

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GEORGE J. TODARO,
DAVID W. LEUNG and
TIMOTHY M. ROSE

Appeal No. 1997-3020
Application 08/149,101

HEARING REQUESTED¹

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

WILLIAM F. SMITH, Administrative Patent Judge

¹ Appellants have requested that this appeal be set for oral argument. However, we have reviewed this case together with related Appeal No. 1996-3538, Application 08/097,869. Appellants in Appeal 1996-3538 also requested oral argument and upon the setting of a hearing date, waived the hearing. In reviewing both appeals it became apparent for the reasons set forth infra that a hearing in this appeal would not be needed.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 28. Subsequently, claims 29 through 33 were added to the application. Claims 29 and 30 are objected to as being dependent upon a rejected base claim. Claims 31 through 33 are allowed. Claims 1 and 12 are illustrative of the subject matter on appeal and read as follows:

1. A hybrid cytokine polypeptide comprising: 1) four α -helical sequences, the α -helical sequences selected from cytokine α -helical sequences, the cytokine being selected from the group consisting of leukemia inhibitory factor (L), granulocyte colony stimulating factor (G), interleukin-6(I), interleukin-11(E), ciliary neurotrophic factor (C), and oncostatin-M (O); and 2) three linking sequences, the linking sequences selected from at least a portion of one or more linking sequences from any of the foregoing cytokines, wherein at least one of the four α -helical sequences is derived from a different cytokine than at least one other of the four α -helical sequences.

12. A DNA molecule that encodes a hybrid cytokine, the hybrid cytokine comprising: 1) four α -helical sequences selected from an α -helical sequence derived from a cytokine, the cytokine being selected from the group consisting of L, G, I, E, C and O; and 2) three linking sequences selected from at least a portion of a linking sequence from any of the foregoing cytokines, wherein at least one of the four α -helical sequences is from a different cytokine than at least one other of the four α -helical sequences, said DNA molecule comprising:

(A) complementary strands;

(B) DNA molecules which hybridize, under conditions of high stringency, to a probe consisting of any of the foregoing DNA molecules or their complementary sequences; and

(C) DNA molecules which would hybridize to the DNA molecules set forth above or a probe derived from a DNA molecule encoding any of the foregoing hybrid cytokines, but for a degeneracy of genetic code.

No prior art has been relied upon by the examiner in the rejection of the claims under appeal.

Claims 1 through 28 stand rejected under 35 U.S.C. § 112, first paragraph, (enablement). We reverse.

DISCUSSION

1. Claims 1 through 11 and 27

The patent examiner bears the initial burden of providing reasons why a supporting disclosure does not enable one skilled in the art to make and use a claimed invention. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). The examiner's position concerning the enablement of the appealed claims is two-fold. First, the examiner is of the opinion that it would require undue experimentation for one skilled in the art to make the hybrid cytokines such that the hybrid cytokines possess a desired activity. Second, the examiner is of the opinion that there is an unpredictability in the activity of any one hybrid cytokine encompassed by the claims on appeal.

It is noted that the examiner has stated on the record that the specification is enabling for hybrid cytokines having the conformation LLLI, LLLI" , IIIL, IIIL" , IIIG and IGGI since specific examples are set forth in the specification concerning the manufacture and use of these hybrid cytokines. However, the examiner is of the opinion that the specification does not reasonably provide enablement for all of the hybrid cytokines encompassed by claim 1.

Claim 1 recites a hybrid cytokine comprising 1) four α -helical regions, wherein the four α -helical regions are derived from the corresponding α -helical region of a factor selected from the group consisting of leukemia inhibitory factor (L), granulocyte-colony stimulating factor (G), interleukin-6 (I), interleukin-11 (E), ciliary neurotrophic factor (C) and oncostatin-M (O), and 2) three linking sequences, the linking sequences selected from at least a portion of one or more linking sequences from any of the foregoing cytokines. At least one of the α -helical regions of the hybrid cytokine is derived from a factor different from that of the other α -helical regions.

The specification describes the hybrid cytokines as being useful in treating “indications for which their native counterparts are often employed.” See lines 22-23 on page 13 of the specification. The native counterparts used to make the hybrid cytokines as well as certain of their activities and uses are described on pages 1 through 3 of the specification.

In initiating and maintaining the rejection of the claims under 35 U.S.C. § 112, first paragraph, it does not appear that the examiner has considered the relevant legal standards which govern the issue of enablement. As a consequence, the requisite factual analysis has not been undertaken by the examiner. For example, the examiner has not presented a reasoned analysis of the state of the prior art in regard to the known uses of the native cytokines which are used to make the hybrid cytokines of the invention. Such an analysis is needed since the specification need not disclose what is well known in the art.

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Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1366, 42 USPQ2d, 1001, 1005 (Fed. Cir. 1997); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). As indicated, the specification describes the hybrid cytokines are useful for treating the indications for which their native counterparts are employed, and describes several of the known, prior art uses for the native cytokines. The examiner has not explained why the hybrid cytokines would not be useful in the same manner.

In the Examiner's Answer (Paper No. 22, May 16, 1997), the examiner states on page 5 that "This, then, makes the claimed Invention unpredictable and therefore undue experimentation would be incurred by one of ordinary skill in the art to use the claimed Invention," and on page 14 that one "cannot pick and choose " -helices from the native cytokines of this invention to make a hybrid cytokine having a predictable function." Again, in making these statements, it does not appear that the examiner has taken into consideration the proper legal standards concerning issues of enablement under 35 U.S.C. § 112, first paragraph, in that the examiner has not presented a fact-based analysis concerning how and why any experimentation needed to practice the invention would be "undue." As explained in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996),

The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive". Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent

and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex Parte Jackson, 217 USPQ 804, 807 (1982).

