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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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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 2 5 1991

Examiner-in-Chief: Mike Nisbet BC

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

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submitted herewith as Groups III and IV.

The Group III items relate to the expression of immunoglobulin mRNA microinjected into <u>Xenopus</u> (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 <u>both</u> 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. <u>Nature</u> 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)

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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. <u>Nature</u> 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. <u>Nucleic Acids Res.</u> 11(11):3581-3591 (1983) Roberts Promoters Structures and Function Rodriguez, R. L. (Ed.) 452-461 (1982)

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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. <u>Biochemistry</u> 19:2711-2719 (1980)

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

## GROUP III

Stevens et al. <u>J. Mol. Biol.</u> 78:517-525 (1973)
Deacon et al. <u>Biochem. Soc. Trans.</u> 4:818-820 (1976)
Colman et al. <u>Cell</u> 17:517-526 (1979)
Valle et al. <u>Nature</u> 291:338-340 (1981)
Colman et al. <u>J. Mol. Biol.</u> 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. <u>Nature</u> 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.

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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 Reg. No. 27, 043

Dated: September 18, 1991

hereby certify that this correspondence is being sposited with the United States Postal Service as wat class mail in an envelope addressed to: Comissioner of Patents and Trademarks, Washington, 9/18/91 J.C., 20231 on -(Date of Deposit) 4 ARILYN SATIAGL Signature

Date of Signature