

Appeal No. 1995-3257
Application 08/056,382

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(2) is not binding precedent of the Board.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. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARIO GHIONE,
ANDREA BALSARI,
and MARIA I. COLNAGHI

Appeal No. 1995-3257
Application No. 08/056,382¹

ON BRIEF

Before WILLIAM F. SMITH, ELLIS, and LORIN, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

¹ Application for patent filed May 4, 1993. According to appellants, this application is a continuation-in-part of application 07/848,753, filed March 10, 1992, now abandoned.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. ' 134 from the final rejection of claims 1-3, 6-9, 11-15, and 18-20, all the claims pending in the application. On consideration of the record, we reverse the rejections.

Representative Claims

1. A topical pharmaceutical composition useful in cytostatic therapy comprising an anthracycline antibiotic and an antidotal effective amount of an anti-anthracycline antibiotic monoclonal antibody produced from hybridoma deposited at ECACC under No. 90011003 on January 12, 1990 and a pharmaceutically acceptable topical carrier.

12. A method of cytostatic therapy in animals, comprising topically administering to an animal in need of such therapy an anthracycline antibiotic and an antidotal effective amount of an anti-anthracycline antibiotic monoclonal antibody produced from a hybridoma deposited at ECACC under No. 90011003 on January 12, 1990 in a pharmaceutically acceptable topical carrier.

The references relied upon by the examiner are:

Balsari et al. (Balsari I), A New Monoclononal Antibody Recognizing Anthracyclenic Molecule, Anticancer Research 10:129-132 (1990).

Balsari et al. (Balsari II), Monoclonal Antibodies Against Doxorubicin, J. Cancer: 42, 798-802 (1988).

The rejections are:

Claims 6-9, 11, 19 and 20 are rejected under the judicially created doctrine of obviousness-type double

Appeal No. 1995-3257
Application 08/056,382

patenting over claim 1 U.S Patent No. 5,177,016.

Claims 1-3, 6-9, 11-15 and 18-20 are rejected under
35 U.S.C. ' 112, first paragraph, for failing to provide
an enabling disclosure.

Claims 6-9, 11, 19 and 20 are rejected under 35 U.S.C. ' 102(b) as being anticipated by Balsari I or II.²

Decision

In rendering our decision, we have considered the following:

The entire specification and record in 08/056,382;

Final Rejection (paper no. 5, mailed December 13, 1993);

Brief (paper no. 13, filed August 8, 1994);

Examiner's Answer (paper no. 17, mailed November 18, 1994);

Supplemental Examiner's Answer (paper no. 19, mailed November 29, 1994);

Reply Brief (paper no. 20, filed January 17, 1995);

2nd Supplemental Examiner's Answer (paper no. 21, mailed March 7, 1995);

Remand to Examiner (paper no. 24, mailed May 23, 1995);
and,

² We have combined the rejections that were separately presented in the examiner's answer:

Claims 6, 7, 9, 11, 19 and 20 are rejected under 35 U.S.C. ' 102(b) as being anticipated by Balsari I.

Claims 6, 7, 9, 11, 19 and 20 are rejected under 35 U.S.C. ' 102(b) as being anticipated by Balsari II.

Claim 8 is rejected under 35 U.S.C. ' 102(b) as being anticipated by Balsari I or II.

Appeal No. 1995-3257
Application 08/056,382

2nd Remand to Examiner (paper no. 28, mailed December 12,
1995).

Obviousness-Type Double Patenting

Claims 6-9, 11, 19 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 5,177,016.

Claim 19, the independent claim, is representative of the rejected claims and reads as follows:

19. A topical pharmaceutical composition useful for decreasing the toxic affect [sic] in animals caused by the administration of an anthracycline antibiotic for cytostatic therapy comprising an antidotal effective amount of an anti-anthracycline antibiotic monoclonal antibody produced by a hybridoma deposited at ECACC under No. 90011003 on January 12, 1990, and a pharmaceutically acceptable topical carrier.

Below, we reproduce claim 1 of U.S. Patent No. 5,177,016:

1. Monoclonal antibody which specifically binds anthracycline glycosides belonging to subclass IgG2 secreted by the hybridoma deposited at European Collection of Animal Cell Cultures (ECACC) under N. 90011003.

The issue is whether claim 19, with its additional features, is an obvious variation of patent claim 1. In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). If it is, then the rejection is proper and can only be overcome by filing a terminal disclaimer.

Otherwise, claim 19 must be patentably distinct from patent claim 1. In re Goodman, 11 F.3d 1046, 1052, 29

Appeal No. 1995-3257
Application 08/056,382

USPQ2d 2010, 2015 (Fed. Cir. 1993).

