants this application is a continuation of application Serial No. 07/480,102, filed February 14, 1990, now abandoned, and a continuation of application Serial No. 06/572,414, filed January 19, 1984, now U.S. Patent No. 4,859,596, issued August 22, 1989 and a continuation of application Serial No. 07/078,539 filed July 28, 1987, now U.S. Patent No. 4,934,529 issued July 24, 1990 and a continuation of application Serial No. 07/300,608, filed January 23, 1989, now abandoned.

This appeal was taken from the examiner's decision rejecting claims 43, 45 through 49, 52, 54 and 56 through 58, which are the only claims remaining in the application.

Claims 43 and 54, which are illustrative of the subject matter on appeal, read as follows:

43. A method for producing a polypeptide of interest in a *Kluyveromyces* host cell, said method comprising:

growing a *Kluyveromyces* host cell comprising an expression cassette which comprises as components, in the direction of transcription, a transcriptional regulatory region and translational initiation region functional in said host cell;

a DNA sequence which encodes said polypeptide of interest;
and

translational and transcriptional termination regions functional in said host cell, wherein expression of said DNA sequence is under regulatory control of said transcriptional and translational regions and wherein said components are operably linked so as to provide for expression of said DNA sequence, whereby said polypeptide of interest is expressed in and secreted by said host cell. [emphasis added]

54. A method for obtaining a polypeptide of interest using a transformed *Kluyveromyces* cell, said method comprising:

growing said transformed *Kluyveromyces* cell comprising a DNA sequence comprising a region encoding a polypeptide heterologous to said cell, wherein said DNA sequence results from joining

at least two DNA molecules to provide a gene functional for expression in said *Kluyveromyces* cell, wherein said gene functional for expression comprises at least a promoter regulation

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region and a structural gene, whereby said DNA sequence is expressed and said polypeptide is obtained.

The references relied on by the examiner are:

Hitzeman et al. (Hitzeman)	4,775,622	Oct. 04, 1983
Kurjan et al. (Kurjan)	4,546,082	Oct. 08, 1985
Hollenberg et al. (Hollenberg)	4,859,596	Aug. 22, 1989
Hollenberg et al. (Hollenberg) (European Patent Application)	EP 0 096 430	Dec. 21, 1983

Sunil Das, et al. (Das) "A High-Frequency Transformation System for the Yeast *Kluyveromyces lactis*", Current Genetics, Vol. 6, pgs 123-128 (1982).

The issues presented for review are: (1) whether the examiner erred in rejecting claims 43, 45, 46, 48, 49, 52, 54, 56 and 57 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 6 through 12 of U.S. Patent No. 4,859,596; (2) whether the examiner erred in rejecting claims 47 and 58 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 6 through 12 of U.S. Patent No. 4,859,596 considered with Hitzeman; and (3) whether the examiner erred in rejecting claims 43, 45, 46, 49, 52, 54 and 56 through 58 under

35 U.S.C. § 103 as unpatentable over Hollenberg (European Patent Application 096 430) in view of Das, Kurjan, and Hitzeman.

On consideration of the record, we reverse the double patenting rejection of claims 43, 45 through 49 and 52. However, we affirm the double patenting rejection of claims 54 and 56 through 58. We reverse the rejection of claims 43, 45, 46, 49, 52, 54 and 56 through 58 under 35 U.S.C. § 103.

DOUBLE PATENTING

In rejecting the appealed claims for obviousness-type double patenting, the examiner refers to claims 1 and 6 through 12 of U.S. Patent No. 4,859,596. In our judgment, however, the examiner has not adequately explained how claims 43, 45 through 49, and 52 in this application define merely an obvious variation of the invention set forth in claims 1 and 6 through 12 of the '596 patent. See In re Vogel 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). Claims 43, 45 through 49 and 52 define a method for producing a polypeptide of interest in a *Kluyveromyces* host cell, where the polypeptide of interest is expressed in and secreted by the host cell. In view of this limitation, that the polypeptide is secreted by the host cell, we find that the examiner has not established a *prima facie* case of obviousness-type double patenting.

As correctly pointed out by the examiner, claims 1 and 6 through 12 of the '596 patent define a transformed *Kluyveromyces* cell in essentially the same terms found in appealed claims 54 and 56 through 58. That, however, is not sufficient to support a

conclusion of obviousness-type double patenting of method claims 43, 45 through 49 and 52, requiring that the polypeptide of interest not only be expressed in, but also be secreted by, the host cell.

Claims 54 and 56 through 58, however, stand on different footing. These claims are drawn to a method for obtaining a polypeptide of interest by growing a transformed *Kluyveromyces* cell, whereby DNA encoding a polypeptide heterologous to the cell is expressed and the polypeptide is obtained. These claims do not require that the polypeptide of interest be secreted by the host cell. The transformed *Kluyveromyces* cell recited in claim 1 of U.S. Patent No. 4,859,596 is described in essentially the same terms in claim 54 on appeal.

