The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN A. ARCHER, MAXIMILLIAM T. FOLLETTIE,
and ANTHONY J. SINSKEY

Appeal No. 1995-2789
Application No. 07/788,114

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, 5-7, and 10-13, which are all the claims pending in the application.

Claims 1 and 7 are representative of the subject matter on appeal and are reproduced below:

1. A method for the production of threonine comprising
   constructing a gene isolated from a genome selected from the group consisting of Corynebacterium glutamicum, Escherichia coli, and Bacillus subtilis, encoding an enzymatically active homoserine dehydrogenase not subject to allosteric inhibition by threonine, wherein the homoserine dehydrogenase gene is mutated at the carboxy terminus, and
   expressing the gene.

7. An enzymatically active homoserine dehydrogenase, isolated from bacteria selected from the group consisting of Corynebacterium glutamicum, Escherichia coli, and Bacillus subtilis, not subject to allosteric inhibition by threonine, wherein the enzyme is altered at the carboxy terminus.

The references relied upon by the examiner are:

Ernst-L. Winnacker (Winnacker), Directed Mutagenesis, in FROM GENES to CLONES, INTRODUCTION to GENE TECHNOLOGY, 452-481 (Horst Ibelgaufts trans., VCH 1987)

Follettie et al. (Follettie), "Metabolic Engineering of Corynebacteria," Proceedings of the sixth International Symposium on Genetics of Industrial Microorganisms, pp. 315-325 (1990)

Reinscheid et al. (Reinscheid), "Analysis of a Corynebacterium glutamicum hom Gene Coding for a Feedback-Resistant Homoserine Dehydrogenase," J. Bacteriology, Vol. 173, pp. 3228-3230 (1991)

GROUNDS OF REJECTION[1]

Claims 1, 2, 5, 7 and 10 stand rejected under 35 U.S.C. § 112, first paragraph as lacking a written description and enabling disclosure.[2]

Claims 1, 2, 5-7 and 10-13 stand rejected under 35 U.S.C. § 102(a) as being unpatentable because the claimed invention was known by others, as evidenced by Follettie.[3]

Claims 1, 2, 5 and 7 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Reinscheld.

Claims 6 and 10-13 stand rejected under 35 U.S.C. § 103 as being unpatentable over Reinsheld in view of Winnacker.

We reverse the rejections under 35 U.S.C. §§ 112, first paragraph, and 103. We affirm the rejection under 35 U.S.C. § 102(a) as being anticipated by Reinscheld. We vacate the rejections under 35 U.S.C. § 102(a) as evidenced by Follettie, and remand for further consideration.

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[1] We note the examiner withdrew (Answer, page 5) the Final rejection of claims 1, 2, 5-7 and 10-13 under 35 U.S.C. 103 as being obvious over Beskrovnaya in view of Peoples and Winnacker.

[2] We note the rejection of claims 1, 2, 5, 7 and 10 is directly connected and relates to the objection to the specification. In re Hengehold, 440 F.2d 1395, 1403-1404, 169 USPQ 473, 479-480 (CCPA 1971).

[3] This rejection was originally presented as a New Ground of Rejection (see Answer, page 10) relying on Follettie to meet the "described in a printed publication in this or a foreign country" clause of 35 U.S.C. § 102(a). However, the examiner subsequently withdrew this basis for the rejection, relying instead on the "known or used by others in this country" clause of 35 U.S.C. § 102(a).

DISCUSSION

Initially, we note that on March 25, 1998[4], this appeal was remanded at the request of the Office of the Group Director of Technology Center 1600, "so that the issues raised in this appeal can be reconsidered." However, on January 19, 1999[5] the examiner, after consideration of the issues on appeal, maintained the pending rejections and returned the application to the Board, where it resumed its original place on appeal.

