

The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte PREETI G. LAL, RICHARD GRAUL,
APRIL J.A. HAFALIA, NARINDER K. CHAWLA,
MICHAEL B. THORNTON, DANNIEL B. NGUYEN, YAN LU,
AMEENA R. GANDHI, CHANDRA S. ARVIZU,
DEBORAH A. KALLICK, MARIAH R. BAUGHN,
JAYALAXMI RAMKUMAR, CATHERINE M. TRIBOULEY,
ERNESTINE A. LEE, LI DING, NEIL BURFORD,
MONIQUE G. YAO, JUNMING YANG, and
JENNIFER A. GRIFFIN

Appeal 2007-2517
Application 10/311,196
Technology Center 1600

Decided: June 29, 2007

Before DEMETRA J. MILLS, NANCY J. LINCK, and
RICHARD M. LEOVITZ, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-7, 9,
11, 16, and 17. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF CASE

The invention relates to a G-protein coupled receptor (GPCR) having the amino acid sequence of SEQ ID NO: 2. Claims 1-7, 9, 11, 16, 17, 19, 22, 25, and 26 are pending (Br. 2). Claims 19, 22, 25, and 26 are withdrawn from consideration (Br. 2).

Claims 1-7, 9, 11, 16, and 17 stand rejected under 35 U.S.C § 101 as lacking utility; under 35 U.S.C § 112, first paragraph, as failing to teach how to use the claimed rejection; and under 35 U.S.C § 112, first paragraph, as failing to comply with the written description requirement (Answer 3, 6).

All the claims stand or fall together within each rejection because Appellants' did not provide separate reasons for the patentability for any of the individual claims. *See* 37 C.F.R. 41.37(c)(1)(vii). We select claim 1 as representative for the purpose of deciding all issues in this appeal. Claim 1 reads as follows:

1. An isolated polypeptide selected from the group consisting of:
 - a) a polypeptide comprising SEQ ID NO: 2;
 - b) a polypeptide comprising at least 500 contiguous amino acids of SEQ ID NO: 2, wherein the polypeptide has taste-specific receptor activity.

DISCUSSION

The issue in this appeal is whether the instant application discloses a specific and substantial utility for the claimed invention. Appellants' contend that their application discloses that the claimed polypeptide having the amino acid sequence of SEQ ID NO: 2 is a human taste-specific receptor useful for screening new sweetener compounds (Br. 4, 9). The Examiner contends that instant application does not disclose that the claimed

polypeptide's utility is a human taste-specific receptor (Answer 11). The Examiner also contends that "taste-specific receptor activity" is not a specific and substantial utility because Appellants' have not discovered the "taste" for which the receptor is specific (Answer 7).

The threshold question is whether the Specification discloses that SEQ ID NO: 2 is a human taste-specific receptor. Because we decide the answer to this question is no, it is unnecessary for us to address the issue of whether taste-specific receptor activity is a specific and substantial utility.

The dispute between the Examiner and Appellants' centers on the following facts:

1) "The metabotropic glutamate receptor family also includes pheromone receptors, the GABA_B receptors, and the taste receptors" (Spec. 4: 5-6). *See* Br. 5. The Ca²⁺ sensing receptor is also a member (Spec. 4: 1-5).

2) Table 2 lists mouse (*Mus musculus*) taste receptor T1R3 "as the nearest GenBank homolog for the polypeptide of SEQ ID NO:2 based on a zero (0) probability score for a match by BLAST analysis" (Br. 6). "The BLAST probability score . . . indicates the probability of obtaining the observed polypeptide sequence alignment by chance" (Spec. 25: 35 to 26: 1-2). ("[A] probability score of zero (0) means that there is zero probability of having obtained the match by chance" (Br. 6)). The relevant portion of Table 2 (Spec. 81) is reproduced below:

Polypeptide SEQ ID NO:	Incyte Polypeptide ID	GenBank ID NO:	Probability Score	GenBank Homolog
1	7474927CD1	g3892596	6.20E-26	[<i>Mus musculus</i>] pheromone receptor 2 (seven domain GPCR)
		g10732802	0	[<i>Homo sapiens</i>] vomeronasal receptor 1
2	7475194CD1	g683747	2.10E-100	[<i>Homo sapiens</i>] extracellular calcium-sensing receptor (GPCR) (Garrett, J.E. et al. (1995) <i>J. Biol. Chem.</i> 270:12919-12925)
		g13936377	0	[<i>Mus musculus</i>] taste receptor T1R3

3) Table 3 of the Specification shows “Signature Sequences, Domains and Motifs” that are characteristic of “metabotropic glutamate GPCR” signature sequences (Spec. 82).