With regard to the hybrid cytokines possessing a predictable function, we note that it is not a requirement for enablement under 35 U.S.C. § 112, first paragraph, that a specification describe how to achieve a desired activity for a product or be able to predict with certainty the function of a product. It is sufficient that appellants demonstrate that the hybrid cytokines are active to some degree. In this regard we refer to the examples set forth on pages 15 through 20 of the specification.

With regard to testing the hybrid cytokines for properties associated with their native counterparts, it is noted that the specification on page 14, lines 17-31 describes in vitro tests which can be used to assess the properties that a particular hybrid cytokine has. Appellants urge that such tests are known and fully described in the cited literature articles. Since the examiner has not established that assays are not known or would require undue experimentation to perform in order to ascertain the various properties of a given hybrid cytokine, we find appellants' position reasonable that persons skilled in the art would understand how to conduct such routine characterization studies of the inventive

hybrids, using the standard techniques and accepted parameters which have been applied previously to known native cytokines.

While not expressly stated by the examiner, to the extent that the examiner is concerned that the claims might be inclusive of “inoperative” embodiments, such concerns were addressed in Atlas Powder Co. v. E.I. DuPont De Nemours & Co.,

750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. “It is not a function of the claims to specifically exclude... possible inoperative substances...” In re Dinh-Nguyen, 492 F.2d 856, 859, 181 USPQ 46, 48 (CCPA 1974).

The examiner has criticized example 1 on pages 15-16 of the specification on the basis that the media containing the hybrid cytokine IGGG has less activity than conditioned media from mock transfected control cells in supporting the growth of 32D cells, a cytokine-dependent cell line. The examiner feels that example 1 does not show that hybrid cytokines encompassed by the claims have predictable activity. However, the activity of IGGG at concentrations of 2.5%, 5.0% and 10.0% is greater than the activity of the mock transfected control cells at the same concentrations. Contrary to the examiner’s opinion, example 1 demonstrates that the hybrid cytokine IGGG supports the growth of 32D cells. Thus, one skilled in the art would, at the very least, know how to use the claimed hybrids as culture reagents for maintaining in vitro cultures of cytokine-dependent cell lines, similar to their native counterparts. Again, it is not necessary to be able to predict with absolute

certainty a claimed hybrid's activity is not a criteria for enablement under 35 U.S.C. § 112, first paragraph.

The examiner has criticized concerning example 2 on pages 16 through 18 of the specification on the basis that all of the different hybrid cytokines tested, having different native " -helical regions, demonstrate the same activity concerning the growth of Il-6-dependent cells 7TD1. Therefore, the examiner is of the opinion that these results underscore the unpredictability of the activity of the claimed hybrids. However, the examiner has again misapplied the standard of enablement based solely on predictability in assessing the evidence presented in example 2. This example presents data which indicate that the hybrid cytokines prepared had activity levels approximately equivalent to leukemia inhibitory factor (LIF) in supporting the growth of 7TD1 cells. Therefore, example 2 demonstrates that claimed hybrid cytokines can be made and used for supporting the growth of 7TD1 cells.

The examiner has further criticized examples 3 through 7 on pages 18 through 20 of the specification by stating that these examples evidence the unpredictability of the invention because they fail to correlate particular " -helices to particular biological properties. However, we agree with appellants that precise knowledge of the particular biological activities inherent in the native " -helices is not necessary for the enablement of the claims on appeal. The activity of the hybrid cytokines can be determined through the practice of the routine in vitro tests as described on page 14 of the specification. The

activity identified through the use of such routine characterization studies will confirm the ability or inability of a given hybrid cytokine to function for a given purpose.

For these reasons, we reverse the examiner's rejection of claims 1 through 11 and 27 under 35 U.S.C. § 112, first paragraph (enablement).

2. Claims 12 through 26 and 28

Claim 12 on appeal recites a DNA molecule that encodes a hybrid cytokine comprising 1) four α -helical regions, wherein the four α -helical regions are derived from the corresponding α -helical region of a factor selected from the group consisting of leukemia inhibitory factor (L), granulocyte-colony stimulating factor (G), interleukin-6 (I), interleukin-11 (E), ciliary neurotrophic factor (C) and oncostatin-M (O), and 2) three linking sequences, the linking sequences selected from at least a portion of one or more linking sequences from any of the foregoing cytokines.

In the Examiner's Answer (Paper No. 22, May 16, 1997), the examiner states on page 17 that if the hybrid cytokines are not enabled under 35 U.S.C. § 112, first paragraph, then making a non-enabled product through the use of the DNA molecule recited in claims 12 through 26 and 28 is also not patentable under this statute. However, the examiner does not dispute in any manner that one skilled in that would be able to use the claimed DNA, vectors and hosts to make the hybrid cytokines.

We reverse the rejection of claims 12 through 26 and 28 under

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35 U.S.C. § 112, first paragraph (enablement), for the reasons stated above to the extent the examiner's position is based upon the non-enablement of hybrid cytokines. Since the examiner has conceded that one skilled in the art would be able to make and use the DNA molecules recited in claims 12 through 26 and 28 to produce recombinant hybrid cytokines, we reverse this rejection.

REVERSED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Fred E. McKelvey
Senior Administrative Patent Judge

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