Respecting claims 54 and 56 through 58, we agree that it would have been obvious to a person having ordinary skill to grow the transformed *Kluyveromyces* cell recited in claims 1 and 6 through 12 of the '596 patent to achieve expression of the recombinantly introduced gene. As stated by the examiner, "Such a procedure is

standard in the art, is in fact the reason for introducing the genes into the host cell, and would be well within the knowledge and skill of the ordinary practitioner" (Examiner's Answer, page 3, lines 6 through 8). Claim 58 depends from claim 54 and requires that the polypeptide is human serum albumin. We agree with the examiner that the choice

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of human serum albumin as the expressed polypeptide would have been obvious in view of Hitzeman, disclosing yeast organisms which are caused to express, process, and secrete protein that is normally heterologous to yeast, e.g., human serum albumin.

Appellants argue that claims 1 and 6 through 12 of the '596 patent are drawn to a transformed *Kluyveromyces* cell; that claims 54 and 56 through 58 on appeal are drawn to a method for obtaining a polypeptide of interest by growing a transformed *Kluyveromyces* cell; and that the cell and method of growing or culturing a cell are patentably distinct statutory classes of invention (Appeal Brief, pages 13 and 14).

According to appellants,

Appellant has claimed a method of using a product, not a product itself; appellant is entitled to a patent on that method, which has not been claimed or disclosed before, that extends for its full statutory term of 17 years. [Appeal Brief, page 14]

The argument lacks merit. As stated in a similar context in In re Lonardo 119 F.3d 960, 968, 43 USPQ2d 1262, 1268 (Fed. Cir. 1997),

Restorative Care argues that the method of using the device would not have been obvious over a claim to the device. We do not agree that there is a patentable distinction between the method of using the device and the device itself. The claimed structure of the device suggests how it is to be used and that use thus would have been obvious.

We affirm the obviousness-type double patenting rejection of claims 54 and 56 through 58.

SECTION 103

We have carefully considered the record, but do not find a coherent explanation why claims 43, 45, 46, 49, 52, 54 and 56 through 58 in this application are unpatentable over the cited prior art. Rather, the examiner refers us to Paper No. 6 in parent application Serial No. 07/480,102, mailed November 29, 1990, where the combined disclosures of Hollenberg (European Patent Application 096 430), Das, Kurjan, and Hitzeman were applied against a different set of claims (Examiner's Answer, page 3, lines 20 through 23; page 5, lines 1 through 10). Simply put, the examiner does not explain why the claims in this application are unpatentable over the cited prior art.

The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents. 35 U.S.C. § 7 (b). In other words, the Board serves as an appellate tribunal and reviews adverse decisions of examiners on the written record. Here, the examiner has not provided us with a position susceptible to meaningful review.

Further, appellants rely on the following objective evidence of non-obviousness: (1) Dixon et al., "Purification and Properties of an Inducible β -Galactosidase Isolated from the Yeast *Kluyveromyces lactis*", Journal of Bacteriology, vol. 137, pages 51-61 (1979), attached as appendix C to the Appeal Brief; (2) International Publication WO 83/04418 published December 22, 1983, copies of the front page and introduction attached as appendix D to the appeal Brief; and (3) Dr. Van Den Berg's Declaration

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executed May 12, 1986, attached to Paper No. 22 in this record and referred to in the Reply Brief, page 6, footnote 4. The examiner, however, does not acknowledge or respond to appellants' evidence in the Examiner's Answer or Supplemental Answer. The examiner does not step back and reevaluate patentability in light of the rebuttal evidence. 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. [citation omitted].

The rejection of claims 43, 45, 46, 49, 52, 54 and 56 through 58 under 35 U.S.C. § 103 is reversed.

OTHER ISSUES

On return of this application to the examining corps, we recommend that the examiner step back and reassess patentability of the appealed claims under 35 U.S.C. § 103. In so doing, the examiner should note that there are two independent claims on

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appeal. Claim 43 and the claims dependent therefrom require that the polypeptide of interest be expressed in and secreted by the host cell. Claim 54 and the claims dependent therefrom do not require that the polypeptide be secreted. Both appellants and the examiner appear to have overlooked this salient point in presenting arguments before the board.

The face of the file wrapper indicates that this application is derived from a series of continuation applications. On return of this application to the examining corps, the examiner should determine (1) whether each parent application is correctly denominated a continuation of the immediately preceding application; or (2) whether any of the parent applications should be denominated a continuation-in-part of its immediately preceding application. Merely by way of example, parent application Serial

No. 06/572,414, now U.S. Patent No. 4,859,596 does not appear to contain the same set of figures or the same written description compared with the instant application.

If the examiner determines that any of the parent applications should be denominated a continuation-in-part of its preceding application, we recommend that the examiner engage in a claim by claim analysis to ascertain the effective filing date of each claim in this application. Ascertaining the effective filing date of each claim would be a crucial first step in reassessing patentability of the appealed claims under 35

U.S.C. § 103.

CONCLUSION

For the reasons set forth in the body of this opinion, we reverse the rejection of claims 43, 45 through 49 and 52 for obviousness-type double patenting. However, we affirm the rejection of claims 54 and 56 through 58 for obviousness-type double patenting. We reverse the rejection of claims 43, 45, 46, 49, 52, 54 and 56 through 58 under 35 U.S.C. § 103. On return of this application to the examining corps, we recommend that the examiner step back and reassess patentability of the appealed claims under 35 U.S.C. § 103.

The examiner's decision is affirmed in part.

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

AFFIRMED IN PART

BRUCE H. STONER, JR.)
Chief Administrative Patent Judge)
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SHERMAN D. WINTERS
Administrative Patent Judge

WILLIAM F. SMITH
Administrative Patent Judge

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