4) Other than in Tables 2 and 3, there is no description of SEQ ID NO: 2 in the Specification.

Based on these facts, Appellants’ conclude: “Therefore, because the specification indicates that Table 2 provides data related to the function of the polypeptides, the only reasonable interpretation is that SEQ ID NO:2 is asserted to be a taste receptor, in particular, a human homolog for the mouse T1R3 taste receptor” (Br. 8). The other information in the Specification, including Table 3, is asserted to support this conclusion.

The Examiner challenges Appellants’ contention that Table 2 of the Specification constitutes an assertion that SEQ ID NO: 2 is the amino acid sequence of a taste receptor (Answer 11). The Examiner contends that the Specification’s disclosure that the nearest GenBank homolog of SEQ ID NO: 2 is a taste-specific receptor “[a]t best” means that the match is “not the result of random chance,” but does not lead to the conclusion that the polypeptide of SEQ ID NO: 2 is itself a taste-specific receptor possessing taste receptor activity (Answer 11). In essence, the Examiner is saying that identifying a GenBank entry as the nearest matching homolog based on a probability score is not the same as asserting that the polypeptide has the activity possessed by the GenBank entry.

To support his position, the Examiner points to another sequence disclosed in the Specification, SEQ ID NO: 5 which, unlike SEQ ID NO: 2, is described in more detail in the Specification. Table 2 lists the mouse olfactory receptor P2 as a GenBank homolog of SEQ ID NO: 5, but the

Specification does not assert that SEQ ID NO: 5 is the human olfactory receptor P2, instead characterizing it in the more detailed description as a G-protein coupled receptor (Answer 11; Spec. 26: 8-12). “This hardly rises to the level of an assertion that a specific sequence presented in Table 2 has the same function as the closest known Gen[]bank homolog and certainly does not constitute a disclosure of a specific and substantial utility for a protein comprising any one of those sequences” (Answer 11-12).

We agree with the Examiner that the disclosure in the Specification that SEQ ID NO: 2 is a GenBank homolog of mouse taste receptor T1R3 – based only on a probability score – does not constitute an assertion of utility for the purpose of meeting the statutory requirement of 35 U.S.C. § 101. The Examiner’s point that, while SEQ ID NO: 5 is listed in Table 2 as the GenBank homolog of olfactory receptor P2, the Specification chooses to describe it as a GPCR (Spec. 26: 8-12), raises doubt that the only “reasonable interpretation” of Table 2 (Br. 8) is that it communicates the utility/functional activity of the disclosed sequences. If this were so, we agree with the Examiner’s logic that the Specification should have characterized SEQ ID NO: 5 as the human olfactory receptor P2, rather than generically as a GPCR.

In addition, there is no evidence in the record that the BLAST probability score is a measure of sequence identity or sequence similarity that would have led persons of skill in the art to reasonably believe that a high probability score is indicative of a functional activity. According to the Specification, “[t]he BLAST probability score . . . indicates the probability of obtaining the observed polypeptide sequence alignment by chance” (Spec. 25: 35 to 26: 1-2); it does not assert to be a measure of how much sequence

identity/similarity is shared and whether the identity/similarity occurs over conserved functional activity domains.

