

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT R. BARTLETT

Appeal No. 94-2990
Application 07/932,577¹

ON BRIEF

Before RONALD H. SMITH, WINTERS and GRON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

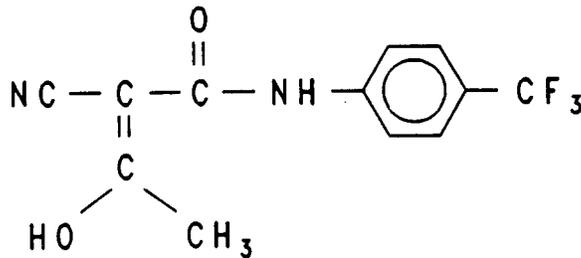
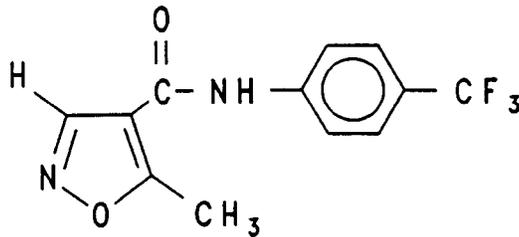
This appeal was taken from the examiner's rejection of claims 11 through 23, which are all of the claims remaining in the application.

REPRESENTATIVE CLAIMS

¹ Application for patent filed August 20, 1992.

Claims 11 and 16, which are illustrative of the subject matter on appeal, read as follows:

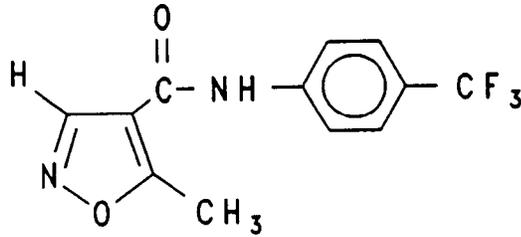
11. A method of treating hyperacute rejection reactions of an organ recipient to a transplanted organ, which comprises administering to said organ recipient an effective amount of a pharmaceutical composition containing as an active ingredient at least one compound having the formula I or II:



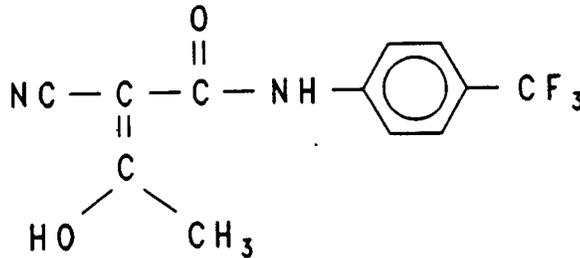
II

or the compound of formula II in the form [sic, of] a physiologically tolerable salt [emphasis added].

16. A
treating
reactions of an
recipient to a
organ from a
species, which
administering
recipient an
amount of a
composition
an active
least one
having formula



method of
rejection
organ
transplanted
different
comprises
to said organ
effective
pharmaceutical
containing as
ingredient at
compound
I or II:



I

II

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or the compound of formula II in the form [sic, of] a physiologically tolerable salt [emphasis added].

THE REFERENCES

In rejecting claims 11 through 23 on prior art grounds, the examiner relies on the following references:

Ertel et al. (Ertel)	4,061,767	Dec. 6, 1977
Kammerer et al. (Kammerer)	4,284,786	Aug. 18, 1981
Bartlett et al. (Bartlett)	4,965,276	Oct. 23, 1990

Auchincloss, Transplantation, "Xenogeneic Transplantation", Vol. 46, No. 1, pages 1-10 (July 1989).

Appellant cites and relies on the following references:

Fundamental Immunology, William E. Paul, Second Edition, Chapter 33, pages 906 and 907 (1989).

Roitt et al. (Roitt), Immunology, Gower Medical Publishing, New York, page 24.5 (1985).

THE ISSUE

The issue presented for review is whether the examiner erred in rejecting claims 11 through 23 under 35 USC § 103 as unpatentable over the combined disclosures of Auchincloss, Ertel, Kammerer, and Bartlett.

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DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) The instant specification, including all of the claims on appeal;
- (2) Appellant's main Brief and Reply Brief before the Board;
- (3) The Examiner's Answer and the communication mailed by the examiner February 22, 1994; and
- (4) The above-cited references relied on by both appellant and the examiner.

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection under 35 USC § 103.

DISCUSSION

Claims 11 through 15, 22 and 23 are directed to a method of treating hyperacute rejection reactions of an organ recipient to a transplanted organ. Based on our review of the record, we find

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that the timing of administration is critical when treating hyperacute rejection reactions. This follows because hyperacute rejection occurs within minutes after transplantation. See appellant's discussion of the Roitt reference in the main Brief before the Board, page 12, first full paragraph. A fortiori, in order to treat these rejection reactions, administration to the recipient of an effective amount of the pharmaceutical composition must be essentially contemporaneous with transplantation. Administering an effective amount of the pharmaceutical composition must occur before transplantation, during transplantation, or within minutes after transplantation lest the hyperacute reaction takes place.

