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Hoffmann-La Roche Inc. Overlook at Great Notch 150 Clove Road 8th Floor, Suite 8 - Legal Department Little Falls, NJ 07424			TURNER, SHARON L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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WASHINGTON, DC 20005

***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/014,063.

PATENT NO. _.

ART UNIT 3991.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Sharon Turner

Primary Examiner

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Ex Parte Reexamination

1. A Request for *Ex Parte* Reexamination of claims 1-7, 9-13, 15-16, 18 and 20 of U.S. Patent No. 8,314,225 ('225) was filed 01/10/2018 by third party requester.

Scope of Reexamination

2. The reexamination proceeding provides a complete reexamination of the patent claims on the basis of prior art patents and printed publications. 37 CFR 1.552, MPEP 2258.

Decision on Reexamination Request

3. A substantial new question of patentability (SNQ) affecting claims 1-20 of the '225 patent is raised by the request for reexamination.

Substantial New Question of Patentability

4. The presence or absence of "a substantial new question of patentability" (SNQ) determines whether or not reexamination is ordered.

For a "substantial new question of patentability" to be present, it is only necessary that:

A) the prior art patents and/or printed publications raise a substantial new question of patentability for at least one claim, such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim was patentable. A SNQ may be based on newly cited art or even solely on old art where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in earlier concluded examination(s), in view of a material new argument or interpretation presented in the request. (MPEP 2242).

B) the same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

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The '225 Patent and Claims

5. The '225 patent was filed 12/14/09 as U.S. application 12/664,401 and issued 11/20/12.

The patent is a 371 of PCT/EP2008/005136 filed 6/25/08 and claims the benefit of foreign priority to EPO07012774 filed 6/29/07.

The '225 patent consists of claims 1-20. Claims 1, 13, 15 and 20 are independent as appended below. Claims 2-12, 14 and 16-19 depend directly or indirectly therefrom.

1. A nucleic acid encoding the amino acid sequence of the C-terminal part of the CH3-domain of an immunoglobulin of the class IgA or IgG, or the amino acid sequence of the C-terminal part of the CH4-domain of an immunoglobulin of the class IgE or IgM, wherein the glycine-lysine-dipeptide comprised in said amino acid sequence of the C-terminal part of the CH3- or CH4-domain is encoded by one of the following nucleic acid sequences, ggaaca, ggcaac, gggaaa, ggaaag, ggcaag, and gggaag, the nucleic acid ggaaaa, or the nucleic acid ggcaaa.

13. A nucleic acid comprising the nucleotide sequence of SEQ ID NO: 17, 18, 19, 20, 21, 22, 23, 30, or 31.

15. A method for the production of an immunoglobulin in a mammalian cell comprising the following steps: a) transfecting said mammalian cell with a nucleic acid encoding an immunoglobulin heavy chain, wherein a nucleic acid of SEQ ID NO: 17, 18, 19, 20, 21, 22, 23, 30, or 31 encodes the C-terminal part of the immunoglobulin heavy chain, b) cultivating the transfected mammalian cell under conditions suitable for the expression of the immunoglobulin, c) recovering the immunoglobulin from the culture or the cell.

20. A method for improving the expression of an immunoglobulin in a mammalian cell, comprising the following steps: a) transfecting a mammalian cell with a nucleic acid encoding an immunoglobulin heavy chain, wherein the nucleic acid encoding the immunoglobulin heavy chain comprises the nucleic acid ggaaaa, or the nucleic acid ggcaaa, or the nucleic acid gggaaa, or the nucleic acid ggaaag, or the nucleic acid ggcaag, or the nucleic acid gggaag encoding the glycine-lysine-di peptide contained in the CH3- or CH4-domain of the immunoglobulin heavy chain, b) cultivating the transfected mammalian cell under conditions suitable for the expression of the immunoglobulin, c) recovering the immunoglobulin from the culture or the cell.

Claim Interpretation

6. In making the determination of whether to order reexamination, the Office will determine the proper meaning of the patent claims by giving the claims their broadest reasonable interpretation consistent with the specification (see *In re Yamamoto*, 740 F.2d 1569 (Fed. Cir. 1984)). See MPEP 2240, 2258.

Documents Cited as Raising an SNQ

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PCT Publication No. W02007/068429, entitled "ANTIBODIES AGAINST AMYLOID BETA 4 WITH GLYCOSYLATED IN THE VARIABLE REGION" ("the '429 Publication") June 21, 2007.

