

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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 LEONARD H. EVANS and WILLIAM J. BRITT

Appeal No. 1997-2374
Application 08/064,352

ON BRIEF

Before STONER, Chief Administrative Patent Judge, and WILLIAM F. SMITH and LORIN, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 and 3-8, all the claims pending in the application.¹ A copy of the claims is attached.

¹ Pursuant to 35 U.S.C. § 6(b), we review the adverse decision of the examiner. In doing so, we have considered the record, including:

- Final Rejection (paper no. 28);
- Request for Reconsideration (paper no. 30) and Declaration (paper no. 31);
- Advisory Action (paper no. 33);
- Appeal Brief (paper no. 38) and Amendment with Remarks (paper no. 37);
- Advisory Action (paper no. 39);
- Examiner's Answer (paper no. 42);
- Reply Brief (paper no. 44);
- Supplemental Examiner's Answer (paper no. 45);
- Reply Brief (paper no. 46); and,

Appeal No. 1997-2374
Application No. 08/064,352

The references relied upon by the examiner are:

- "Research Agreement for Material Provided by the National Institute of Allergy and Infectious Diseases, NIH," to Dr. Townsend [UR1];
- "Research Agreement for Material Provided by the National Institute of Allergy and Infectious Diseases, NIH," to Dr. Hoffman [VR1];
- "Research Agreement for Material Provided by the National Institute of Allergy and Infectious Diseases, NIH," to Dr. Hayes [UR2];
- Sevier et al. (Sevier), "Monoclonal Antibodies in Clinical Immunology," Clinical Chemistry 27(11), 1981, pp. 1797-1806;
- Britt et al. (Britt), "Use of Monoclonal Anti-gp70 Antibodies to Mimic the Effects of the Rfv-3 Gene in Mice with Friend Virus-Induced Leukemia," Journal of Immunology, vol. 130, no. 5 (May 1983, pp. 2363-2367; and,
- Harlow et al. (Harlow), "Antibodies A Laboratory Manual", Cold Spring Harbor Laboratory, Cold Spring, 1988, pp. 148-152 and 567-569.

The claims stand rejected as follows²:

- 1) "Claim 1 is rejected under 35 U.S.C. § 103 as being unpatentable over any one of the references of record cited as UR1, VR1, and UR2 in view of Harlow et al." (see p. 2 of the Supplemental Examiner's Answer, paper no. 45);
- 2) "Claim 7³ [is] rejected under 35 U.S.C. § 102(b) as anticipated by any of the material transfer agreements referred to as UR1, VR1, and UR2" (see p. 4 of the Examiner's Answer, paper no. 42);
- 3) "Claims 3, 5, 6, and 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Sevier et al. in view of any of the references cited as UR1, VR1, and UR2" (see p. 6 of the Examiner's Answer, paper no. 42); and,

-
- Second Supplemental Examiner's Answer (paper no. 47).

² We reproduce the statements of the rejections as they appear in the Examiner's Answer of May 20, 1994 (paper no. 23) and the Supplemental Examiner's Answer of December 1, 1995 (paper no. 45). The statements in the Final Rejection (paper no. 28) included additional references which are no longer relied upon.

³ In the Examiner's Answer, claim 1 was also rejected over UR1, VR1 and UR2. However, the rejection of claim 1 was withdrawn in the subsequent Supplemental Examiner's Answer (paper no. 45, p. 2) in favor of a new ground of rejection rejecting claim 1 over any of UR1, VR1 and UR2 in view of Harlow.

Appeal No. 1997-2374
Application No. 08/064,352

- 4) "Claim 4 is rejected under 35 U.S.C. § 103 as being unpatentable over Britt et al. in view of any of the references cited as UR1, VR1, and UR2" (see p. 7 of the Examiner's Answer, paper no. 42).

We reverse.