In reaching our decision in this appeal, we considered appellants' specification and claims, in addition to the respective positions articulated by appellants and the examiner. We make reference to the examiner's Answer[6], and the examiner's Supplemental Answer[7] for the examiner's reasoning in support of the rejections. We further reference appellants' Brief[8], and appellants' Reply Brief[9] for the appellants' arguments in favor of patentability.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 6) "the specification does not provide an adequate written description so as to enable the ordinary skilled

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See Reply Brief, page 2. The "updated" basis for the rejection is set forth herein.
[4] Paper No. 26.
[5] See Paper No. 27.
[6] Paper No. 20, mailed April 28, 1994.
[7] Paper No. 23, mailed December 14, 1997.
[8] Paper No. 19, received March 22, 1994.
[9] Paper No. 21, received June 30, 1994.

artisan to either make or use the invention as it is broadly claimed." The examiner finds (id.) that "[i]t is not clear from the specification what appellants consider to be the carboxy terminus of the enzyme." Notwithstanding this finding, the examiner argues (Answer, bridging paragraph, pages 6-7) that:

> Regardless of what appellants regard as the carboxy terminus of the homoserine dehydrogenase gene, a single example disclosed by appellants certainly does not suffice as an adequate written description requirement for the legion of mutants being claimed. In the absence of further information and guidelines with regard to other mutants in "the carboxy terminus" of the homoserine dehydrogenase gene, it would require undue experimentation for the ordinary skilled artisan to either make or use the invention as it is claimed.

Initially we note that there is some confusion on this record as to whether the examiner intends a written description rejection, because the specification fails to provide adequate descriptive support for the claimed invention, or an enablement rejection because the specification fails to enable the full scope of the claimed invention. We note that appellants understood, and responded to the examiner's rejection as if the examiner rejected the claims as "based on non-enablement." See e.g., Brief, page 14. However, we note the examiner's statement of the rejection (see e.g., Answer, pages 6) refers to the specification's failure to provide adequate descriptive support for the claimed invention, a "written description" rejection.

The written description provision is separate and distinct from the enablement requirement. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (CAFC 1991). To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116. The enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d at 1365, 42 USPQ2d at 1004 (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

While, the examiner recognizes (Answer, page 13) the distinction between the written description provision and the enablement provision of 35 U.S.C. § 112, first paragraph, the examiner's subsequent arguments blend the two requirements back together. Accordingly we will separately review this rejection under the written description and the enablement provisions of 35 U.S.C. § 112, first paragraph.

Written Description:

As set forth in Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) the written description "inquiry is a factual one and must be assessed on a case-by-case basis." Furthermore, "the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). As set forth in Wertheim, 541 F.2d at 262, 191 USPQ at 96:

> The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (CCPA 1973), and cases cited therein. It is not necessary that the application describe the claim limitations exactly, In re Lukach, [442 F.2d 967, 169 USPQ 795 (1971]… but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. In re Smythe, 480 F.2d 1376, 1382, 178 USPQ 279, 284 (CCPA 1973).
>
> The primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.

Here the examiner interprets the claims to read on a genus of mutants. See Answer, bridging sentence, pages 13-14, it is a "genus of mutants being claimed"; see also Answer, page 6, "a broad class of homoserine dehydrogenase mutants being claimed." In this regard, we note the examiner's

agreement (Answer, page 13) with appellants' interpretation of Amgen Inc. v. Chugai Parmaceuticals Co. Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) "that generic claims to nucleotide sequences would be valid when of a scope appropriate to the disclosure." However, determining whether generic claims are "of a scope appropriate to the disclosure" requires a fact-based analysis of the record.

Therefore, we are not persuaded by the examiner's conclusion (Answer, page 13) that "[a] single example is not considered to be representative of the genus of mutants being claimed." We remind the examiner, as do appellants (Reply Brief, page 6) that working examples are not required to satisfy the requirements of 35 U.S.C. § 112, first paragraph. In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982).

By failing to provide a fact based analysis of appellants' specification, that addresses the specific deficiencies in its descriptive support of the claimed invention, the examiner failed to meet his burden in finding appellants' specification does not provide an adequate description of the claimed invention. Therefore, in our opinion, the examiner failed to meet his burden of establishing that the specification fails to provide an adequate written description of the claimed invention.

