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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,542	05/13/2005	6331415	10244P0010US	7585

7590 09/13/2005

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action in Ex Parte Reexamination	Control No. 90/007,542	Patent Under Reexamination 6331415	
	Examiner David J. Blanchard	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☒ Responsive to the communication(s) filed on *13 May 2005* . b☐ This action is made FINAL.
c☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO-1449.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-36* are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☐ Claims _____ are patentable and/or confirmed.
4. ☒ Claims *1-36* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

DETAILED ACTION

1. Claims 1-36 are pending and are considered in this re-examination.

2. The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 6,331,415 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of US

Patent No. 4,816,567 in view of Axel et al (US Patent 4,399,216, issued 8/16/1983, Ids filed 5/13/05) and Rice et al (Proc. Natl. Acad. Sci. USA 79:7862-7865, December 1982, Ids filed 5/13/05) and Kaplan et al (EP 0 044 722, published 1/27/1982, Ids filed 5/13/05) and Accolla et al (Proc. Natl. Acad. Sci. USA 77(1):563-566, January 1980, Ids filed 5/13/05) and Builder et al (US Patent 4,511,502, issued 4/16/85).

The instant claims (US Patent 6,331,415 B1; the '415 patent) are drawn to recombinant processes, vectors and host cells for producing immunoglobulins comprising transforming a single host cell with a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain and a second DNA sequence encoding at least a the variable domain of the immunoglobulin light chain and independently expressing said first and second DNA sequences so that immunoglobulin heavy and light chains are so produced as separate molecules in the transformed host cells wherein the DNA sequences can be present in different vectors or in a single vector that is the plasmid pBR322 and the host cell can be *E. coli* strain X1776 or S. *cerevisiae* and wherein the immunoglobulin heavy and light chains are expressed in the host cells and secreted therefrom as a functional immunoglobulin or is produced in insoluble form and subsequently solubilized and refolded in solution to form a functional immunoglobulin. Further, the claimed method for producing an immunoglobulin wherein the first and second DNA sequences further encode at least one constant domain derived form the same source or derived from a species or class different from that which the variable domains are derived and wherein the

variable domains are derived from one or more hybridomas. The claims are also drawn to vectors comprising said first and second DNA sequences encoding at least the heavy and light chain immunoglobulin variable domains and host cells, including mammalian host cells transformed with said first and second DNA sequences as well as insoluble particles of heavy and light chains or Fab region produced in *E.coli* or yeast cells (i.e., inclusion bodies). Additionally, the claims recite wherein the heavy and light chains are the heavy and light chains of an anti-CEA antibody and wherein the heavy chain is of the gamma family and the light chain is of the kappa family and wherein the method further comprises attaching the immunoglobulin to a label or drug.

Claims 1-7 of US Patent 4,816,567 (the '567 patent) are also drawn to recombinant processes, vectors and host cells for producing immunoglobulins, comprising preparing a DNA sequence encoding a chimeric immunoglobulin heavy or light chain having specificity for a particular known antigen wherein a constant region is homologous to the corresponding constant region of an antibody of a first mammalian species and a variable region is derived from a second different mammalian species, inserting the sequence into a replicable expression vector operably linked to a suitable promoter compatible with a host cell, transforming the host cell with said vector, culturing the host cell and recovering the chimeric heavy or light chain from the host cell culture, wherein the first mammalian species is human. Further, the claims are drawn to a composition comprising said chimeric immunoglobulin heavy or light chain having specificity for a particular known antigen as well as a replicable vector comprising

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