U.S. Patent No. 6,800,735, entitled "INTERFERON-BETA FUSION PROTEINS AND USES" ("the '735 patent") October 5, 2004.

U.S. Publication No. 20060204506, entitled "ANTI-MESOTHELIN ANTIBODIES" ("the '506 Publication") September 14, 2006.

U.S. Publication No. 20040063911, entitled "PROTEIN REMODELING METHODS AND PROTEINS/PEPTIDES PRODUCED BY THE METHODS" ("the '911 Publication") April 1, 2004.

U.S. Publication No. 20040038304, entitled "ANTIBODY LIBRARIES" ("the '304 Publication") February 26, 2004.

PCT Publication No. W02002/024909, entitled "NOVEL RECEPTOR NUCLEIC ACIDS AND POLYPEPTIDES" ("the '909 Publication") March 28, 2002.

PCT Publication No. W02004060041, entitled "KIM-I ANTAGONISTS AND USE TO MODULATE IMMUNE SYSTEM" ("the '041 Publication") July 22, 2004.

PCT Publication No. W02004/033651, entitled "ERYTHROPOIETIN: REMODELING AND GLYCOCONJUGATION OF ERYTHROPOIETIN" ("the '651Publication") April 22, 2004.

U.S. Publication No. 20050069552, entitled "FUSION ANTIBODIES" ("the '552 Publication") March 31, 2005.

Lee et al., Biochem. J. (2002) 366:603-611 May 21, 2002 ("Lee").

Discussion of the Documents Cited as Raising an SNQ

7. The request proposes that a substantial new question of patentability as to claims 1-5, 10-12 and 20 is raised by the '429 publication (SNQ1 pp. 11-17) and a SNQ as to claims 6-7, 9, 13, 15-16 and 18 is raised by the '429 publication and Lee (SNQ10 pp. 75-85).

Neither the '429 publication nor Lee were previously cited for rejection or otherwise discussed within the prosecution history.

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The '429 publication teaches the nucleic and amino acid sequence of IgG-Fc antibodies with glycosylation sites in the constant/non-variable region, particularly glycosylated asparagine in the variable region of the heavy chain (p. 3, lines 25-27, p. 4, lines 25-26, p. 39, lines 3-4,). In addition, '429 SEQ ID NO:6 contains within the C-terminal CH3 region a peptide ending in GK corresponding to glycine-lysine-dipeptide ('429 pp. 7-8). The peptide is encoded for example by '429 SEQ ID NO:23 with nucleic acid ggcaaa, optimized for recombinant production (pp. 10-12). Also taught are '429 SEQ ID NO:26 sharing identity with '225 SEQ ID NO:5, and SEQ ID NO:23 which contains a single nucleotide mutation in comparison to '225 SEQ ID NO:20 and 30 but which also encodes a serine. The '429 publication also teaches plasmids/vectors encoding the antibodies as well as such production in mammalian/CHO host cells (pp. 33-34, 54, 64, 66, Fig. 1).

Lee teaches site-specific mutagenesis of a serine residue via overlap extension PCR and the alternative serine coding sequence TCT (Lee p. 604).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such has expired.

Accordingly, the '429 publication either alone or with Lee raises a SNQ as to claims 1-20 of the '225 patent.

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8. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '735 patent (SNQ2 pp. 18-27).

The '735 patent was not previously cited for rejection or otherwise discussed within the prosecution history.

The '735 patent teaches a polypeptide X-Y-Z in which the Z portion contains at least a portion of the constant region of an antibody in which IgM and IgE contain CH4 and IgG, IgA and IgD contain CH3 C-terminal hinge regions (2:34-67). One example is the peptide interferon-beta-1a/Fc fusion containing the constant domain hinge regions and the CH2 and CH3 domains (3:45-53, 13:30-15:7, 33:41-43, Fig. 2, SEQ ID NO:1-2, Example 2). SEQ ID NO:1 includes the sequence cgggaaa, see residues 1191-97. The glycine-lysine dipeptide of SEQ ID NO:2 is located within a CH3 domain and correlates with SEQ ID NO:5 of the '225 patent. The disclosure and examples further describe the nucleic acid within a plasmid vector and expression in mammalian CHO cells (3:7-14, 32:29-36:35, Examples 2-3 and 5).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '735 patent raises a SNQ as to claims 1-20 of the '225 patent.

