

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

Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

Ex parte MARC ALIZON, LUC MONTAGNIER,  
DENISE GUETARD FRANCOIS CLAVEL,  
PIERRE SONIGO, and MIREILLE GUYADER

---

Appeal No. 1997-2528  
Application No. 07/810,908

---

ON BRIEF

---

Before WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.  
MILLS, 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 44-46, which are all of the claims pending in this application.

We reverse and enter a new ground of rejection under 37 CFR § 1.196(b).



Appeal No. 1997-2528  
Application No. 07/810,908

### Grouping of Claims

Appellants submit that claims 44-46 stand or fall together. Brief, page 2. Therefore, we decide this appeal on the basis of claim 44 as representative of claims 44-46. 37 CFR § 1.192(c)(7)(1996).

### DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejection, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

### 35 U.S.C. § 112, first paragraph

Claims 44-46 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" [Emphasis added.] Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir.1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Conversely, the first paragraph

Appeal No. 1997-2528  
Application No. 07/810,908

of § 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification.

In addition, analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contains sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. In order to establish a prima facie case of lack of enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Morehouse, 545 F.2d 162, 165, 192 USPQ 29, 32 (CCPA 1976). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

The examiner argues that the claimed invention is not enabled by the specification because there is no disclosure for the use of either cell lysate or individual proteins in a diagnostic kit or method for the detection of anti-HIV-2 antibodies. Answer, page 3. The examiner also argues that the proteins are not enabled for use in the various assay formats.

In the instant case, the examiner has not presented a reasoned analysis of the state of the prior art in regard to immunoassay formats and methods for the detection of HIV as claimed in the instant application. It appears that the examiner considered the

Appeal No. 1997-2528  
Application No. 07/810,908

enablement issue and utility issue solely in light of that portion of the supporting specification which describes appellants' invention, not in light of the prior art. It is well established that enablement issues must be decided on the basis of the information imparted by appellants in the specification of the patent application under review in conjunction with the relevant prior art. Viewing a given patent specification in a vacuum apart from the prior art to determine whether the claims of such a patent application are enabled is incorrect. See, e.g., Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), ("A specification need not disclose what is well known in the art.")

Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted). In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The examiner has provided no analysis of the factors indicated above and has provided no evidence on which to base the lack of enablement rejection. 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

Appeal No. 1997-2528  
Application No. 07/810,908

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. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

In the present case the examiner has not presented a prima facie case of lack of enablement which would shift the burden to appellants to provide evidence of enablement. Although the examiner argues that no literature cited by appellants show how one of ordinary skill in the art would be able to produce all of the claimed proteins, isolate them, and use them in a fashion so as to detect antibodies, the consideration of such literature is not appropriate unless and until the examiner has established a prima facie case of lack of enablement. Answer, page 5.

In view of the above, the rejection of claims 44-46 for lack of enablement is reversed.

New grounds of rejection - 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b), we enter the following new grounds of rejection against appellants' claims 44-46.

35 U.S.C. § 102(a)

Claims 44-45 stand rejected under 35 U.S.C. § 102(a) as anticipated by Clavel.

The examiner previously rejected Claims 44-46 under 35 U.S.C. § 102(b) as anticipated by Clavel, however, we are unclear on what basis the examiner made this

Appeal No. 1997-2528  
Application No. 07/810,908

determination. The effective filing date of the present application would appear to be February 11, 1987. Clavel has a publication date of July 18, 1986, which is within one year of the February 11, 1987 filing date of the present application. Thus, it would appear that if Clavel was to be prior art to the present application it would qualify as prior art under 35 U.S.C. § 102(a) and not § 102(b). Appellants previously put forth argument suggesting that Clavel was not prior art to the claimed invention and the examiner withdrew the rejection.

Clavel is prior art to the present application only if appellants cannot claim the benefit of the filing date under § 120 of application Serial No. 06/835,228 (now U.S. Patent No. 4,839,288). Although we have been unable to obtain the original file for Serial No. 06/835,228, we have assumed that the disclosure of the issued patent is consistent with the disclosure of Serial No. 06/835,228 as originally filed.

#### Claim 44

Thus claim 44<sup>2</sup> on appeal is directed to:

---

<sup>2</sup> We acknowledge the examiner's indication of the entry of amendments with respect to the claims on appeal in paper no. 22. Appellants provide an accurate presentation of the claims on appeal in the appendix to paper no. 21.

Appeal No. 1997-2528  
Application No. 07/810,908

An *in vitro* diagnostic method for detecting the presence or absence of antibodies, which bind to antigens of Human Immunodeficiency Virus Type 2 (HIV-2), comprising:

(a) contacting a biological sample with one or more isolated polypeptide expression products of HIV-2 selected from the group consisting of p12, polymerase, Q protein, R protein, X protein, env protein, F protein, TAT, and ART; and

(b) detecting the formation of antigen-antibody complex between said polypeptide expression products and said antibodies present in the biological sample.

