

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#11 (N/E)  
RECEIVED

In re Application of:  
SHMUEL CABILLY ET AL.  
Serial No. 07/205,419  
Filed: 06/10/88  
For: RECOMBINANT IMMUNOGLOBULIN  
PREPARATIONS



) Art Unit: 185  
)  
) SEP 25 1991  
) Examiner-in-Chief:  
) Mike Nisbet BOARD OF PATENT APPEALS  
) AND INTERFERENCES  
)  
)  
) 460 Point San Bruno Boulevard  
) South San Francisco, CA 94080  
) (415) 266-1994  
)

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

The following items are supplied to the United States Patent and Trademark Office to advance the prosecution of the subject application.

This application is a continuation of U.S.S.N. 06/483,457, now issued as US Patent 4,816,567. The '567 patent is directed to the production of chimeric immunoglobulin heavy or light chains. The claims of the '567 patent do not exclude the additional expression of light or heavy chain, respectively, and therefore cover the production of chimeric immunoglobulins. Therefore, in the interests of good order, all of the citations of record in the parent also should be made of record here. These citations are listed in Group I below. Copies of the citations are not supplied since they are available in the file history of the parent. If they should be missing for some reason the undersigned will supply an additional copy upon request.

In addition, this application presently is involved in interference 102,572 with US Patent 4,816,397 to Boss et al. Group II below contains the citations of record from the face of the Boss Patent, copies of which are supplied herewith.

Further citations have come to the attention of the undersigned, in particular from applications related to the Boss and Cabilly Patents. These are

submitted herewith as Groups III and IV.

The Group III items relate to the expression of immunoglobulin mRNA microinjected into Xenopus (frog) oocytes (unfertilized eggs). These are substantially cumulative to Valle et al. (1982) of record in the parent to the instant case, but are cited as of interest and to complete the record. Work of this sort is readily distinguishable from the instant claims in that the oocytes are not transformed with DNA, but instead are used to transiently express mRNA preparations.

For the most part the citations in Group IV are concerned with hybridoma or myeloma cells transformed with DNA encoding either an immunoglobulin light or heavy chain, or relate to the processing or secretion of immunoglobulins from hybridoma and myeloma cells. Thus, they are substantially cumulative to Rice et al. (1982), which is of record in the parent, or are of theoretical interest only. These disclosures are clearly distinguishable from the instant claims in that the cells are not transformed with exogenous DNA encoding both of the heavy and light chains.

#### GROUP I

U.S. Pat. 4,444,878

U.S. Pat. 4,512,922

U.S. Pat. 4,518,584

U.S. Pat. 4,704,362

EPO 0057107

EPO 0073656

EPO 0068763

EPO 0120694

Dolby et al. Proc Natl. Acad. Sci. 77(10):6027-6031 (1980)

Rice et al. Proc. Natl. Acad. Sci. 77:7862-7865 (1982)

Accolla et al. Proc. Natl. Acad. Sci. 77(1):563-566 (1980)

Raso et al. Cancer Res. 41:2073-2078 (1981)

Nisonoff et al. Arch. Biochem. Biophys. 93:460-462 (1960)

Glennie et al. Nature 295:712-714 (1982)

Eisen Immunology Harper & Row, Publishers, pp. 415 and 428-436 (1974)

Hozumi et al. Nuc. Acids. Res. 5(6):1779-1799

Wetzel et al. Gene 16:63-71 (1981)