The crux of the inquiry lies in a comparison of the claims. In re Borah, 354 F.2d 1009, 1017, 148 USPQ 213, 220 (CCPA 1966). When comparing the claims, we see that patent claim 1 is directed to a specific monoclonal antibody while claim 19 provides for:

a topical pharmaceutical composition useful for decreasing the toxic affect [sic] in animals caused by the administration of an anthracycline antibiotic for cytostatic therapy;
an antidotal effective amount of the antibody of patent claim 1; and,
a pharmaceutically acceptable topical carrier.

Therefore, in assessing whether claim 19 is patentably distinct from patent claim 1, it is incumbent on examiner to demonstrate that the three additional features listed supra are not indicative of the existence of patentable differences over patent claim 1. General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1278-79, 23 USPQ2d 1839, 1844 (Fed. Cir. 1992). In this respect, examiner (examiner's answer, p. 4) states:

"Although the conflicting claims are not identical, they are not patentably distinct from each other because they vary only in the recitation of various carriers and in the recitation of an intended use. Because the prior art and claimed antibody are the same, it would have been obvious to formulate the claimed antibodies with at [sic] topical carrier for any [examiner's emphasis] desired use of said antibodies, because it is known in the art that

Appeal No. 1995-3257
Application 08/056,382

whatever [examiner's emphasis] the intended use, the antibodies must generally be in solution..."

After careful review of examiner's position, we conclude that examiner has not demonstrated that claim 19 is an obvious variation of patent claim 1. We reach this decision for two reasons.

First, an essential element of claim 19 - "an antidotal effective amount" of the antibody - is ignored. This feature presents a limitation on the antibody within the remaining topical composition and places a constraint not suggested in patent claim 1. The purpose of supplying this amount is to decrease the toxic effect in animals caused by administration of an anthracycline antibiotic (claim 19, preamble). Patent claim 1 is directed broadly to the antibody and recites no particular amount. For claim 19 to be an obvious variation of patent claim 1, examiner would have to show that it would have been obvious to provide an antidotal effective amount of the antibody of patent claim 1. However, no reason for doing so is given.

Second, examiner dismisses the "use" language and carrier recited in claim 19 because they are conventional but does not explain why they would have been obvious

over patent claim 1. Even if their conventionality were true (and examiner provides no substantiating evidence), it is

not clear how one with ordinary skill would have found it obvious to combine an antidotal effective amount of the antibody with a "pharmaceutically acceptable topical" carrier based only on the information provided by patent claim 1. The only reason for doing so would be for the purpose and the potential benefits appellants have disclosed. However consulting the disclosure of U.S. Patent 5,177,016 is impermissible because when considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as though it were prior art. In re Sarett, 327 F.2d 1005, 1012-13, 140 USPQ 474, 481 (CCPA 1964). To the extent that examiner is reading patent claim 1 to inherently include a carrier, we merely point out that patent claim 1 defines nothing more than a monoclonal antibody. "We are not here concerned with what one skilled in the art would be aware from reading

Appeal No. 1995-3257
Application 08/056,382

the claims but with what inventions the claims define."

Ibid.

For the foregoing reasons, the rejection is
reversed.

Enablement

All the appealed claims are finally rejected under the first paragraph of 35 U.S.C. ' 112 as being drawn to a non-enabling disclosure. Examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). We conclude that examiner has not met this burden.

After reading examiner's position¹, it is evident that examiner focuses exclusively on whether the claims are enabled for preventing alopecia in humans and yet does not question enablement with respect to other treatments. Of all the claims on appeal (1-3, 6-9, 11-15 and 18-20), only claims 12-15 and 18 are directed to methods of therapy and only one claim, claim 18, is directed to preventing alopecia. The other claims are directed to topical compositions. We reproduce claims 12-15 and 18:

12. A method of cytostatic therapy in animals, comprising topically administering to an animal in need of such therapy an anthracycline antibiotic and an antidotal effective amount of an anti-anthracycline antibiotic monoclonal antibody produced from a hybridoma deposited at ECACC under No. 90011003 on January 12, 1990 in a pharmaceutically acceptable topical carrier.

13. The method of claim 12 wherein the monoclonal antibody is administered before, during and after administration of the anthracycline antibiotic.

14. The method of claim 13 wherein the monoclonal antibody in the carrier is applied

directly to extravasation lesions produced by administration of the anthracycline antibiotic.

15. The method of claim 14 wherein the monoclonal antibody is carried in a solvent therefor.

18. The method of claim 12 wherein the monoclonal antibody is topically applied as a preventative for anthracycline-induced alopecia.

