

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte IRA PASTAN, VIJAY CHAUDHARY
DAVID FITZGERALD and JANEDRA BATRA

Appeal No. 95-2052
Application 07/620,939¹

ON BRIEF

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

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 8, 10, 14 and 15. Claims 1 through 7, which are the only other claims pending in the application, stand withdrawn from further

¹ Application for patent filed December 3, 1990.

consideration by the examiner as directed to a non-elected invention.

The invention relates to specific fusion proteins in which a truncated diphtheria toxin (DT 388), consisting of the first 388 amino acids of the toxin, is fused to the amino terminus of a heavy chain or a light chain variable region of an antibody.

Claim 8, which is illustrative of the subject matter on appeal, reads as follows:

8. A DT388-antibody recombinant protein comprising a fusion protein including a diphtheria toxin (DT) portion that consists of the first 388 amino acids of DT, wherein the toxin is at the amino terminus of a heavy chain or light chain variable region of an antibody.

In setting forth the rejection under 35 U.S.C. § 103, the examiner relies on the following references:

Janendra K. Batra, et al., "Antitumor activity in mice of an immunotoxin made with anti-transferrin receptor and a recombinant form of *Pseudomonas* exotoxin", Proc. Natl. Acad. Sci., USA, Vol. 86, pp. 8545-8549. (Nov. 1989)

Janendra K. Batra, et al., "Anti-Tac(Fv)-PE40: A Single Chain Antibody *Pseudomonas* Fusion Protein Directed at Interleukin 2 Receptor Bearing Cells", The Journal of Biological Chemistry, Vol. 265, No. 25, pp. 15198-15202. (Sep. 1990).

Ira Pastan, et al., "Immunotoxins", Cell Vol. 47, pp. 641-648, published Dec. 5, 1986 by Cell Press.

R.J. Youle, et al., "Genetic engineering of immunotoxins", Immunotoxins, published 1988 by Kluwer Academic Publishers (Boston), pp. 113-122.

Toshihiko Kondo, et al., "Activity of Immunotoxins Constructed with Modified *Pseudomonas* Exotoxin A Lacking the Cell Recognition Domain", The Journal of Biological Chemistry, Vol.

263, No. 19, pp. 9470-9475. (Jul. 1988).

Previously entered rejections of the claims under 35 U.S.C. § 112, first and second paragraphs, have been withdrawn. See the Examiner's Answer, pages 2 and 5.

The issue remaining for review is whether the examiner erred in rejecting claims 8, 10, 14 and 15 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Batra 1989, Batra 1990, Pastan, Youle, and Kondo.

On consideration of the record, we shall reverse the examiner's prior art rejection.

DISCUSSION

As a preliminary matter, we note the Frankel² and Williams et al.³ references cited in the Appeal Brief, pages 4 and 5. In the Examiner's Answer, page 6, the examiner states that these references are relied on to "buttress" the rejection under 35 U.S.C. § 103. See also the Supplemental Examiner's Answer (paper no. 31), sentence bridging pages 2 and 3, where the examiner again refers to Frankel and Williams et al. The problem here is that Frankel and Williams et al. are not included in

² Frankel, "Immunotoxins", published 1988 by Kluwer Academic Publishers (Boston), pages 123-140 .

³ Williams et al, J. Biol. Chem., vol. 265, pages 11885-11889, (1990).

the statement of rejection. As stated in In re Hoch, 428 F.2d 1341, 1343-44 n3, 166 USPQ 406, 407 n3 (CCPA 1970),

Where a reference is relied on to support a rejection, whether or not in a "minor capacity," there would appear to be no excuse for not positively including the reference in the statement of the rejection.

Where, as here, Frankel and Williams et al. are not included in the statement of rejection under 35 U.S.C. § 103, we shall not consider them further. We have limited our review to the references positively included in the examiner's statement of rejection, namely, Batra 1989, Batra 1990, Pastan, Youle, and Kondo.

Turning to the merits, we find that independent claim 8 defines a specific fusion protein "including a diphtheria toxin (DT) portion that consists of the first 388 amino acids of DT". In our judgment, the prior art relied on by the examiner is insufficient to support a conclusion of obviousness of claims containing that limitation.

Appellants argue strenuously that the prior art relied on by the examiner would not have suggested a fusion protein "including a diphtheria toxin (DT) portion that consists of the first 388 amino acids of DT." For example, see the Appeal Brief filed October 28, 1993, page 6, second paragraph; and the Reply Brief filed March 4, 1994, page 3, third full paragraph; page 4, last paragraph; and page 5, first full paragraph. The examiner does not adequately come to grips with that argument. The examiner relies on Youle's disclosure (page 117) of a portion of the diphtheria toxin extending from

amino acid 1 to 382. On this record, however, the examiner has not established how a person having ordinary skill would have been led from "here to there", i.e., from a portion of the diphtheria toxin extending from amino acid 1 to 382 (Youle) to "a

diphtheria toxin (DT) portion that consists of the first 388 amino acids of DT" recited in independent claim 8.

In resolving the question of obviousness, we must consider the claimed subject matter as a whole. 35 U.S.C. § 103. Here, the claimed subject matter includes the limitation of a diphtheria toxin (DT) portion that consists of the first 388 amino acids of DT. The examiner has not established how the cited prior art, relied on in the statement of rejection, would have led a person having ordinary skill to a fusion protein containing that limitation. In this regard, the reference to "variant forms" of DT (Examiner's Answer, page 5, line 2) does not provide an adequate factual foundation to support the rejection. Simply stated, the examiner has not established that the claimed subject matter as a whole, including the limitation of a diphtheria toxin (DT) portion that consists of the first 388 amino acids of DT, is unpatentable over the cited prior art.

For these reasons, we conclude that the examiner has not established a *prima facie* case of obviousness of claims 8, 10, 14 and 15. Accordingly, we find it unnecessary to discuss the Pastan

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declaration, filed under the provisions of 37 CFR § 1.132 and executed June 23, 1993, or the objective evidence presented in the specification, pages 22 and 23. Appellants rely on the Pastan declaration and the specification evidence to rebut a *prima facie* case of obviousness if a *prima facie* case were established by the examiner.

In conclusion, we do not sustain the rejection of claims 8, 10, 14 and 15 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Batra 1989, Batra 1990, Pastan, Youle, and Kondo. The examiner's decision is reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
WILLIAM F. SMITH)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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HUBERT C. LORIN)	
Administrative Patent Judge)	

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