In our judgment, the only reasonable interpretation which these facts permit is that claims 11 through 15, 22 and 23 require administering an effective amount of the pharmaceutical composition to the organ recipient before, during, or within minutes after transplantation. Later administration would not and could not effectively treat hyperacute rejection reactions, because hyperacute rejection occurs so quickly after transplantation. Again, see the discussion in appellant's main Brief, page 12, first full paragraph. The term "hyperacute" is a limitation in claim 11 restricting the timing of administration

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of appellant's pharmaceutical composition.

On this record, we find that Bartlett constitutes the closest prior art. Bartlett discloses a method of treating chronic rejection reactions of an organ recipient to a transplanted organ by administering to the recipient an effective amount of a pharmaceutical composition containing, as an active ingredient, the same compounds illustrated in claim 11. Accordingly, the sole difference between the method defined in claims 11 through 15, 22 and 23 and the method disclosed by Bartlett is the difference between treating hyperacute rejection and chronic rejection.

The examiner does not point to any portion of Bartlett, or any other reference of record, disclosing or suggesting that chronic rejection be treated by administering an effective amount of the pharmaceutical composition before transplantation, during transplantation, or within minutes after transplantation. In setting forth the rejection under 35 USC § 103, the examiner does not rely on prior art disclosing or suggesting that chronic rejection be treated by administering an effective amount of the pharmaceutical composition essentially contemporaneous with transplantation. On the contrary, Bartlett discloses that "[t]he animals were treated for the first time on the 17th day after the

first injection of the donor cells". See Bartlett, column 2, lines 63 through 65. Bartlett further discloses an experimental protocol for treatment "[f]rom day 17 onwards" in column 3, lines 4 through 30. Manifestly, the Bartlett reference, considered alone or in conjunction with the remaining references relied on by the examiner, is insufficient to support a conclusion of obviousness of method claims containing the limitation "hyperacute". As discussed supra, that limitation is critical and restricts the timing of administration of appellant's pharmaceutical composition in method claims 11 through 15, 22 and 23.

We next consider claims 16 through 21, drawn to a method of treating rejection reactions of an organ recipient to a transplanted organ from a different species.²

Again, we find that Bartlett constitutes the closest prior art. Having carefully reviewed the Bartlett patent in its entirety, we find that this patent is restricted to allogeneic transplantation. This follows because:

² As explained in the Auchincloss reference, relied on by the examiner, xenogeneic transplantation is the transplantation of organs or tissues from a member of one species to that of another. Allogeneic transplantation is the transplantation of organs or tissues between members of the same species.

(1) Bartlett does not contain any disclosure, express or implicit, suggesting that patentee contemplates carrying out xenogeneic transplantation;

(2) The pharmacological tests disclosed by Bartlett use the same species; and

(3) Bartlett discloses the use of medicaments to combat chronic graft-versus-host diseases. Manifestly, Bartlett's method is directed to treating recipients who survive in the long-term, whereas Auchincloss discloses that "no long term successful xenograft has ever been achieved". See Auchincloss, page 1, right-hand column, last paragraph. For these reasons, we believe it reasonable to infer that Bartlett is restricted to allogeneic transplantation.

The dispositive question is whether it would have been obvious, on this record, to extend Bartlett's method of treating chronic rejection reactions to a method of treating rejection reactions resulting from xenogeneic transplantation. We answer that question in the negative.

The examiner does not point to any evidence of record suggesting that the recipients of xenogeneic transplantation suffer from chronic rejection or a chronic graft-versus-host disease state. In the absence of such evidence, the question

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arises why a person having ordinary skill in the art would have considered it desirable to treat those recipients with Bartlett's composition. For all this record shows, it would have been more plausible to treat the recipients of xenogeneic transplantation for acute rejection or "accelerated rejection". See the Paul text on Fundamental Immunology, relied on by the appellant, page 907, section entitled "Acute Rejection". Again, the Bartlett reference, considered alone or in conjunction with the remaining references relied on by the examiner, is insufficient to support a conclusion of obviousness of method claims drawn to treating rejection reactions resulting from xenogeneic transplantation. The Bartlett reference, considered alone or in conjunction with the remaining references relied on by the examiner, is insufficient to support a conclusion of obviousness of claims 16 through 21.

As in In re May, 574 F.2d 1082, 1092, 197 USPQ 601, 609 (CCPA 1978), "the record reflects both an expected beneficial result . . . and an unexpected beneficial result." Consequently, "it is necessary to determine the weight to be accorded each prior to making the ultimate determination on the issue of obviousness." Id. We have carefully reviewed the Kammerer and Ertel disclosures for motivation to use their compounds to treat

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organ transplant recipients. We find none. Moreover, the record in its entirety indicates that persons having ordinary skill in the art reasonably would not have expected to treat organ transplant recipients for heretofore untreatable rejection reactions.

For the reasons set forth in the body of this opinion, the rejection of claims 11 through 23 under 35 USC § 103 is reversed.

REVERSED

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RONALD H. SMITH)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
SHERMAN D. WINTERS)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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TEDDY S. GRON)	
Administrative Patent Judge)	

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