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9. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '506 publication (SNQ3 pp. 27-34).

The '506 publication was not previously cited for rejection or otherwise discussed within the prosecution history.

The '506 publication teaches anti-mesothelin antibodies which are IgG and may also include IgA, IgE, IgD and IgM (¶13, 58, 69). The heavy chain sequence ends in a glycine-lysine dipeptide and is encoded by the sequence gggaaa (SEQ ID NOs:1-2, ¶79-80) which also correlates to '225 SEQ ID NO:5. The MSAb-1 antibody was developed by cloning the variable domain of a mesothelin Fab fragment to human IgG1 constant region (¶122). Also disclosed are plasmids vectors, mammalian host cells and methods of production (¶91-92).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '506 publication raises a SNQ as to claims 1-20 of the '225 patent.

10. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '911 publication (SNQ4 pp. 34-41).

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The '911 publication was not previously cited for rejection or otherwise discussed within the prosecution history.

The '911 publication teaches TNF receptor-IgG Fc fusion antibodies with heavy chain of an IgG as well as production of in vitro glycosylated peptides (§9, 1225, 1250-53). The antibody is produced with the nucleotide sequence of SEQ ID NO:49 and has the amino acid sequence of SEQ ID NO:50 (Fig 86, ¶1251). The nucleic acid includes the sequence gggaaa and encodes a C-terminal glycine-lysine dipeptide. SEQ ID NO:50 of the '506 publication further correlates with SEQ ID NO:5 of the '225 patent. The '506 publication also teaches plasmid vectors, host cells and expression of the recombinant antibodies for example in CHO cells (§73, 978, 1008-1012, 1059).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '911 publication raises a SNQ as to claims 1-20 of the '225 patent.

11. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '304 publication (SNQ5 pp. 41-47).

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The '304 publication was not previously cited for rejection or otherwise discussed within the prosecution history.

The '304 publication teaches combinatorial antibody libraries including antibodies having a heavy chain IgG (§8). The technology generates libraries via retroviral transfection of host cell to produce antibodies with recombined heavy and light chains (§109, 146, 152, Fig. 1-2). Fig. 5 notes a specific plasmid clone pLBC-L2HCF with sequence of SEQ ID NO:1 containing gggaaa encoding a glycine-lysine dipeptide. Fig. 6 also notes a cline pLBC-M4HCF with sequence of SEQ ID NO:2 also containing the gggaaa sequence encoding a glycine-lysine dipeptide. Further as to the presence of the plasmid vectors in mammalian host cells such as CHO-K1, and methods of producing the antibodies in culture, the '304 publication teaches expression and secretion of the antibodies into the culture medium and recovery (§71, 130-139).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '304 publication raises a SNQ as to claims 1-20 of the '225 patent.

12. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '909 publication (SNQ6 pp. 47-53).

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The '909 publication was not previously cited for rejection or otherwise discussed within the prosecution history.

The '909 publication teaches BAFF-R:Fc fusion antibodies with the Fc portion of an IgG1 immunoglobulin with the nucleic acid sequence of residues 280-960 identified as SEQ ID NO:11 with sequence gggaaa encoding SEQ ID NO:12 with a glycine-lysine dipeptide (p. 1, lines 5-8, p. 4, lines 26-30, Fig. 9, p. 42, lines 23-25, 10-12 sequence listing). SEQ ID NO:12 of the '909 publication also correlates with '225 SEQ ID NO:5. In addition, the '909 publication teaches the sequences in plasmid vectors and methods of producing and recovering the polypeptide antibodies in mammalian cultures (p. 39, lines 12-17, p. 41, lines 27-28, p. 43, lines 11-32, claim 17).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '909 publication raises a SNQ as to claims 1-20 of the '225 patent.

13. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '041 publication (SNQ7 pp. 53-59).

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The '041 publication was not previously cited for rejection or otherwise discussed within the prosecution history.