Enablement:

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, that "nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

Initially, we note that the examiner finds (Answer, page 6) that "[i]t is not clear from the specification what appellants consider to be the carboxy terminus of the enzyme. … Are appellants considering that approximately one third of the gene comprised of about 700 nucleotides as the carboxy terminus of the gene or

the nucleotides shown in Figure 4?" In this regard, we remind the examiner that before issues related to the patentability of the claimed subject matter can begin to be considered, the examiner must determine what is being claimed. As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971):

> [T]he claims must be analyzed first in order to determine exactly what subject matter they encompass....
>
> The first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed – not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

However, not withstanding the examiner's concern about the clarity of the claimed invention, the examiner does not reject the claimed invention under 35 U.S.C § 112, second paragraph. The legal standard for indefiniteness under 35 U.S.C § 112, second paragraph, is whether a claim reasonably apprises those of skill in the art of its scope. See, Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). As set forth in Amgen:

> The statute requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A decision as to whether a claim is invalid under this

> provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits.").

Furthermore, claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

We note that appellants provide an explanation (Brief, page 13) of what is intended by the use of the phrase "carboxy terminus." Specifically, appellants argue (id.) that "[a]s shown in Figure 4 of the application on appeal, the carboxy terminus of the wild type homoserine dehydrogenase gene has only approximately 72 bases." It can only be assumed from the examiner's failure to respond to appellants' argument that the examiner agrees with appellants' position.

Next, the examiner argues (Answer, bridging sentence, pages 6-7) "[i]n the absence of further information and guidelines with regard to other mutants in 'the carboxy terminus' of the homoserine dehydrogenase gene, it would require undue experimentation for the ordinary skilled artisan to either make or use the

invention as it is claimed." This however, is merely a conclusion, not a fact-based reasoned analysis of the claimed invention in view of appellants' supporting disclosure.

As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988) the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. We find no analysis of the Wands factors by the examiner. Instead, we find only the examiner's unsupported conclusion that the specification does not enable the claimed invention.

Similarly, the examiner argues (Answer, page 7) "it is questioned whether one can even predictably isolate viable mutants of E. coli and B. subtilis which are insensitive to feedback inhibition by threonine. … Thus, it would require undue experimentation for the ordinary skilled artisan to either make or use the claimed invention for E. coli and B. subtilis." The examiner, however, fails again to provide a factual basis upon which to question the predictability of appellants' claimed invention.

We remind the examiner, as set forth in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971) it:

> is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

On reflection, it is our opinion, for the reasons given above, that the examiner failed to meet his burden of establishing that appellants' specification fails to provide adequate descriptive support for the claimed invention; or provide an enabling disclosure of the claimed invention. Accordingly we reverse the rejection of claims 1, 2, 5, 7 and 10 under 35 U.S.C. § 112, first paragraph.

THE REJECTIONS UNDER 35 U.S.C. § 102(a):

Follettie:

According to the examiner (Supplemental Answer, page 2) "[t]he rejection of claims 1, 2, 5-7 and 10-13 under 35 U.S.C. § 102(a) over Follettie et al. has been withdrawn in view of the declaration under 37 CFR [§] 1.132 which accompanied the appeal brief…." Accordingly, this rejection is not before us for review.

However, the examiner appears to maintain a rejection (id.) of claims 1, 2, 5-7 and 10-13 under 35 U.S.C. § 102(a) "based on prior knowledge more than

one year before applicants' filing date." The examiner notes (id.) "page 16 of the [e]xaminer's Answer where the previous [e]xaminer alluded to maintaining a [rejection under] 35 U.S.C. § 102(a)…" [emphasis added]. The examiner appears to rely (id.) on Follettie as evidence of this "prior knowledge."

The Answer, however, contains no rejection of claims 1, 2, 5-7 and 10-13 under 35 U.S.C. § 102(a) based on prior knowledge. Therefore, any such rejection is not properly before us for review. Nevertheless, for completeness, to the extent the claims could be considered, we note that neither the Answer, nor the Supplemental Answer, provides a fact-based analysis that addresses the limitations of the claimed invention relative to what the examiner considers "prior knowledge." Accordingly, we vacate[10] any such rejection under 35 U.S.C. § 102(a) based on prior knowledge, and remand the application to the examiner for further consideration.