DISCUSSION

The claimed subject matter is directed to the monoclonal antibody 83A25, a hybridoma secreting monoclonal antibody 83A25, a reagent kit that includes monoclonal antibody 83A25 and methods of using monoclonal antibody 83A25. In rejecting the claims under 35 U.S.C. §§ 102 and 103, examiner relies on UR1, VR1 and UR2 for teaching monoclonal antibody 83A25.

To be accurate, although the rejections are styled as though the claims are rejected over UR1, VR1 or UR2, in point of fact, the examiner is rejecting the claims on the ground that the monoclonal antibody 83A25 was in "public use"⁴ in this country more than one year prior to the filing date of the application. UR1, VR1 or UR2 are relied upon by the examiner as evidence of that public use. According to the examiner, the "rejections [are] based upon the transfers themselves, which, under the terms of the Research Agreements, are believed to constitute public use more than one year prior to the date of application for patent in the United States" (Examiner's Answer, p. 5). Examiner argues that the "dates of these references indicate that the invention was in public use in this country for more than one year prior to the date of application for

⁴ 35 USC § 102 states, in part, that:

A person shall be entitled to a patent unless - ...
(b) the invention was ... in public use or on sale in this country, more than one year prior to the date of the

patent in the United States" (Examiner's Answer, p. 4, and Second Supplemental Examiner's Answer, p. 1).

Appellants disagree, arguing that "[i]n view of all of the facts surrounding the transfers, the materials transferred were not 'in public use,' and therefore the Research Agreements are not properly deemed prior art" (Brief, pp. 11-12). Appellants cite passages in the agreements themselves, discussed infra, that appellants argue, for example, restrict the transferred materials to noncommercial use. Appellants (Brief, p. 9) also direct our attention to the 37 CFR § 1.132 declaration of Dr. Gangemi, dated January 20, 1994, among others, which attests to the understanding of recipients that research materials transferred per these agreements were to be maintained under a duty of confidentiality.

It is the examiner who bears the initial burden of establishing reasons of unpatentability. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Consequently, the examiner has the burden to establish a prima facie case of public use. To meet that burden, the examiner has relied wholly on Research Agreements UR1, VR1, and UR2. According to the examiner they evidence a public use of monoclonal antibody 83A25 in this country more than one year prior to the filing date of the application. We have carefully reviewed these documents but fail to find evidence that monoclonal antibody 83A25 was used in this country more than one year prior to the filing date of the application.

Appeal No. 1997-2374
Application No. 08/064,352

UR1, signed by co-inventor Evans and non-inventors Chesebro and Galli on March 7, 1988, states that NIAID "will furnish the following research materials: Tissue culture supernatant of monoclonal antibody 83A25' (10 mls)" to Townsend, who signed the agreement on March 17, 1988.

VR1, signed, but not dated, by co-inventor Evans and non-inventors Chesebro and Galli, states that NIAID "will furnish the following research materials: Anti-murine retroviral gp70 monoclonal antibody tissue culture supernat. Name - 83A25" to Hoffman who signed the agreement on April 14, 1988.

UR2, signed by co-inventor Evans and non-inventors Chesebro and Galli on May 10, 1988, states that NIAID "will furnish the following research materials: "Monoclonal antibodies to murine leukemia virus envelope proteins" to Hays who signed the agreement on May 25, 1988.

There is no indication in any of these documents that the materials were used by Townsend, Hoffman and/or Hays. Examiner argues that "the claimed material was distributed [to Townsend, Hoffman and/or Hays] more than one year before the application was filed" (Examiner's Answer, p. 6) but there is no evidence of such a distribution. Nowhere in these agreements does it state that the indicated research materials were in fact transferred to and used by Townsend, Hoffman and/or Hays and that the transfer and subsequent use occurred more than one year prior to the filing date of the application. Examiner appears to have considered the dates these agreements

Appeal No. 1997-2374
Application No. 08/064,352

were signed, which were indeed signed more than one year prior to the filing date of the application, as the dates on which the materials were used. However, the agreements state that the research materials will be furnished to Townsend, Hoffman and/or Hays, not that the research materials were in fact furnished to them, that they used the materials, and on the date the agreements were signed. Whether Townsend, Hoffman and/or Hays actually received the indicated research materials and then used them more than one year prior to the filing date of the application is a matter of speculation.

