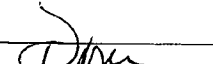|	Control No.	Patent Under Reexamination
Notice of Intent to Issue *Ex Parte Reexamination Certificate*	90/007,859 & 90/007542	6331415
	Examiner	Art Unit	
	Padmashri Ponnaluri	3991	

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

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   (a) ☒ Patent owner's communication(s) filed: *2/12/09, 2/13/09*.
   (b) ☐ Patent owner's late response filed: _____.
   (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.
   (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   (e) ☐ Other: _____.

   Status of *Ex Parte* Reexamination:
   (f) Change in the Specification: ☐ Yes ☒ No
   (g) Change in the Drawing(s): ☐ Yes ☒ No
   (h) Status of the Claim(s):
      (1) Patent claim(s) confirmed: *1-20 and 33-36*.
      (2) Patent claim(s) amended (including dependent on amended claim(s)): *21-32*
      (3) Patent claim(s) cancelled: _____.
      (4) Newly presented claim(s) patentable: _____.
      (5) Newly presented cancelled claims: _____.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).

4. ☒ Note attached LIST OF REFERENCES CITED (PTO/SB/08). *11 pgs!*

5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.

6. ☐ 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
      ☐ been received.
      ☐ not been received.
      ☐ been filed in Application No. _____.
      ☐ been filed in reexamination Control No. _____.
      ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.

7. ☐ Note attached Examiner's Amendment.

8. ☒ Note attached Interview Summary (PTO-474).

9. ☐ Other: _____.

PADMASHRI PONNALURI PRIMARY EXAMINER	EVELYN M. HUANG PRIMARY EXAMINER CRU - AU 3991	DEBORAH D. JONES CRU SPE-AU 3991

cc: Requester (If third party requester)

Reexamination

Procedural Posture

This is the merged *Ex parte* reexamination proceedings of 90/007,542 and 90/007,859.

This is merged reexamination of US Patent 6,331,415 (Cabilly II), issued on December 18, 2001.

Decision merging reexamination proceedings 90/007,542 and 90/007,859 was mailed on 6/6/06.

A First Office Action in this merged proceedings was mailed on 8/16/06.

Patent Owner filed a response on 10/30/06.

Final Rejection was mailed on 2/16/07.

A Request for Continued Reexamination was filed on 5/21/07. The Request for

Continued Reexamination was granted on 6/10/07.

Final Rejection was mailed on 2/25/08.

After Final response was mailed on 6/6/08.

Advisory action was mailed on 7/19/08.

Notice of Appeal was filed on 8/22/08.

Appeal Brief was filed on 12/9/08.

A supplemental response and amendment are filed on 2/12/09. The amendment to claim

21 does not comply with Rule 1.530. A second supplemental amendment is filed on 2/13/09.

Amendment

Claims 21, 27 and 32 are amended by the amendment filed on 2/13/09.

Information Disclosure Statement

The Information disclosure statements (PTO/SB/08) filed on 2/11/09 and 6/6/08 have

been considered. The documents L11 to L30 related to the litigation (cited in the 6/6/08 IDs) are

considered, however a line is drawn through the citations because these documents are not

appropriate for printing on the face of the reexamination certificate.

The Cabilly 6,331,415 Invention (Cabilly II Patent)

The invention is drawn to a method for producing an immunologically functional

immunoglobulin molecule or an immunologically functional immunoglobulin fragment by

transforming a single host cell with a first DNA sequence encoding immunoglobulin heavy chain

and a second DNA sequence encoding immunoglobulin light chain and independently expressing

the first DNA sequence and second DNA sequence so that said immunoglobulin heavy chain and

light chain are produced as separate molecules in said transformed single host cell.

Claims 1, 21 and 33 are representative of the invention.

Based on the prosecution history of the patent at issue, and the interference record from

Interference No. 102,572, the term "immunoglobulin molecule" in claims 1 and 33 is considered

to be immunologically functional molecule and capable of binding to a known antigen.

