UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/635,580	04/15/2024	Dinesh CHIKKANNA	USPF10166756/WO-US-2	1076

12271 7590 01/28/2026

Dennemeyer & Associates, LLC
230 W. Monroe St.
Suite 2100
Chicago, IL 60606

EXAMINER	
DIAMOND, ALAN D	

ART UNIT	PAPER NUMBER
3991	

NOTIFICATION DATE	DELIVERY MODE
01/28/2026	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dgurfinkel@dennemeyer-law.com
docket@dennemeyer-law.com

Office Action Summary	Application No. 18/635,580	Applicant(s) CHIKKANNA et al.	
	Examiner ALAN D DIAMOND	Art Unit 3991	AIA (First Inventor to File) Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance 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.

Disposition of Claims*

5) ☑ Claim(s) 1-24 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-24 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Reissue Applications

For reissue applications filed on or after September 16, 2012, all references to 35 U.S.C. 251 and 37 CFR 1.172, 1.175, and 3.73 are to the current provisions. This application, filed April 15, 2024, is a reissue of U.S. Patent 11,542,275 (hereafter the '275 patent), which issued from U.S. application Serial No. 18/635,580 (the '580 application) with claims 1-19 on January 3, 2023.

Priority

The domestic benefit information in the Application Data Sheet (ADS) filed with the application on 04/15/2024 does not state that the current application is a reissue of the '275 patent, and that the '275 patent is a 371 of PCT/IB2019/052249. The domestic benefit information in said ADS is reproduced below:

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

In accordance with MPEP 211.04, Applicant should file a petition under 37 CFR 1.78 for unintentionally delayed priority claim. The petition must be accompanied by a corrected ADS in compliance with 37 CFR 1.76(c) (for applications filed on or after September 16, 2012)." The petition must also be accompanied by a petition fee under 37 CFR 1.17(m) and a statement that the entire delay between the date the benefit claim was due under 37 CFR 1.78 and the date the claim was filed was unintentional.

While the Director may require additional information whenever there is a question of whether the delay was unintentional, a person filing a petition to accept a delayed benefit claim more than two years after the date the benefit claim was due is **required** to provide additional explanation, i.e., in the petition, of the circumstances surrounding the delay that establishes that the entire delay was unintentional. This requirement is in addition to the requirement to provide a statement that the entire delay was unintentional in 37 CFR 1.78(c)(3) and (e)(3). See Clarification of the Practice for Requiring Additional Information in Petitions Filed in Patent Applications and Patents Based on Unintentional Delay, 85 FR 12222-24 (March 2, 2020). See also MPEP § 711.03(c) for further discussion of the "unintentional" delay standard.

Furthermore, though Indian application No. 201841010656 filed 03/22/2018 is listed in said ADS in the Foreign Priority Information section, foreign priority cannot be granted due to the lack of claiming domestic priority to the '275 patent and to PCT/IB2019/052249.

If foreign priority is desired, Applicant should **also** file a petition under 37 CFR 1.55 to restore the right of priority of the Indian application. A petition to restore the right of priority must include: (1) the priority claim under 35 U.S.C. 119(a)-(d) or (f), 365(a) or

(b), or 386(a) in an application data sheet, identifying the foreign application to which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing (unless previously submitted); (2) the petition fee set forth in 37 CFR 1.17(m); and (3) a statement that the delay in filing the subsequent application within the twelve-month period was unintentional. As with the unintentionally delayed domestic benefit claim, a person filing a petition to accept a delayed foreign priority claim more than two years after the date the foreign priority claim was due is **required** to provide additional explanation, i.e., in the petition, of the circumstances surrounding the delay that establishes that the entire delay was unintentional. This requirement is in addition to the requirement to provide a statement that the entire delay was unintentional in 37 CFR 1.55(e). See MPEP 214.02 and 214.03.

Consent of Assignee

This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

The Consent of Assignee filed 04/15/2024 is defective because it does not state the assignee's name in the box that states: "The assignee(s) owning an undivided interest in said original patent is/are_____and the assignee(s) consent to the accompanying application for reissue." Also, the Consent of Assignee is defective because it states "12/14/2022" as the '275 patent issue date rather than 01/03/2023.

