

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BERNARD ROIZMAN and FENYONG LIU

Appeal No. 1996-2639
Application No. 08/176,320

ON BRIEF

Before WILLIAM F. SMITH, ROBINSON, and SPIEGEL, *Administrative Patent Judges*.
SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 6 through 13, 22, 43, 58, 63 and 66 through 71, which are all of the claims pending in this application.¹

Initially, we note that the examiner entered three new grounds of rejection, i.e., (1) of claims 58 and 63 under 35 U.S.C. § 102 as anticipated by or, in the alternative, under 35 U.S.C.

¹ Notwithstanding entry authorization by the examiner (see answer, page 3), appellants' request to cancel claim 23 (see brief, page 1) has not been physically entered in the file record. This clerical processing oversight should be corrected upon return of the above identified application to the jurisdiction of the examiner.

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§ 103 as obvious over Holland, (2) of claim 8 under 35 U.S.C. § 112, second paragraph, as indefinite and (3) of claims 7 and 8 under 35 U.S.C. § 112, fourth paragraph, as failing to further the subject matter of a previous claim, i.e., claim 6 (answer, pages 6-9, section (10) entitled “New grounds of rejection”). In the answer, page 16, the examiner states as follows:

In view of the new ground of rejection, appellant is given a period of TWO MONTHS from the mailing date of this examiner’s answer within which to file a reply to any new ground of rejection. Such reply may include any amendment or material appropriate to the new ground of rejection. Prosecution otherwise remains closed. Failure to respond to the new ground of rejection will result in dismissal of the appeal of the claims so rejected.

Appellants failed to respond to the new grounds of rejection and, accordingly, the appeal with respect to claims 7, 8, 58 and 63 is *dismissed*.² Thus, claims 6, 9 through 13, 22, 43 and 66 through 71 are the only claims remaining on appeal.

Claims 6 and 13 are illustrative of the subject matter on appeal and read as follows:

6. An isolated and purified nucleic acid molecule comprising a fragment consisting of a sequence encoding a herpes simplex 1 protease, said molecule being engineered through the introduction of one or more genetic control elements to control the expression of said coding sequence, wherein said control element is one that does not normally control expression of the herpes virus protease in the herpes virus genome.

13. The nucleic acid molecule of claim 6 comprising a map region essentially as set forth in Figure 1, line 5 or line 6.

² On March 31, 2000, Gloria Henderson, paralegal with the Board of Patent Appeals and Interferences, spoke on the telephone with Steven L. Highlander, Reg. No. 37,642, counsel for appellants. In that telephone conversation, counsel indicated that no reply brief was filed in response to the new grounds of rejection and that those claims will probably be dropped.

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The examiner relies on the following references of record:

Bruce Alberts et al. (Alberts), *MOLECULAR BIOLOGY OF THE CELL* 98-103 (Garland Publishing, Inc. New York, New York 1983) .

Louis E. Holland et al. (Holland), "Transcriptional and Genetic Analyses of the Herpes Simplex Virus Type 1 Genome: Coordinates 0.29 to 0.45," 49 *Journal of Virology* 3, 947-959 (March 1984).

D.J. McGeoch et al. (McGeoch), "The Complete DNA Sequence of the Long Unique Region in the Genome of Herpes Simplex Virus Type 1," 69 *Journal of General Virology* 1531-1574 (1988).

Benjamin Lewin (Lewin), *GENES* 41-60 (3d ed., New York, John Wiley & Sons, 1987).

J. Sambrook et al. (Sambrook), *MOLECULAR CLONING: A LABORATORY MANUAL* 16.1-16.31, F.1-F.11 (2nd ed., Cold Spring Harbor laboratory Press 1989).

Lubert Stryer (Stryer), *BIOCHEMISTRY* 71-82 (3d ed., New York, W. H. Freeman and Company 1988).

*ISSUES*³

³ According to the advisory action mailed March 28, 1995 (Paper No. 29), the response filed March 13, 1995 (Paper No. 28) overcame the final provisional rejection of claims 23, 58 and 63 under 35 U.S.C. § 101 double patenting over claims 71-75 of copending application no. 07/832,855.

