

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(2) is not binding precedent of the Board.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. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte GERALD E. GAULL

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Appeal No. 95-3337  
Application 07/759,100<sup>1</sup>

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ON BRIEF

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Before WINTERS, KIMLIN, and GARRIS, Administrative Patent  
Judges.

GARRIS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the final rejection  
of claims 40 and 42 through 50 which are all of the claims

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<sup>1</sup> Application for patent filed September 6, 1991.  
According to applicant, the application is a continuation of  
Application 07/247,981, filed September 22, 1988.

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remaining in the application.

The subject matter on appeal relates to an artificial human infant formula which includes recombinant human virus-free human milk protein. Further details of this appealed subject matter are set forth in representative independent claim 40 which reads as follows:

40. In an artificial human infant formula based on bovine or soy proteins, the improvements comprising a recombinant human virus-free human milk protein having the same function as human milk protein in approximately the amount present in human milk wherein the recombinant human milk protein is selected from the group consisting of secretory immunoglobulin-A, lactoferrin, lactoperoxidase, lysozyme, alpha-lactalbumin, alpha-casein, beta-casein, kappa-casein, and combinations thereof.

The references relied upon by the examiner as evidence of obviousness are:

Müeller et al. (Müeller) 4,216,236 Aug. 5, 1980

Friend et al. (Friend), "Newer Advances in Human Milk Substitutes for Infant Feeding," 35 J. Applied Nutrition, no. 2, 88-115 (1983).

Lindblad et al. (Lindblad), "Lactoengineering: A Method for the Estimation of the Human Milk Protein Requirements of Very-Low-Birth-Weight Newborn Infants," in Williams et al. (Editor), Human Milk Banking, 159-169 (New York, Nestlé Nutrition, 1984).

Raiha, "Nutritional Proteins in Milk and the Protein Requirement of Normal Infants," Pediatrics, 136-141 (1985).

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Rhein, Biotechnology, "Freeing Hemophiliacs from the Risk of AIDS," Business Week, 38 (New York, McGraw-Hill, Inc., 1987) (referred to hereinafter as Biotechnology article).

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All of the claims on appeal stand rejected under 35 U.S.C. § 103 as being unpatentable over Müller in view of Lindblad and further in view of Raiha and Friend and the Biotechnology article.<sup>2</sup>

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<sup>2</sup>In the body of the Answer, the examiner also refers to certain portions of the subject specification which she implies represent admitted prior art. For example, on page 6 of the answer in discussing the here-claimed recombinant human virus-free human milk protein, the examiner states: "Appellant has apparently not developed these proteins, but is substituting them for known human milk proteins to make a humanized milk product. See page[s] 7-10 of appellant[']s specification for known genetically engineered proteins" (emphasis added). However, it is well settled that, where prior art is relied on to support a rejection, there would appear to be no excuse for not positively including the prior art in the statement of rejection. In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970). As a consequence, we will assess the examiner's conclusion of obviousness based solely upon the above-noted prior art references which are positively included in the examiner's statement of rejection. The examiner's aforementioned referrals to the subject specification in support of her obviousness conclusion are additionally inappropriate because the record before us is considerably unclear as to specifically what portions of the specification disclosure, including those portions which discuss recombinant human milk protein of the type here claimed, represent subject matter known in the prior art. This last mentioned point is reinforced by the examiner's use of the aforequoted term "apparently." We here emphasize that a rejection under 35 U.S.C. § 103 must rest on a factual basis rather than conjecture, speculation or assumption. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178, cert. denied, 389 U.S. 1057 (1968).

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We refer to the brief and reply brief and to the answer for a complete exposition of the opposing viewpoints expressed by the appellant and the examiner concerning this rejection.

#### OPINION

As correctly indicated by the appellant in the briefs, none of the references applied by the examiner in her rejection contains any teaching or suggestion that any of the recombinant human milk proteins recited in the appealed claims were known in the prior art at the time the here-claimed invention was made much less that it would have been obvious to use such recombinant proteins in an artificial human infant formula so as to avoid the problem addressed by the appellant, namely, the potential of viral contamination. As a result, it is clear to us that we cannot sustain the examiner's Section 103 rejection of the appealed claims as being unpatentable over Müeller in view of Lindblad and further in view of Raiha and Friend and the Biotechnology article.<sup>3</sup>

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<sup>3</sup>In our opinion, the exposition of obviousness set forth in the dissent does not represent the rejection formulated by the examiner and advanced on the subject appeal. Merely by way of example, the EPO application, which the dissent depends upon as support for an obviousness conclusion, is never specifically referred to by the examiner in her Answer.

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The decision of the examiner is reversed.

REVERSED

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
	)	BOARD OF PATENT
	)	APPEALS AND
	)	INTERFERENCES
BRADLEY R. GARRIS	)	
Administrative Patent Judge	)	

KIMLIN, Administrative Patent Judge, dissenting:

I respectfully disagree with the conclusion reached by the majority. Since appellant's specification readily acknowledges that it was known to formulate synthetic infant milk based on cow's milk (page 1 of specification), and that EPO Application 181,634 discloses the production of human lysozyme by recombinant genetic engineering techniques

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Rather, in the Answer, the examiner broadly refers to portions of the specification (e.g., pages 7-10) which she seems to believe represent acknowledged prior art. This merits panel has not been briefed by the appellant or the examiner respecting those portions of EPO Application 181,634 which may teach toward or away from the claimed invention. In fact, it is unclear whether the EPO application is even of record. For these reasons, we will not assess or further comment upon the obviousness exposition of the dissent.

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(paragraph bridging pages 6 and 7 of specification), I am of the opinion that one of ordinary skill in the art would have found it prima facie obvious to include the recombinant lysozyme of EPO '634 in a synthetic human infant formula. In my view, incorporating recombinant lysozyme in an artificial human infant formula would have been an obvious use of the genetically engineered lysozyme disclosed by EPO '634. I find this particularly so since appellant's specification states at page 6 that "it has even been proposed to employ human lysozyme derived from human milk to enrich synthetic cow milk based formula so that the lysozyme-enriched cow-based infant formula more closely approximates human milk with respect to lysozyme content and activity. . . ." I agree with the examiner that one of ordinary skill in the art would have had a reasonable expectation that recombinant lysozyme is free of human viruses. Indeed, appellant acknowledges at page 6 of his specification that contamination with human virus "is not a reasonable possibility when the human milk proteins, including the so-called host resistance factors, are produced as recombinant human milk proteins or recombinant host resistant factors employing genetic engineering techniques."

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I have reviewed the declaration of Dr. Lars Hanson, but absent therein is any discussion of the obviousness of including the recombinant lysosyme disclosed by EPO '634 in an infant formulation.

As a final point, I am aware that only claims 40 and 45 define the use of recombinant lysosyme. However, notwithstanding appellant's submission at page 3 of the principal brief that the appealed claims are considered to be separately patentable, appellant's brief fails to advance any argument that is reasonably specific to any particular claim on appeal. Accordingly, it is my view that all of the appealed claims stand or fall together with claim 40,<sup>4</sup> and, therefore, I would sustain the examiner's rejection under 35 U.S.C. § 103 which relies upon the acknowledged prior art found in appellant's specification.

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) BOARD OF PATENT

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<sup>4</sup>In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987); Ex parte Schier, 21 USPQ2d 1016, 1018-19 (Bd. Pat. App. & Int. 1991). See also 37 CFR § 1.192(c)(7) and (c)(8).

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EDWARD C. KIMLIN ) APPEALS AND  
Administrative Patent Judge ) INTERFERENCES

BRG/ECK:svt

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