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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,859	12/23/2005	6331415	22338-10231	6447

47554 7590 02/23/2009

SIDLEY AUSTIN LLP
ATTN: DC PATENT DOCKETING
1501 K STREET, NW
WASHINGTON, DC 20005

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 02/23/2009

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

**Notice of Intent to Issue
Ex Parte Reexamination Certificate**

Control No. 90/007,859 <i>Ex 90/007542</i>	Patent Under Reexamination 6331415	
Examiner Padmashri Ponnaluri	Art Unit 3991	

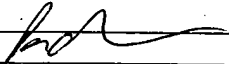
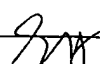

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

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
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cc: Requester (If third party requester)
U.S. Patent and Trademark Office
PTOL-469 (Rev.08-06)

Notice of Intent to Issue Ex Parte Reexamination Certificate

Part of Paper No 20090211

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

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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

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