The examiner withdrew (i) the final rejection of claims 67-69 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure and (ii) the final provisional rejection of claims 6-13, 22, 43 and 66-71 under the judicially created doctrine of obviousness-type double patenting over claims 31, 32, 35-38 and 71-75 of copending application no. 07/832,855 in the answer (page 4).

Moreover, in that the final rejections (1) of claim 13 under 35 U.S.C. § 112, second paragraph, as indefinite and (2) of claims 23, 58 and 63 (now claims 58 and 63) under 35 U.S.C. § 102 as anticipated by Holland are not repeated in the answer, they are presumed to have been withdrawn. *Ex parte Emm*, 118 USPQ 180, 181 (Bd. App. 1957).

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The sole issue remaining on appeal is whether the examiner erred in rejecting claims 6, 9-13, 22, 43 and 66-71 under 35 U.S.C. § 103 as unpatentable over McGeoch in view of Sambrook. We reverse.

Appellants' claimed invention is directed to isolated and purified nucleic acid sequences encoding for a herpes simplex virus type 1 (HSV-1) protease.

OPINION

McGeoch discloses the DNA sequence of the long unique region (U_L) in the genome of HSV-1 strain 17 (abstract; Figs. 1-3), which included 57 identified open reading frames (page 1535). Sambrook describes methods of expressing cloned genes in cultured mammalian cells. According to the examiner, it would have been obvious to one of ordinary skill in the art to have cloned the U_L 26 region described by McGeoch using the methods of Sambrook to further study and characterize the function of this protein (answer, page 6). However, the examiner has failed to point out, and we do not find, where McGeoch discloses or suggests that the U_L 26 region, or any other region of the disclosed HSV-1 U_L sequence for that matter, encodes a protease. *See In re Kratz*, 592 F.2d 1169, 1175, 201

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USPQ 71, 76 (CCPA 1979) . Indeed, in allowing related application no. 07/832,855,⁴ this same examiner stated in her reasons for allowance that

Applicants have shown that the HSV U_L26 open reading frame encodes a protease; the biological activity and function of this protein was not previously known in the art. The newly submitted claims (amendment of 7/3/95) are drawn to an assay to identify agents that inhibit the HSV protease. The amendment overcomes the previous art rejections because, in order to assay for an enzyme-inhibiting agent, one would need to know the enzyme exists. This was not known in the art at the time the invention was made. The claims are thus deemed to be novel and unobvious. [Notice of Allowability, Paper No. 26, mailed July 10, 1995, in application no. 07/832,855, now U.S. Patent No. 5,478,727, issued Dec. 26, 1995, copy attached to this decision.]

It appears incongruous for the same examiner to allow claims which require “a purified HSV protease encoded by at least domains II and III of U_L26 gene”⁵ because it was not even known that HSV possessed a viral protease *and* to maintain that it would have been obvious to clone a nucleic acid sequence for an enzyme not previously known to exist. Therefore, although it may have been within ordinary skill in the art to ligate the U_L26 open reading frame sequence of McGeoch into a cloning

⁴Application No. 08/176,320, filed January 3, 1994, is a continuation of application no. 07/705,814, filed May 24, 1991, now abandoned. U.S. Patent 5,478,727, issued from application no. 07/832,855 which (a) was a continuation-in-part of application no. 07/705,814 and (b) was the same application which was the basis for the withdrawn provisional double patenting rejections noted above.

⁵ Claim 1 in issued U.S. Patent 5,478,787 reads as follows:

1. An assay method to identify a substance capable of inhibiting a herpes virus protease comprising:

- (a) obtaining a purified HSV protease encoded by at least domains II and III of U_L26 gene;
- (b) adding to said protease a protein substrate containing the cleavage site of said protease under conditions appropriate to effect proteolytic cleavage of said substrate;
- (c) adding to said protease a candidate inhibitor substance; and
- (d) determining whether said protein substrate has been cleaved.

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DOUGLAS W. ROBINSON
Administrative Patent Judge

CAROL A. SPIEGEL
Administrative Patent Judge

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