It is also problematic for Appellants' argument that Table 2 lists two GenBank homologs for SEQ ID NO: 2: 1) an extracellular calcium-sensing receptor and 2) the mouse taste receptor T1R3, both which are members of the metabotropic glutamate receptor family (Spec. 4: 1-6). Appellants' have not explained why the disclosure of the taste-specific receptor is an assertion of utility, while the disclosure of the calcium-sensing receptor is not. We recognize that the probability scores differ, but both are very high, and there is no evidence in the record that the score "0" would be recognized as bona fide, while the score "2.10E-100" would be rejected.

Appellants' own evidence suggests that the information disclosed in the Specification is insufficient for persons of skill in the art to have reasonably concluded that SEQ ID NO: 2 is a taste-specific receptor. Li (Exhibit 1) and Montmayeur (Exhibit 3) reach their conclusion that a polypeptide is a taste-specific receptor only after accumulating additional data tying structural information to the polypeptide's function. Li expresses the T1R3 sequence in cells and shows that it is stimulated by a taste ligand, confirming its identity as a taste receptor (Li, Abstract). Montmayeur conclude that the T1R3 is a "candidate taste receptor in mouse and humans" (Montmayeur, p. 495) based on expression data and its correlation with *Sac*, a genetic loci that controls the detection of certain tastes in mice (Montmayeur, p. 495-6). Thus, even after the filing date of the instant application, persons of ordinary skill in the art required more than just structural information to reach a conclusion about a polypeptide's function.

In sum, the record lacks evidence to support Appellants' position. Counsel's argument cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997). Because the Examiner has set forth a reasonable doubt as to why an explicit utility has not been disclosed as of the filing date, the burden shifted to Appellants to provide rebuttal evidence. See *In re Brana*, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). Outside of argument of counsel, Appellants' have supplied no objective evidence that the only reasonable interpretation of the data in Table 2 is that the SEQ ID NO: 2 has taste-specific receptor activity.

Post-filing evidence

Appellants' provide Li – published subsequent to the filing of the instant application – which they state confirms the asserted utility of SEQ ID NO: 2 as a human taste-specific receptor (Br. 8). Appellants' contend that “[a]s is well appreciated, post-filing evidence may be used to substantiate an asserted utility” (Br. 8), but provide no authority upon which this assertion is based.

It is true that post-filing evidence can be relied on for certain purposes. A later dated publication can be used as evidence of the level of ordinary skill in the art at the time of the application, as evidence that the disclosed device would have been operative, and of the state of the art existing on the filing date of an application. See *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ2d 1302, 1305 (Fed. Cir. 1987); *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). However, post-filing evidence can not be used to demonstrate that the Specification, as filed, sets forth a

utility for the claimed invention. “Enablement, or utility, is determined as of the application filing date.” *Brana*, 51 F.3d at 1567 n.19, 34 USPQ2d at 1442 n.19.

Li was published in 2002, after the instant application was filed. Consequently, it cannot be used to determine whether the claimed invention had a utility as of the filing date. Appellants have provided no evidence that the content disclosed by Li in 2002 was available to those skilled in the art before the filing date of the instant application. Therefore, Li’s disclosure that T1R3 is a human taste receptor cannot be relied on to show the utility of the polypeptide comprising SEQ ID NO: 2. Montmayeur was also published after the filing date; for the same reason, it also cannot be relied upon to establish utility of the claimed invention.

Appellants’ contend that *Brana* holds that “[a] declaration, though dated after applicants’ filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification.” (Reply Br. 4). However, in this case, the issue is whether there is a statement in the Specification of an asserted utility, not the accuracy of a statement as in *Brana*.

For the reasons described above, we affirm the rejection of claim 1 for lack of utility. Claims 2-7, 9, 11, 16, and 17 fall with claim 1 because they were not separately argued.

“How to use” rejection

Claims 1-7, 9, 11, 16, and 17 are also rejected under 35 U.S.C. § 112, first paragraph, for failing to teach how to use the claimed invention (Answer 6). If a claim fails to meet the utility requirement of 35 U.S.C. § 101 because it is not useful, then it necessarily fails to meet the how-to-use

aspect of the enablement requirement of 35 U.S.C. § 112, first paragraph. *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) (If “compositions are in fact useless, appellant’s specification cannot have taught how to use them.”); MPEP 2164.07 (Edition 8, August 2001; revised August 2006). Because we have found that the claims do not meet the utility requirement, we also are compelled to find that they do not meet the how to use requirement of 35 U.S.C. § 112. We affirm the rejection of claim 1; claims 2-7, 9, 11, 16, and 17 fall with claim 1 because they were not separately argued.

