

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 41

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GEORGE J. TODARO
and TIMOTHY M. ROSE

Appeal No. 1996-2538
Application 08/097,869

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 APPEAL¹

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 15 and 20. Claims 16 through 19 and 21 through 24 are pending but have been withdrawn from consideration by the examiner. Claims 1 and 20 are illustrative of the subject matter on appeal and read as follows:

1. A hybrid cytokine comprising a first, second, third and fourth " -helical region wherein each of said first, second, third and fourth " -helical regions is derived from the corresponding " -helical region of a factor selected from the group consisting of leukemia inhibitory factor (LIF or L), granulocyte-colony stimulating factor (G-CSF or G), interleukin-6 (IL-6 or I), and oncostatin-M (OSM or O); and

wherein at least one said " -helical region of said cytokine is derived from a factor different from that from which at least one additional region of said cytokine is derived.

20. A pharmaceutical or veterinary composition useful in affecting the proliferation and/or differentiation of target cells which composition comprises an effective amount of the hybrid cytokine of claim 1 in admixture with at least one pharmaceutically acceptable excipient.

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

Claims 1 through 15 and 20 stand rejected under 35 U.S.C. § 112, first paragraph (enablement). We reverse.

¹ This case is related to Application 08/149,101, Appeal No. 1997-3020. We have considered the two appeals together.

DISCUSSION

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.

Claim 1 on appeal recites a hybrid cytokine comprising first, second, third and fourth " -helical regions, wherein each of the first, second, third and fourth " -helical regions is derived from the corresponding " -helical region of a factor selected from the group consisting of leukemia inhibitory factor (L), granulocyte-colony stimulating factor (G), interleukin-6 (I) and oncostatin (O), and wherein at least one of the " -helical regions of the hybrid cytokine is derived from a factor different from that of the other " -helical regions. Claim 20 is directed to a pharmaceutical or veterinary composition which comprises an effective amount of the hybrid cytokine in admixture with a pharmaceutically acceptable excipient.

The specification describes the hybrid cytokines as being useful in treating “indications for which their native counterparts are often employed.” See lines 18-20 on page 17 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 4 of the specification.

In initiating and maintaining the rejection of the claims under 35 U.S.C. § 112, first paragraph (enablement), 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 activity 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. 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 claimed hybrid cytokines would not be useful in the same manner.

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In the Examiner's Answer (Paper No. 31, April 5, 1995), the examiner states on page 4 that "it would require undue experimentation for one of ordinary skill in the art to make the hybrid cytokines such that the hybrid cytokines possess a desired activity and can be used in a beneficial manner. Each hybrid cytokine would have to be tested for all of the activities attributed to each native cytokine from which it is derived, as well as for any 'unique' property." Again, in making this statement, 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).

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With regard to the hybrid cytokines possessing a “desired activity,” 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. It is sufficient that appellants demonstrate that the hybrid cytokines are active to some degree. In this regard we point to the declarations filed March 31, 1993 (Leung #1) and July 27, 1993 (Leung #2).

With regard to testing the hybrid cytokines for properties associated with their native counterparts, it is noted that the specification on pages 19 and 20 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 literature articles cited. 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.

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 Leung #1 on the basis that the media containing the hybrid cytokine IGCG 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 believes that the declaration does not show that hybrid cytokines encompassed by the claims have predictable activity. However, the activity of IGCG 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, Leung #1 demonstrates that the hybrid cytokine IGCG 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 specific hybrid’s activity for enablement under 35 U.S.C. § 112, first paragraph.

The examiner has criticized Leung #2 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 Leung #2. This declaration

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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, the declaration can be viewed as demonstrating that claimed hybrid cytokines can be made and used for supporting the growth of 7TD1 cells

For the reasons, we reverse the examiner's rejection under 35 U.S.C. § 112, first paragraph (enablement).

REVERSED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

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) INTERFERENCES

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