Even if we were to assume, as the examiner has, that Townsend, Hoffman and/or Hays indeed received and used the indicated research materials more than one year prior to the filing date of the application, to establish a prima facie case of public use, examiner still has the burden of showing that the use of the indicated research materials was a public use.

Issues arising under the public use bar of section 102(b) are determined by considering the totality of the circumstances. In re Brigance, 792 F.2d 1103, 1107, 229 USPQ 988, 991 (Fed. Cir. 1986). "A decision on whether there has been a 'public use' can only be made upon consideration of the entire surrounding circumstances," TP Laboratories, Inc. v. Professional Positioners, Inc. et al., 724 F.2d 965, 971, 220 USPQ 577, 582 (Fed. Cir. 1984). However, "[t]he use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a use'," TP Laboratories,

Appeal No. 1997-2374
Application No. 08/064,352

Inc. v. Professional Positioners, Inc. et al., 724 F.2d. 965,970, 220 USPQ 577, 581 (Fed. Cir. 1984), quoting Curtis, Patents, sect. 381; Shaw v. Cooper, 7 Pet. 292.⁵ Here, even if we assumed that monoclonal antibody 83A25 was used more than one year prior to the filing date of the application, the wording of the agreements strongly suggests that the use would not have been a public one but rather an experimental one.

UR1, VR1 and UR2 are Research Agreements signed by officials from the NIAID and from the accepting organizations which state, identically, that the “National Institute of Allergy and Infectious Diseases, NIH [NIAID] will furnish” to the accepting organizations certain research materials under five specified terms:

- Term 1 states that “[y]ou and your organization must retain control over these materials, use them only for noncommercial research purposes and not redistribute them to others for any purpose.” Furthermore, “[a]ny use of these materials which is intended to or may result in the development of a marketable commercial product may be carried out only pursuant” to an agreement with NIAID.
- Term 2 indicates whether a patent application has been filed and states that “[n]o proprietary rights or licenses are granted by this agreement. NIH may make these materials freely available to other scientists for noncommercial purposes.”
- Term 3 states that the “materials are provided without warranty of merchantability...”

⁵ “The experimental use doctrine operates in the inventor's favor to allow the inventor to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute.’ See In re Hamilton, 882 F.2d 1576, 1581, 11 USPQ2d 1890, 1894 (Fed. Cir. 1989) (discussing experimental use in the context of the on-sale bar) (emphasis in original). Providing Cullis, the inventor, with the benefit of Suaudeau's testing is thus contrary to this policy, as Suaudeau was not using or testing the invention for Cullis. Id. Accordingly, we hold that public testing before the critical date by a third party for his own unique purposes of an invention previously reduced to practice and obtained from someone other than the patentee, when such testing is independent of and not controlled by the patentee, is an invalidating public use [our emphasis], not an experimental use.” Baxter International Inc. v. Cobe Laboratories Inc., 88 F.3d 1054, 1060, 39 USPQ2d 1437, 1442 (Fed. Cir. 1996).

Appeal No. 1997-2374
Application No. 08/064,352

- Term 4 discusses compliance with laws, handling requirements and liability for damages.
- Term 5 requests acknowledgment of NIAID as a source in publications.

In accordance with the terms of the agreements, the accepting organizations are prohibited from giving control of the research materials to someone else, can not use them for a commercial purpose and can not redistribute the materials to others for any purpose. Even if a commercial purpose would happen to result from the research, the accepting organization cannot carry out development of a commercial product without agreement with NIAID. All proprietary and license rights remain with NIAID. These agreements limit the accepting organizations from doing anything but noncommercial research on the furnished materials.

