PATENT DOCKET 100/150C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
)
SHMUEL CABILLY ET AL.)
) Art Unit: 183
Serial No. 07/205,419)
) Examiner: J. HULEATT
Filed: 06/10/88)
)
For: RECOMBINANT)
IMMUNOGLOBULIN)
PREPARATIONS)

SUPPLEMENTARY PRELIMINARY AMENDMENT
AND REQUEST FOR INTERFERENCE

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

Sir:

Amendment

Please further amend this application by cancelling claims 53-67 and adding the following new claims:

--67. A process for producing an Ig molecule or an immunologically functional Ig fragment comprising at least the variable domains of the Ig heavy and light chains, in a single host cell, comprising the steps of:

(i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the Ig heavy chain and a second DNA sequence encoding at least the variable domain of the Ig light chain, and

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(ii) independently expressing said first DNA sequence and said second DNA sequence so that said Ig heavy and light chains are produced as separate molecules in said transformed single host cell.--

--68. The process according to claim 67 wherein said first and second DNA sequences are present in different vectors.--

--69. The process according to claim 67 wherein said first and second DNA sequences are present in a single vector.--

--70. A process according to claim 68 wherein the vector is a plasmid.--

--71. A process according to claim 70 wherein the plasmid is pBR322.--

--72. A process according to claim 67 wherein the host cell is a bacterium or yeast.--

--73. A process according to claim 72 wherein the host cell is *E. coli* or *S. cerevisiae*.--

--74. A process according to claim 73 wherein the host cell is *E. coli* strain X1776.--

--75. A process according to claim 67 wherein the Ig heavy and light chains are expressed in the host cell and secreted therefrom as an immunologically functional Ig molecule or Ig fragment.--

--76. A process according to claim 67 wherein the Ig heavy and light chains are produced in insoluble form and are solubilized and

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allowed to refold in solution to form an immunologically functional Ig molecule or Ig fragment.--

--77. A process according to claim 67 wherein the DNA sequences code for the complete Ig heavy and light chains.--

--78. A process according to claim 67 wherein said first or said second DNA sequence further encodes at least one constant domain, wherein the constant domain is derived from the same source as the variable domain to which it is attached.--

--79. A process according to claim 67 wherein said first or said second DNA sequence further encodes at least one constant domain, wherein the constant domain is derived from a species or class different from that from which the variable domain to which it is attached is derived.--

--80. A process according to claim 67 wherein said first and second DNA sequences are derived from one or more monoclonal antibody producing hybridomas.--

--81. A vector comprising a first DNA sequence encoding at least a variable domain of an Ig heavy chain and a second DNA sequence encoding at least a variable domain of an Ig light chain wherein said first DNA sequence and said second DNA sequence are located in said vector at different insertion sites.--

--82. A vector according to claim 81 which is a plasmid.--

--83. A host cell transformed with a vector according to claim 81.--

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--84. A transformed host cell comprising at least two vectors, at least one of said vectors comprising a DNA sequence encoding at least a variable domain of an Ig heavy chain and at least another one of said vectors comprising a DNA sequence encoding at least the variable domain of an Ig light chain.--

--85. The process of claim 67 wherein the host cell is a mammalian cell.--

--86. The transformed host cell of claim 84 wherein the host cell is a mammalian cell.--

Specification Basis

Main claim 67 is based at least on section E.1.9 of the instant specification and the disclosure noted below:

Claim 67	Specification page/line
"A process for producing an Ig molecule	pages 8-9
or an immunologically functional Ig comprising at least the variable domains of the Ig heavy and light chains,	page 13, lines 24-28; page 14, lines 1-12; page 30, lines 10-15; page 43, lines 27-31

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in a single host, comprising the steps of	page 23, lines 5-8 and lines 28-34; page 22, lines 30-34; page 43, line 27 *et seq.*; original claims 43 and 50.
(i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the Ig heavy chain and a second DNA sequence encoding at least the variable domain of Ig light chain, and	page 22, lines 29-34; 23/8; page 23, lines 5 and 8; page 6, line 6; page 43, line 28 *et seq.*; original claims 43 and 50.
(ii) independently expressing said first DNA sequence and said second DNA sequence so that said Ig heavy and light chains are produced as separate molecules in said transformed single host cell.	page 22, lines 30-34; page 23, lines 10-12 and lines 28 34; page 44, lines 5-19; and page 45, line 34.

The basis for the remaining new claims is at least as follows:

Claim	Specification page/line
68	page 22, lines 32-33; section E.1.9

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