A proper Consent of the Assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

Reissue Declaration

The reissue declaration filed 04/15/2024 is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The reissue declaration is defective because the error statement in the declaration does not identify a claim in the '275 patent to be broadened and does not identify a single word, phrase, or expression in said claim, and how it renders the original patent wholly or partly inoperative or invalid. See MPEP 1414.II. A new reissue declaration having a proper error statement is required.

An example of a suitable error statement is as follows:

> Claim 1 is to be broadened. Claim 1 is unduly narrow since it is directed to a "compound". New independent claim 20 presented in the instant reissue application is directed to a method of treatment.

1. Claims 1-24 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the reissue declaration is set forth in the discussion above in this Office action.

Non-Compliant Amendment

The amendment to the claims filed 04/15/2024 is improper. The amendment does not comply with 37 CFR 1.173 which sets forth the manner of making amendments in reissue applications. While the improper amendment has been entered

and considered, a supplemental paper correctly amending the reissue application is required with Applicant's next response. An amendment filed after final rejection that fails to comply with 37 CFR 1.173 will not be entered.

All amendment changes must be made relative to the patent to be reissued, not relative to a previous submitted amendment. Pursuant to 37 CFR 1.173(d), any such changes which are made to the specification, including the claims, must be shown by employing the following markings: (1) the matter to be omitted by reissue must be enclosed in brackets, i.e., single brackets; and (2) the matter to be added by reissue must be underlined.

The non-compliance issues are as follows:

At line 1 in each of claims 4-10, the term "claim 1" has been changed to "claim1" without using appropriate markings. The term should be "claim 1" as in issued claims 4-10.

The compound of formula IH in claim 8 and the compound of formula IK in claim 9 are currently underlined. They should not be underlined since they are present in issued claims 8 and 9.

Double Patenting

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. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at

least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *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); *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) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for

reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

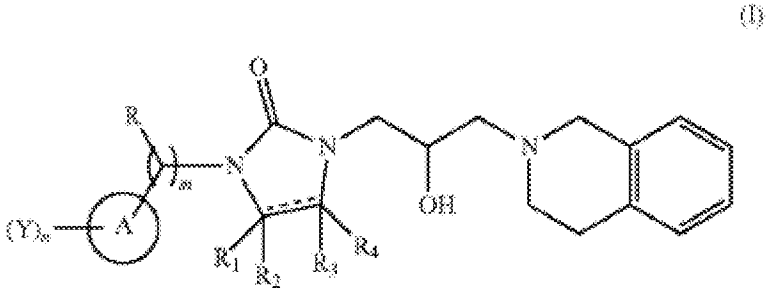
The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

2. Claims 1-3, 5, 6 and 10-24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 11,365,205 (the '205 patent).

Although the claims at issue are not identical, they are not patentably distinct from each other for the following reasons.

With respect to instant claims 1-3, 10-12 and 15-17, claims 10-12 of the '205 patent are pertinent and are reproduced below along with claim 1 from which they are dependent:

1. A compound of formula (I),



(I)

or a pharmaceutically acceptable salt or a stereoisomer thereof; wherein,

====== represents a single bond or double bond;

A is aryl, heteroaryl, cycloalkyl or heterocycloalkyl;

Y is hydrogen, —SO_2R_a, —NR_aR_b, —$C(O)R_a$, —$C(O)NR_aR_b$, —$NHC(O)R_a$, —COOH, cyano, halogen, haloalkyl, alkyl, alkenyl, alkynyl, alkoxy, hydroxyl or oxo; wherein the said alkyl, alkenyl and alkynyl are optionally substituted with 1 to 3 groups selected from hydroxyl, halogen, acyl and heterocycloalkyl;

R is hydrogen, alkyl or halogen;

R_a is hydrogen, alkyl, halogen, alkoxy, heterocycloalkyl or cycloalkyl; wherein the heterocycloalkyl and cycloalkyl are optionally substituted with 1 to 3 groups selected from alkyl, hydroxyl, halogen and acyl;

R_b is hydrogen or alkyl;

R_1 is hydrogen or alkyl; R_2 is hydrogen, alkyl or absent; or R_1 and R_2 together represents an oxo group;

