



[54] **INFANT FORMULA COMPOSITIONS AND NUTRITION CONTAINING GENETICALLY ENGINEERED HUMAN MILK PROTEINS**

[76] Inventor: **Gerald E. Gaull**, 2949 Harrison St., Evanston, Ill. 60201

[21] Appl. No.: **07/759,100**

[22] Filed: **Sep. 6, 1991**

**Related U.S. Application Data**

[63] Continuation of application No. 07/247,981, Sep. 22, 1988, abandoned.

[51] **Int. Cl.<sup>7</sup>** ..... **A23C 9/00**

[52] **U.S. Cl.** ..... **426/580**; 426/72; 426/74; 426/801; 530/360; 530/365; 530/387; 435/192; 435/206

[58] **Field of Search** ..... 426/72, 74, 580, 426/801; 530/387, 365, 360; 435/192, 206

[56] **References Cited**

**U.S. PATENT DOCUMENTS**

4,112,123	9/1978	Roberts	426/74
4,216,236	8/1980	Mueller et al.	426/801
4,303,692	12/1981	Gaull	426/580
4,419,369	12/1983	Nichols et al.	426/2
4,497,836	2/1985	Marquadt	426/239
4,519,821	5/1985	Palmiter	435/172.3
4,617,190	10/1986	Montgomery	426/61
4,670,268	6/1987	Mahmoud et al.	426/72
4,670,285	6/1987	Clandinin et al.	426/602
4,753,926	6/1988	Lucas et al.	426/72
4,782,138	11/1988	Rialland et al.	426/543
4,977,137	12/1990	Nichols et al.	426/74
5,795,611	8/1998	Slattery	426/580

**FOREIGN PATENT DOCUMENTS**

8511447	6/1986	European Pat. Off.	.
8830111	2/1988	European Pat. Off.	.
8022390	2/1982	France	.
60-05892	4/1985	Japan	.
8704050	7/1987	WIPO	.
880239	1/1988	WIPO	.
8801648	8/1988	WIPO	.
8810118	12/1988	WIPO	.

**OTHER PUBLICATIONS**

Rhein, Jr. et al. 1987. Freeing Hemophiliacs from the Risk of Aids, *Business Weeks*, McGraw Hill, Inc. p. 38.

Lindblad et al. 1984. Human Milk Banking, Vevey/Raven Press, N.Y. pp. 159-169.

Raiha, N.C.R. 1985. "Nutritional Proteins in Milk and the Protein Requirement of Normal Infants" in *Pediatrics* pp. 136-141.

Friend, B.A. 1983. "Newer Advances in Human Milk Substitutes for Infant Feeding" *J. of Applied Nutrition*, vol. 35, No. 2, pp. 88-115.

Haneberg et al. "Lyzomes in Feces from Infants and Children" *Acta Paediatr Scand.* 63:588-594 (1974).

"Aids Risk in Breast Milk", *New York Times*, Jun. 14, 1988.

Mortimer, Letter to the *Lancet*, Aug. 20, 1988, p. 452.

Tedder, Letter to the *Lancet*, Aug. 20, 1988, p. 453.

Hilpert et al "Bovine Milk Immunoglobulins," in *Acute Diarrhea: Its Nutritional Consequences*, Bellanti, J.A., ed. 1983, pp. 123-128.

Mietens, "Potential Use of Bovine Milk Immunoglobulins" in *Acute Diarrhea: Its Nutritional Consequences* Bellanti, J.A., ed., 1983, pp. 111-121.

Simon, *Nature*, Aug. 87, 328:530-533.

Hall, *Biochemical Journal*, "Organization and sequence of the human alpha-lactalbumin gene", Jan. 1987 (London, England), 242:735-742.

Sharmonov, "Multicomponent Additive for Infant Formula Enriched with Essential and Protective Factors," *Kazakhstan Division of the Institute of Nutrition, Vopr. Pitan* 1986, #3, 59-62.

Palmiter et al, "Transgenic Mice," *Cell*, Jun., 1985, 41:343-345.

Reiter, "The Biological Significance and Exploitation of Some of the Immune Systems in Milk—A Review", *Microbiologie*, 1984, 2:1-20.

Glover, "Principles of Ultrafiltration and the Concentration and Fractionation of Cow's Milk," in *Human Milk Banking*, A.F. Williams, ed., (Raven Press 1984), p. 1-16.

Hilpert, "Preparation of A Milk Immunoglobulin Concentrate from Cow's Milk", in *Human Milk Banking*, A.F. Williams, ed., (Raven Press 1984), p. 17-28.

Reiter, "Role of Nonantibody Proteins in Milk in the Protection of the Newborn," *Human Milk Banking*, A.F. Williams, ed., (Raven Press 1984), p. 29-54.

Hylmo et al, "Preparation of Fat and Protein from Banked Human Milk: Its Use in Feeding Very-Low-Birth-Weight Infants", *Human Milk Banking*, A.F. Williams, ed., (Raven Press 1984), p. 55-62.

(List continued on next page.)

*Primary Examiner*—Helen Pratt

*Attorney, Agent, or Firm*—McDonnell, Boehnen, Hulbert & Berghoff

[57] **ABSTRACT**

Compositions containing human milk proteins, including the so-called host resistance factors of human milk, prepared by chemically synthesizing the human milk proteins or by genetic engineering techniques for producing recombinant human milk proteins, are useful for supplementing or enhancing the diet of infants, particularly very-low-birth-weight infants. The human milk proteins include the host resistance factors (HRF) found in human milk, such as lactoferrin (LF), lactoperoxidase (LP), lysozyme (LZ), immunoglobulin-A (IgA), alpha-lactalbumin, alpha, beta, kappa-caseins, and others. The compositions may also include components other than the human milk proteins useful for improved infant nutrition. In the utilization of the compositions of this invention, the compositions would be administered to an infant in at least an amount that the infant would receive if fed substantially only fresh human milk. Also, the proportions of the human milk proteins would preferably be present in the compositions in about the proportions these proteins are found in human milk.

**8 Claims, No Drawings**