| Notice of Intent to Issue Ex Parte Reexamination Certificate | Control No. | Patent Under Reexamination | |
|---|---|---|---|
| | 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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.