Written description rejection

Claim 1-7, 9, 11, 16, and 17 stand rejected under § 112, first paragraph, as failing to comply with the written description requirement for the limitation of “a polypeptide comprising at least 500 continuous amino acids of SEQ ID NO: 2, wherein the polypeptide has taste-specific receptor activity” (Answer 6). The Examiner contends that the limitation is “new matter,” not supported by the application as it was filed (Answer 6).

We have found that the Specification does not disclose that SEQ ID NO: 2 is a polypeptide possessing taste-specific receptor activity. “To fulfill the written description requirement, the patent specification ‘must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.’ *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). An applicant complies with the written description requirement ‘by describing the invention, with all its claimed limitations.’ *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997).” *Gentry Gallery v. The Berkline Corp.*,

45 USPQ2d 1498, 1502-1503 (Fed. Cir. 1998). Here, the instant application does not describe the claimed limitation that the polypeptide has taste-specific activity. Consequently, we agree with the Examiner that recited limitation is new matter. We affirm the rejection of claim 1; claims 2-7, 9, 11, 16, and 17 fall with claim 1 because they were not separately argued.

SUMMARY

We affirm the rejections of claims 1-7, 9, 11, 16, and 17 for lack of utility under 35 U.S.C § 101; for failing to teach how to use the claimed invention under 35 U.S.C § 112, first paragraph; and for lack of written description under 35 U.S.C § 112, first paragraph.

OTHER ISSUES

Appellants' have claimed priority dates of a series of U.S. provisional applications filed from June 16, 2000 to July 19, 2000 (Request for Updated Filing Receipt, dated May 9, 2005; Amendment to Specification, dated May 9, 2005). Based on 35 U.S.C. § 119(e), it is presumed that this constitutes a claim for benefit of the filing dates of the provisional applications for the purpose of determining what is prior art to the claims of the instant application. However, in the Reply Brief, Appellants' state "[i]n addition to Montmayeur et al. adopting the designation 'T1R3' for a mouse receptor for sweet ligands, at least three additional references *published before* the present application's filing date used the designation 'T1R3' for a mouse receptor for sweet ligands" (Reply Br. 2) (emphasis added). The three cited

references¹ are listed as having been published in 2001 (Reply Br. 2-3) which is *after* the 2000 filing dates of the provisional applications. If Appellants do not intend to rely on the 2000 provisional filing date as the effective filing date of the instant application, they should have expressly stated this during prosecution. It is crystal clear from the record that the Examiner used the date of July 7, 2000 as the effective date of the instant application based on the first disclosure of SEQ ID NO: 2 in Provisional Application No. 60/216,595 (Office action, dated Feb. 9, 2005, at 3). Only prior art available before this date was applied to the claims. Appellants' did not rebut or challenge the Examiner's finding.

Although Appellants accepted the date of July 7, 2000 for the prior art determination, it appears they now intend to rely on the later filing date of June 15, 2001 (when International Application No. PCT/US01/19354 was filed; Request for Updated Filing Receipt, dated May 9, 2005) for the purposes of determining utility. Prior art and utility are determined on one and the same date: the date on which the application was filed or the date of an earlier filed application to which benefit is accorded under 35 U.S.C. § 119 or § 120.

If prosecution is resumed, the effective filing date of the application *must* be clarified. If the filing date of June 15, 2001 is asserted, the Examiner should consider all intervening prior art between July 7, 2000 and June 15, 2001.

¹ We have not considered these references because they constitute new evidence. "A reply brief shall not include . . . any new . . . evidence." 37 C.F.R. § 41.41(a)(1). "A reply brief that is not in compliance with paragraph (a) of this section shall not be considered." 37 C.F.R. § 41.41(b).

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TIME PERIOD

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

AFFIRMED.

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