- Williams et al. Science 215:687-689 (1982)  
Falkner et al. Nature 298:286-288 (1982)  
Boss et al. Gene Expressions-Proc. Cetus-UCLA Symposium pp. 513-522, March 26-  
April 1, 1983  
Amster et al. Nucleic Acid Research 8(9):2055-2065 (1980)  
DeBoer et al., Rodriguez et al. (Ed.) Promoters 462-481 (1982)  
Gough Tibs 6(8):203-205 (August, 1981)  
Morrison J. of Immunology 123(2):793-800 (August, 1979)  
Kohler Proc. Natl. Acad. Sci. 77(4):2197-2199 (April, 1980)  
Roberts Promoters 452-461 (1982)  
Kemp et al. Proc. Natl. Acad. Sci. 78(7):4520-4524 (July, 1981)  
Valle et al. Nature 300:71-74 (November 4, 1982)  
Microbiology 3rd edition, Harper Int. Ed. 338-379 (1980)  
Hitzeman et al. Science 219:620-625 (1983)  
Mercereau-Puijalon et al. Expression of Eukaryotic Viral and Cellular Genes  
Pettersson et al. (Ed.) 295-303 (1981) Academic Pr.  
Keshet et al. Nucleic Acids Res. 9(1):19-30 (1981)  
Taniguchi et al. Proc. Natl. Acad. Sci. 77(9):5230-5233 (1980)  
Ohsuye et al. Nucleic Acids Res. 11(5):1283-1295 (1983)  
Kadonaga et al. J. Biol. Chem. 259(4):2149-2154 (1984)  
Maniatis Molecular Cloning p.433 (September, 1985)  
Fujisawa et al. Nucleic Acids Res. 11(11):3581-3591 (1983)  
Roberts Promoters Structures and Function Rodriguez, R. L. (Ed.) 452-461 (1982)

## GROUP II

- U.S. Pat. 4,403,036  
U.S. Pat. 4,642,334  
EPO 0037723  
EPO 041313  
EPO 041767  
EPO 055945  
EPO 075444  
EPO 088994  
EPO 0125023  
Adams et al. Biochemistry 19:2711-2719 (1980)

- Haley et al. DNA 1:155-162 (1982)  
Gough et al. Biochemistry 19:2702-2710 (1980)  
Iserentant et al. Gene 9:1-12 (1980)  
Seidman et al. Nature 271:582-585 (1978)

## GROUP III

- Stevens et al. J. Mol. Biol. 78:517-525 (1973)  
Deacon et al. Biochem. Soc. Trans. 4:818-820 (1976)  
Colman et al. Cell 17:517-526 (1979)  
Valle et al. Nature 291:338-340 (1981)  
Colman et al. J. Mol. Biol. 160:459-474 (September, 1982)

## Group IV

- Cowan et al. J. Mol. Biol. 90:691-701 (1974)  
Morrison et al. J. Immunol. 114:655-659 (1975)  
Mosmann et al. J. Immunol. 115:955-962 (1975)  
Levy et al. Proc. Nat. Acad. Sci. 75:2411-2415 (1978)  
Robertson et al. Nature 287:390-392 (1980)  
Mosmann et al. Cell 20:283-292 (1980)  
Wilde et al. Eur. J. Immunol. 10:462-467 (1980)  
Ochi et al. Nature 302:340-342 (March 24, 1983)  
Kemp et al. in Nagley et al., Ed., Manipulation and Expression of Genes in Eukaryotes Proceedings of an International Conference, 12th International Congress of Biochemistry, in Australia 9-13 August, 1982 (1983)  
Picard et al. Proc. Nat. Acad. Sci. 80:417-421 (January, 1983)  
Oi et al. Proc. Nat. Acad. Sci. 80:825-829 (February, 1983)  
Hawley et al. Proc. Nat. Acad. Sci. 79:7425-7429 (December, 1982)  
Boss et al. Immunology Today 6(1):12-13 (1985)  
Lewin, Ed. Genes 3rd Edition, 359-360 (1987)  
Skerra et al. Science 240:1038-1040 (1988)  
Kohler et al. Eur. J. Immunol. 6:292-295 (1976)

One copy of each item cited above in Groups II-IV is supplied, along with a completed Form PTO-1449. The Examiner is requested to make the citations of record.

This submission is understood to complement the results of the Examiner's own independent search. The submission of this Disclosure Statement should not be construed as a representation that a search was made, that the cited items are inclusive of all the relevant and material citations that may be available publicly, or that designation of membership in a Group means that all disclosure relates exclusively to that Group.

The citation of any item is not an admission that the item is prior art. The right is reserved to antedate any item in adherence with standard procedures.

Respectfully submitted,  
GENENTECH, INC.

*Max D. Hensley*  
Max D. Hensley  
Reg. No. 27, 043

Dated: September 18, 1991

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C., 20231 on 9/18/91

(Date of Deposit)

MARILYN BATAGLIA  
Name of Depositing Party

*Marilyn Battaglia*  
Signature of Depositing Party

9/18/91  
Date of Signature