A plain reading of the Research Agreements, especially the terms under which the research materials will be furnished, indicate to us that the accepting organizations would be limited to using the materials experimentally and that the NIAID would still retain significant control of the research materials even after the materials are furnished. Even if there was evidence that the research materials were used by Townsend, Hoffman and/or Hays more that one year prior to the filing date of the application, their use of the materials, consistent with the terms of the agreements, would not have been a public use but rather an experimental one.

Examiner does not dispute that activities consistent with the agreements would be experimental rather than public in nature. Rather the examiner resorts to

Appeal No. 1997-2374
Application No. 08/064,352

speculation that a public use might occur. Examiner (Examiner's Answer, p. 5) argues that the "form does not contain an integration clause that is standard in agreements meant to memorialize complete agreements between parties. In the absence of such an integration clause, the parties may make additional agreements. There is an unresolved question here as to the content of any such additional agreements."

Examiner (Examiner's Answer, p. 6) also argues that the "Research Agreements do not contain a restriction on publication of results obtained using the transferred material."

These speculations about a possible situation that could arise leading to a public use of the monoclonal antibody are not supported by any objective evidence.

We find that UR1, VR1 and UR2 do not evidence a public use of the claimed invention and thus are not properly deemed prior art. Accordingly, examiner has not met its burden of establishing a prima facie case of a public use of monoclonal antibody 83A25 in this country more than one year prior to the filing date of the application.

Since the rejections of the claimed subject matter are predicated on the view that the monoclonal antibody 83A25 was in public use in this country more than one year before the filing date of the application, we shall not sustain the rejections of the claims under 35 U.S.C. §§ 102 and 103.

Appeal No. 1997-2374
Application No. 08/064,352

Examiner's decision is REVERSED.

REVERSED

BRUCE H. STONER, JR.
Chief Administrative Patent Judge

WILLIAM F. SMITH
Administrative Patent Judge

HUBERT C. LORIN
Administrative Patent Judge

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

Appeal No. 1997-2374
Application No. 08/064,352

Townsend and Townsend and Crew
Two Embarcadero Center\
Eighth Floor
San Francisco, CA 94111

APPENDIX

CLAIMS:

1. A hybridoma secreting monoclonal antibody 83A25 having the identifying characteristics of ATCC deposit no. HB 10392.
3. A method of detecting murine leukemia virus (MuLV) in a sample or a culture, comprising:
 - a) contacting said sample or culture with a monoclonal antibody against a common epitope that specifically binds monoclonal antibody 83A25, said epitope being present on the envelope glycoproteins of ecotropic, xenotropic, polytropic, and amphotropic murine leukemia virus, under conditions such that an immunocomplex can form between said monoclonal antibody and said envelope glycoprotein epitope; and
 - b) detecting the presence of an immunocomplex consisting essentially of said monoclonal antibody and said envelope glycoprotein.
4. A method for neutralizing murine leukemia virus in vitro, comprising:
 - reacting murine leukemia virus with a sufficient amount of a monoclonal antibody against a common epitope that specifically binds monoclonal antibody 83A25, said epitope being present on the envelope glycoproteins of ecotropic, xenotropic, polytropic, and amphotropic murine leukemia virus, to form a neutralizing immunocomplex between said monoclonal antibody and said envelope glycoprotein epitope.
5. A method of purifying leukemia virus or viral protein comprising attaching antibody 83A25 to a matrix and adsorbing the leukemia virus or viral protein to said attached antibody, thereafter washing the impurities and then eluting the adsorbed virus or the viral protein from said matrix and recovering the purified virus or viral protein.
6. The method according to claim 3, wherein said murine leukemia virus is selected from the group consisting of ecotropic, xenotropic, polytropic, and amphotropic MuLV.
7. A monoclonal antibody against a common epitope on the envelope glycoprotein of ecotropic, xenotropic, polytropic, and amphotropic murine leukemia virus that specifically binds monoclonal antibody 83A25.
8. A reagent kit comprising a container having an immunoreactive amount of monoclonal antibody 83A25 and instructional materials to perform appropriate assays or tests.