Upon return of the application, the examiner should step back and reconsider the claimed invention, together with relevant prior art and other evidence of record. If, the examiner finds that a rejection is necessary, the examiner should issue an appropriate Office Action, clearly explaining the basis for such a rejection, and providing appellants an opportunity to respond.

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[10] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

While we take no position on the merits of any such rejection under 35 U.S.C. § 102(a) based on prior knowledge, to assist in his analysis of this issue, we recommend that the examiner consider Massachusetts Inst. of Technology v. AB Fortia, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Reinscheid:

According to the examiner (Answer, page 8) Reinscheid "teach a mutant homoserine dehydrogenase of Corynebacterium glutamicum which is insensitive to feedback inhibition by threonine due to an altered amino acid at the carboxyl terminal and a method of producing and selecting for such mutant…." In response appellants' explain (Reply Brief, page 9) that:

> The [e]xaminer commented in the Advisory Action mailed December 10, 1993 that the description in the parent application was insufficient for benefit under 35 U.S.C. § 120 and that the description was lacking for the broad scope of the mutants claimed. Appellants assumed that the 35 U.S.C. § 102(a) rejection was maintained and filed the 131 Declaration with [a]ppellants' Brief.

The examiner, however, with reference to 37 CFR § 1.195, did not consider or enter the declaration into the record. According to the examiner (Answer, bridging paragraph, pages 16-17), "the declaration was not timely filed, and appellants have failed to shown good and sufficient reasons as to why they [sic] were [sic] not earlier presented…." At this point, we note that appellant made no attempt on this record to petition the examiner's refusal to enter the

declarations. We remind appellants that "[r]eview of an examiner's refusal to enter an affidavit as untimely is by petition and not by appeal to the Board of Patent Appeals and Interferences." In re Deters, 515 F.2d 1152, 1156, 185 USPQ 644, 648 (CCPA 1975); Ex parte Hale, 49 USPQ 209 (Bd. App. 1941).

We also note appellants' comment (Reply Brief, page 9), "the [e]xaminer did not comment on [a]ppellants' offer [to supply a declaration] and did not request a [d]eclaration." We remind appellants, that the burden is on appellants to establish the facts necessary to "overcome" a reference. In re Facius, 408 F.2d 1396, 1404, 161 USPQ 294, 300 (CCPA 1969). Thus, in our opinion, it is not the examiner's burden to "request a declaration".

Accordingly we affirm the rejection of claims 1, 2, 5 and 7 under 35 U.S.C. § 102(a) as being anticipated by Reinscheld.

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 8) Reinscheid "teach a mutant homoserine dehydrogenase of Corynebacterium glutamicum which is insensitive to feedback inhibition by threonine due to an altered amino acid at the carboxy terminus and a method of producing and selecting for such mutant…." The examiner finds (Answer, page 9) that Reinscheid "teach that the region after codon 400 is the threonine recognition or binding site for feedback inhibition … and suggest[s] site-directed mutagenesis experiments in that region to obtain

other homoserine dehydrogenase mutants which are insensitive to feedback inhibition by threonine." However, as the examiner explains (id.), Reinsheid "does not teach a mutant homoserine dehydrogenase which has a single base deletion in codon 429."

The examiner relies on Winnacker to make up for this deficiency. According to the examiner (Answer, page 9) Winnacker "teaches a general method of producing deletion or localized point mutations within a gene." Based on the teachings of Reinscheid and Winnacker the examiner concludes (Answer, page 9), "one of ordinary skill in the art would have been motivated to have mutagenized [using the techniques of Winnacker] the suggested carboxy terminus of the homoserine dehydrogenase gene for its known and expected benefit."

In response appellants argue (Brief, pages 23 and 24) that the prior art relied upon by the examiner fails to provide the motivation or suggestion "to make the proposed modifications needed to arrive at the claimed invention." At page 24 of the Brief, appellants emphasize that the references fail to:

> suggest or imply a single base deletion in the nucleotide sequence encoding amino acid 429 of the hom gene … as specified in [c]laim 6, a truncated homoserine dehydrogenase protein as specified in [c]laim 10, a homoserine dehydrogenase protein truncated after amino acid 438 as specified in [c]laim 11, or a homoserine dehydrogenase having the specific nucleotide or amino acid sequence as specified in [c]laims 12 and 13.