The '041 publication teaches a KIM-1 antagonist fusion antibody described as having a C-terminal heavy chain of an IgG1 immunoglobulin particularly including either the CH3 of IgA, IgD and IgG or CH4 of IgE and IgM (p. 2, line 9-p. 3, line 10, p. 14, line 15-p. 16, line 11). The nucleotide sequence of the KIM-1Fc with human IgG1 is disclosed as having the gggaaa sequence encoding a glycine-lysine dipeptide (Example 4, pp. 33-34). In addition, the sequence in Example 4 correlates to SEQ ID NO:5 of the '225 patent. Also taught are plasmid vectors encoding the antibodies and methods of production and recovery from mammalian host cells (pp. 14, lines 13-p. 15, line 8, pp. 23-27, 33-34).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '041 publication raises a SNQ as to claims 1-20 of the '225 patent.

14. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '651 publication (SNQ8 pp. 59-64).

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The '651 publication was not previously cited for rejection or otherwise discussed within the prosecution history. It is noted that the '651 publication is related to and shares priority lineage with the '911 publication discussed above.

The '651 publication also teaches a TNF receptor-IgG Fc fusion antibody having an Fc sequence of IgG with nucleic acid sequence of SEQ ID NO:49 including gggaaa and encoding a glycine-lysine dipeptide of SEQ ID NO:50 (p. 42, lines 23-25, p. 324, lines 14-20, p. 340, line 20-p. 341, line 5-6, Fig 86, sequence listing pp. 50-52). In addition, SEQ ID NO:50 starting at amino acid 214 correlates with SEQ ID NO:5 of the '225 patent. The teachings also include expression and recovery of the polypeptide antibodies via plasmid vectors, mammalian including CHO host cells and recombinant expression in culture (p. 169, line 29, p. 267, lines 4-13, p. 276, line 8-p. 277, line 7).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '651 publication raises a SNQ as to claims 1-20 of the '225 patent.

15. The request proposes that a substantial new question of patentability as to claims 1, 2, 5, 10-12 and 20 is raised by the '552 publication (SNQ9 pp. 65-75).

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The '552 publication was not previously cited for rejection or otherwise discussed within the prosecution history.

The '552 publication teaches fusion antibodies made via modification of the nucleotide sequence so as to remove unwanted splice junctions (¶164-165, Example 2, Fig. 7, SEQ ID NO:12). The sequence is modified via an oligonucleotide primer SEQ ID NO:18 which introduces the sequence gggaaa into the plasmid, and the plasmid vectors were introduced into mammalian CHO cells for production of the antibody heavy and light chain genes (¶164-165, Example 2, Fig. 7).

The above newly cited teachings are relevant to claims 1-20 of the '225 patent, and a reasonable examiner would consider these teachings relevant in the prosecution of these claims. The citations above are new technical teachings which were not previously considered or discussed within the prosecution history of the '225 patent. In addition, the same question of patentability as to the claims has not been decided by the Office in a previous examination or pending reexamination of the patent, or in a final holding of invalidity by the Federal Courts, after appeals, or time for such have expired.

Accordingly, the '552 publication raises a SNQ as to claims 1-20 of the '225 patent.

Amendment in Reexamination Proceedings

16. Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

Extension of Time

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17. Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to “an applicant” and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that ex parte reexamination proceedings “will be conducted with special dispatch” (37 CFR 1.550(a)). Extensions of time in ex parte reexamination proceedings are provided for in 37 CFR 1.550(c).

Duty to Disclose

18. 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. 8,314,225 throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Waiver of Right to file Patent Owner Statement

19. In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The document needs to contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester, see 37 C.F.R 1.550(f).

Future Correspondence

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Turner whose telephone number is 571-272-0894. The examiner can normally be reached on Monday through Thursday from 7:00 a.m. to 5:00 p.m. If the attempts to reach the examiner are unsuccessful, the examiner’s supervisor, Jean Witz can be

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reached by dialing 571-272-0927. The official fax number for the organization where this application is assigned is 571-273-9900.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By EFS web: <https://efs.uspto.gov/efile/myportal/efs-registered>

By U.S. Postal Service Mail to:

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

/Sharon Turner/
Patent Reexamination Specialist
Central Reexamination Unit 3991

Conferees:
/Bruce Campell/
Patent Reexamination Specialist
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/Stephen J. Stein/
Supervisory Patent Reexamination Specialist
Central Reexamination Unit 3991

Order Granting Request For Ex Parte Reexamination	Control No. 90/014,063	Patent Under Reexamination 8314225
	Examiner Sharon Turner	Art Unit 3991

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

The request for *ex parte* reexamination filed 10 January 2018 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) PTO-892, b) PTO/SB/08, c) Other: _____

1. The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

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cc:Requester (if third party requester)