As can be seen by these claims, the invention is directed to topically applying an antidotal effective amount of an anti-anthracycline antibiotic monoclonal antibody produced from a hybridoma deposited at ECACC under No. 90011003 on January 12, 1990 in a pharmaceutically acceptable topical carrier. The invention has a number of different methods of using the claimed compositions. One is for the treatment of extravasation (spec., p. 7, lines 13-22; and claim 13, supra). Another is for the prevention of alopecia (spec., p. 8, lines 13-16; and claim 18, supra). However, the invention has a broader application. As explained in the specification (pp. 1-2), the treatment is intended to reduce the toxifying effects that accompany the administration of anthracycline antibiotics while retaining the antibiotic's antitumor efficacy (spec., p. 3, lines 3-6). This broader application is reflected in claims 12, 13 and 25 supra.

Given the varying scopes and uses for the claimed invention, we fail to understand why examiner questions only the enablement of the invention when directed to preventing alopecia. By not raising the issue with respect to other asserted methods of use, examiner implicitly agrees that the claims are enabled to perform these other applications; that is, the specification provides sufficient information on how to use the claimed compositions and process. With respect to claim 18, which is specifically drawn to preventing alopecia, this claim depends on a

claim that is directed to any use. Since examiner has not questioned that the claimed monoclonal antibody does in fact work as an antidote to anthracycline antibiotics, it is unclear why examiner is questioning the same antidotal effect in the particular context of preventing alopecia.

Since examiner has not met the initial burden of providing reasons why a supporting disclosure does not enable the claims, we reverse the rejection.

Anticipation

Claims 6-9, 11, 19 and 20 are rejected under 35 U.S.C. ' 102(b) as being anticipated by Balsari I or II.

For a prior art reference to anticipate in terms of 35 U.S.C. ' 102, every element of the claimed invention must be identically shown in the single reference, @ In re Bond, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Since the prior art does not teach every element of the claimed invention, we reverse the rejection.

Setting aside whether the references teach the particular monoclonal antibody recited in the claims, they do not teach a composition comprising the mAb at an "antidotal effective amount". Examiner has not directed us to where in the references this is disclosed

and we cannot find it. Furthermore, the claims require a "pharmaceutically acceptable topical carrier". Examiner takes the position that this is met by the references' teaching of a buffer. In order to make that conclusion, examiner would have to show that they are identical. The mere argument that the "buffers ... are deemed to meet the limitations of 'pharmaceutically acceptable topical carrier'" does not satisfy examiner's burden of showing identity in support of a rejection for anticipation under ' 102(b). The rejection is reversed.

REVERSED

	WILLIAM F. SMITH)	
	Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF
PATENT)	
	JOAN ELLIS)	APPEALS
	Administrative Patent Judge)	AND
)	INTERFERENCES
)	
)	
	HUBERT C. LORIN)	
	Administrative Patent Judge)	

Appeal No. 1995-3257
Application 08/056,382

GRIFFIN, BUTLER, WHISENHUNT
And KURTOSSY
STE. PH-1
2300 NINTH STREET, SOUTH
ARLINGTON, VA 22204-2316

HCL/dal

¹ "With regard to the prevention of alopecia, the Examiner does not consider 8 day old Wistar rats to be an accepted model system; the growth of first hair in a development stage characterized by rapid growth and cell division is not analogous to the growth of hair in an adult animal. Further, the prevention of inhibition of new hair growth is not analogous to the prevention of hair loss.... It has not been established that the growth of hair on rats is analogous to human hair growth on the scalp (as opposed to other body hair), nor is it believable that methods such as those disclosed in the current specification as filed would have an analogous effect regardless of the type of hair growth to which they were applied. Therefore, applicants have not taught how to use the method of the invention for prevention or treatment of alopecia.... The model system has not been shown to be predictive of the effect achieved in humans; in the current case, as no

results were presented from the human trials, it cannot be established that the results obtained with immature rats were predictive of efficacy in human [sic, humans], and it is deemed that the model system was not adequately validated but that the art recognized the *potential* [examiner's emphasis] utility of the model system. It is not predictable that the results presented in the current specification as filed would be successfully applied to the proposed methods of treatment; to investigate such and determine the appropriate/optimal methods of administration and dosage levels *for human subjects* [examiner's emphasis] is deemed to constitute undue experimentation in the absence of any information as to the efficacy in humans, or alternatively any data generated using an acceptable model system.

Appellants method claims are directed to treating animals, including human, however enablement of the current specification as filed is commensurate in scope only with the use of the claimed methods in mice." Examiner's Answer, pp. 4-6.