In response, the examiner argues (Answer, page 17) "given various mutagenesis techniques taught by Winnacker, it would have been prima facie obvious for the ordinary skilled artisan to have further extended the work taught by Reinscheid et al. and to obtain other carboxy terminus mutants of homoserine dehydrogenase which are deregulated."

We remind the examiner that while a person of ordinary skill in the art may possess the requisite knowledge and ability to modify the protocol taught by Reinscheid, the modification is not obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 211 USPQ 1125, 1127 (Fed. Cir. 1984). Here while Reinscheid suggests (page 3230, last paragraph) performing site-directed mutagenesis experiments "[t]o gain more information on the proposed L-Threonine recognition or binding locus (amino acids 403 to 417)" there is no suggestion to make the specific modifications claimed.

Furthermore, as set forth in In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991), in addition to the suggestion or motivation to modify the references or combine reference teachings, to establish a prima facie case of obviousness, there must also be a reasonable expectation of success. In this regard, we note that Reinscheid teach (page 3230, first paragraph, last sentence) "the region from amino acid 403 to 417 may be the L-threonine

recognition or binding site for feedback inhibition." In the last paragraph (page 3230) Reinscheid teach "[t]o gain more information on the proposed L-threonine recognition or binding locus (amino acids 403 to 417), site-directed mutagenesis experiments must be done." Therefore, in our opinion, a person of ordinary skill in the art would consider making site directed modifications in the L-threonine recognition or binding locus, amino acids 403 to 417. Each of appellants' claims 6 and 11-13 are outside this region. We further note, that Reinscheid's focus on amino acids 403 to 417 fails to suggest the truncated protein required by claim 10. Therefore, in our opinion a person of ordinary skill in the art would not have had a reasonable expectation of success in obtaining the modified enzymes claimed.

On the record before us, we find no reasonable suggestion, and no reasonable expectation of success, in obtaining the claimed invention from the combination of references relied upon by the examiner. The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On these facts, the examiner failed to provide the evidence necessary to support a prima facie case of obviousness. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, we reverse the rejection of claims 6 and 10-13 under 35 U.S.C. § 103 as being unpatentable over Reinsheld in view of Winnacker

Having determined that the examiner has not established a prima facie case of obviousness, we find it unnecessary to discuss the Declaration, filed under 37 CFR § 1.131, relied on by appellants to rebut any such prima facie case.

OTHER ISSUES

If upon further prosecution the merits of appellants' declaration filed under 37 C.F.R. § 1.131 becomes an issue, we make the following observation. In evaluating a declaration filed under 37 CFR § 1.131, attention should be given to the requirements set forth in 37 CFR § 1.131(a)(1). Specifically, "[t]he oath or declaration must include facts showing a completion of the invention in this country or in a NAFTA or WTO member country … before the date of the printed publication." In our review of this record we note of interest that appellants' declaration filed under 37 CFR § 1.131 does not demonstrate "completion of the invention in this country or in a NAFTA or WTO member country before the date of the printed publication.

We note that this appeal was briefed prior to our appellate reviewing court's decision in U.C. v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). In the event of further prosecution, the examiner should step

back and consider whether appellants' written description of the claimed invention is consistent with the principles set forth in Lilly.

We state that we are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond. This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01 (7th ed., rev. 1, February 2000). Accordingly, we hold the finality of our affirmance of the rejection of claims 1, 2, 5 and 7 under 35 U.S.C. § 102(a) as being anticipated by Reinscheld in abeyance until the proceedings on remand before the examiner are concluded. 37 C.F.R. § 1.196(e). It is important that the Board be informed promptly of any action affecting the appeal in this case.

AFFIRMED-IN-PART, VACATED-IN-PART and REMANDED-IN-PART

SHERMAN D. WINTERS Administrative Patent Judge	)))
WILLIAM F. SMITH Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
DONALD E. ADAMS Administrative Patent Judge	))

Appeal No. 1995-2789
Application No. 07/788,114

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