Withdrawn Rejections

The obviousness-type double patenting rejection of claims 1-36 of U.S. Pat. No.

6,331,415 (Cabilly 2) over claims 1-7 of U.S. Patent No. 4,816,567 (Cabilly 1) in view of Axel et

al. U.S. Pat. No. 4,399,216 (8/83), Rice and Baltimore, PNAS USA 79 (12/82):7862-7865,

Kaplan et al. EP 0044722 (1/82), Builder et al U.S. Pat. No. 4,511,502 (issued 4/85), Accolla et

al PNAS USA 77(1): 563,566 (1980), Dallas (WO 82/03088), Deacon (Biochemical. Society

Transactions, 4 (1976):818-820), 1981 Valle (Nature, 291 (May '81) pages 338-340; Ochi

(Nature, 302(3/24/83) pages 340-342 alone, or further in view of Moore et al. U.S. Pat. No.

5,840,545 (Nov. 24, 1998: effectively filed March 15, 1982) is withdrawn upon reconsideration

and in view of Patent Owner's response and Declarations presented in this reexamination

proceedings.

Cabilly I Patent (the `567 patent) claims are drawn to a method for preparing chimeric

immunoglobulin heavy chain or immunoglobulin light chain molecules separately from

transformed host cells. The host cell in the Cabilly I patent claims is transformed with either

immunoglobulin heavy chain or immunoglobulin light chain. Cabilly I patent claims do not

recite a single host cell transformed with DNA sequences encoding both immunoglobulin heavy

chain and immunoglobulin light chain independently as required in the present Cabilly II claims.

Axel et al taught a process for inserting foreign DNA into eukaryotic cell by

cotransformation with the disclosed foreign DNA I and DNA II that encodes a selectable marker.

Axel et al did not teach a single host cell transformed with immunoglobulin heavy chain and

immunoglobulin light chain independently. Axel et al did not teach co-expression of two foreign

DNA sequences (see Harris declaration, McKnight declaration, Botchan declaration, Rice

declaration, and Colman declaration).

Rice exogenously introduced a recombinant murine kappa light chain gene into a mutant

lymphoid cell line (81A-2 cell line) that contains heavy chain (endogenous). Rice taught the co-

expression of immunoglobulin heavy and light chain in the mutant cells. However, Rice did not

teach that a single host cell is transformed with both immunoglobulin heavy chain and light

chain (see Rice Declarations, Colman declaration, Harris declaration, Botchan declaration, and

McKnight declaration). Rice taught the successful expression of immunoglobulin light chain

genes is linked to the ongoing ability of the cell to express its endogenous heavy chain gene (see

Harris declaration, and Rice declaration).

Kaplan taught a method for producing an immunoglobulin multimer, wherein the

individual immunoglobulin heavy chain and light chain are produced in separate cell culture.

Kaplan did not teach producing immunoglobulin heavy chain and light chain in a single host cell

(see Harris declaration, McKnight declaration, Botchan declaration, Colman declaration, and

Rice declaration).

Dallas taught a method of making an E.coli vaccine by inserting into one E.coli cell

genes obtained from another strain of E.coli. Dallas did not teach a method for producing

multiple eukaryotic proteins from a single host cell (see Harris declaration, McKnight

declaration, Rice declaration, and Botchan declaration).

Moore patent disclosed a method for producing "rFv" binding molecule comprising

variable regions of immunoglobulin heavy chain and light chain. Moore patent taught producing

immunoglobulin heavy chain and light chain in separate host cells. Moore patent taught the

immunoglobulin heavy chain and light chain are inserted into two separate single-marker pGM1

based plasmids, resulting in pGM1H and pGM1L. Since both pGM1H and pGM1L plasmids

contain the same selectable marker, two separate host cell cultures are transformed with each

plasmid (see Scott declaration, McKnight declaration, Altman declaration). Thus, the Moore

patent taught producing immunoglobulin heavy chain and light chain in separate host cells.

DOCKET ALARM

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