It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112. 35 U.S.C. § 120. In re Van Langenhoven, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972); Mendenhall v. Cedarapids Inc., 5 F.3d 1557, 1566, 28 USPQ2d 1081, 1088-89 (Fed. Cir. 1993)("A patentee cannot obtain the benefit of the filing date of an earlier application where the claims in issue could not have been made in the earlier application."), cert. denied, 114 S. Ct. 1540 (1994); see also Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1438, 221 USPQ 97, 106 (Fed. Cir. 1984) (discussing filing dates of CIP applications). As to given claimed subject matter, only one effective date is applicable. Whether or not the requirements of § 120 are satisfied, including the requirement that the specification comply with § 112, is determinative of that date. In re Van Langenhoven, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA

Appeal No. 1997-2528  
Application No. 07/810,908

1972). See also, Studiengesellschaft Kohl mbH v. Shell Oil Co., 112 F.2d 1561, 1563, 42 USPQ2d 1674, 1677 (Fed. Cir. 1997) ; In re Chu, 66 F.3d 292, 297, 36 USPQ2d 1089, 1093 (Fed. Cir. 1995); and In re Gosteli, 872 F.2d 1008, 1011, 10 USPQ2d 1614 (Fed. Cir. 1989).

If the effective filing date for subject matter claimed in a U.S. Application is in issue, the foreign application relied upon for priority under Section 119 must be examined to determine whether it supports, within meaning of 35 U.S.C. § 112, first paragraph, what is claimed in U.S. Application, and thus, claims in issue are entitled to benefit of foreign priority date only if foreign application properly supports such claims as required by § 112.

Where an applicants claim, as here, a class of compositions, he must describe that class in order to meet the description requirement of the statute. See In re Ahlbrecht, 435 F.2d 908, 912, 168 USPQ 293, 296 (CCPA 1971); In re DiLeone and Lucas, 436 F.2d 1404, 1405, 168 USPQ 592, 594 (CCPA 1971); In re DiLeone, 436 F.2d 1033, 1034, 168 USPQ 598, 598 (CCPA 1971). In addition, Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997) held:

It is the disclosures of the applications that count. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that

which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. . . [A]ll that is necessary to satisfy the description requirement is to show that one is “in possession” of the invention . . . One shows that one is “in possession” of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . . Although the exact terms need not be used in haec verba, . . . the specification must contain an equivalent description of the claimed subject matter. (Citations omitted).

...  
It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose. Each application in the chain must describe the claimed features.

The question then, is whether appellants have done so in the parent, grandparent and priority applications.

Clavel<sup>3</sup> teaches using HIV-2 cell lysates to radioimmuno-precipitate anti-HIV-2 antibodies from patient sera. Clavel discloses that antigens from LAV-1 and LAV-2 can be used for seroepidemiological studies, including envelop protein. Clavel, page 345, column 1. Clavel is proper prior art to the present application because the parent cases of the present application include no written description of all of the polypeptides within the scope of the claimed invention. We find that the disclosure of parent application Serial No. 06/835,228, U.S. Patent No. 4,839,288, describes, at best, the claimed polypeptides polymerase, Q protein, Env, and F protein (figure 1), and fails to describe

---

<sup>3</sup> The Clavel publication is authored by a different inventive entity than the claimed invention.

Appeal No. 1997-2528  
Application No. 07/810,908

the claimed p12, X protein, TAT and ART polypeptides. Thus, appellants cannot rely on the filing date of Serial No. 06/835,228 of March 3, 1986 to support the written description requirement under § 112 for the present claims.

#### Claim 45

Claim 45 is dependent upon claim 44 and further requires that the formation of an antigen-antibody complex is detected by a process selected from the group consisting of radioimmunoassay, radioimmunoprecipitation assay, immunofluorescence assay, enzyme linked immunosorbent assay, and Western blot, which is disclosed in Clavel at pages 344-345, and Figures 2 and 3.

#### Claim 46

Claim 46 is rejected under 35 U.S.C. § 103 over Clavel in view of Luciw. Clavel describes an the use of peptides from the envelope portion of LAV-2 for use in ELISA, Western blot and radioimmunoprecipitation assays. Clavel, page 344. It would have been obvious to one of ordinary skill in the art at the time of the present invention to provide the components of such a known assay in a diagnostic kit for the detection of antibodies in a biological sample which bind to Human Immunodeficiency Virus Type 2 in view of the desirability in the art to determine the presence of HIV antibodies in patient samples (Clavel, page 346) and general knowledge in the art of the convenience of immunoassay diagnostic test kits. See, for example, Luciw, U.S. Patent No. 5,156,949 describing an article of manufacture for use in an immunoassay for the detection of Human Immunodeficiency Virus (claim 17).

CONCLUSION

The rejection of claims 44-46 under 35 U.S.C. § 112 first paragraph is reversed.

A new rejection of claims 44-45 under 35 U.S.C. § 102(a) is made. A new rejection of claim 46 under 35 U.S.C. § 103 is made.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

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

REVERSED - 37 CFR § 1.196(b).

)

Appeal No. 1997-2528  
Application No. 07/810,908

WILLIAM F. SMITH  
Administrative Patent Judge

DEMETRA J. MILLS  
Administrative Patent Judge

ERIC GRIMES  
Administrative Patent Judge

)  
)  
)  
) BOARD OF PATENT  
) APPEALS AND  
) INTERFERENCES  
)  
)  
)

Appeal No. 1997-2528  
Application No. 07/810,908

FINNEGAN, HENDERSON, FARABOW  
GARRETT AND DUNNER  
1300 I STREET, N.W.  
WASHINGTON, DC 20005-3315

DJM/jlb