R_3 is hydrogen or alkyl; R_4 is hydrogen, alkyl, aryl or absent; or R_3 and R_4 together with the atoms to which they are attached form 3- to 8-membered cycloalkyl ring;

alternatively, R_1 and R_3 together with the atoms to which they are attached form, an optionally substituted aryl, heteroaryl or cycloalkyl, wherein the optional substituent is selected from 1 to 3 occurrences of R_5;

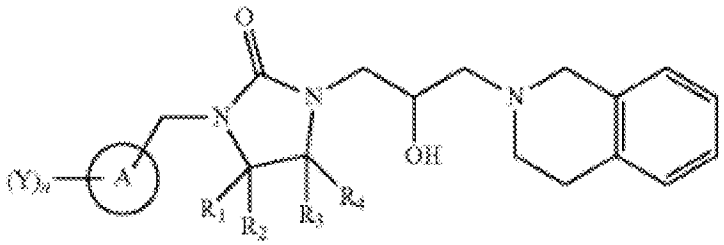
R_5 is alkyl, halogen or cyano;

'n' is 1, 2 or 3;

'm' is 0 or 1.

10. The compound of claim **1**, having compound of formula (IB)

(IB)



or a pharmaceutically acceptable salt or a stereoisomer thereof; wherein, A, Y, R_1, R_2, R_3, R_4 and 'n' are as defined in claim **1**.

11. The compound of claim **10**, wherein R_1, R_2, R_3 and R_4 are hydrogen.

12. The compound of claim **10**, wherein Y is hydrogen, —C(O)R_a, —C(O)NR_aR_b, —COOH, alkyl, alkoxy or cyano.

Claims 10-12 of the '205 patent differ from the instant claims in that, for example, claims 10-12 set forth that "A" in formula (IB) can be "aryl", but do not teach that the aryl is biphenyl.

However, the '205 patent specification defines the term "aryl" as follows (col. 72, lines 8-20, emphasis added):

> As used herein, the term "aryl" is optionally substituted monocyclic, bicyclic or polycyclic aromatic hydrocarbon ring system of about 6 to 14 carbon atoms. Examples of a C_6-C_{14} aryl group include, but are not limited to phenyl, naphthyl, **biphenyl**, anthryl, fluorenyl, indanyl, biphenylenyl and acenaphthyl. Aryl group can be optionally substituted with one or more substituents selected from alkyl, halogen, hydroxyl, carboxylic acid, alkoxycarbonyl, formyl, acyl, thiocarbonyl, thioester, thioacetate, thioformate, alkoxyl, oxo, phosphoryl, a phosphate, phosphonate, phosphinate, amino, amido, amidine, imine, cyano, nitro, azido, sulfhydryl, alkylthio, sulfate, sulfonate, sulfamoyl, sulfonamido and sulfonyl group.

Accordingly, it would have been obvious to one of ordinary skill in the art to have selected biphenyl for the aryl of "A" in the compound of formula (IB) in claims 10-12 of the '205 patent so as to fully practice the scope of claims 10-12 as the '205 patent specifies that aryl for "A" can be biphenyl.

With respect to instant claims 5, 6, 13, 14 and 18, claims 10-12 of the '205 patent differ from the instant claims in that claims 10-12 set forth that "A" in formula (IB) can be "heteroaryl", but do not teach that the heteroaryl is, for example, bipyridinyl as per instant claims 5 and 14, bipyrazinyl as per instant claim 6, tripyridinyl as per instant claim 13, or, for example, pyrazinyl-pyridyl as per compound 37 in instant claim 18.

However, the '205 patent specification defines the term "heteroaryl" as follows (col. 71, line 39 through col. 72, line 7, emphasis added):

> As used herein, the term "heteroaryl" refers to an aromatic heterocyclic ring system containing 5 to 20 ring atoms, suitably 5 to 10 ring atoms, which may be a single ring (monocyclic) or multiple rings (**bicyclic**, tricyclic or **polycyclic**) fused together or linked covalently. Preferably, "heteroaryl" is a 5- to 6-membered ring. The rings may contain from 1 to 4 heteroatoms selected from N, O and S, wherein the N or S atom is optionally oxidized or the N atom is optionally quarternized. Any suitable ring position of the heteroaryl moiety may be covalently linked to the defined chemical structure.
>
> Examples of heteroaryl include, but are not limited to: furanyl, thienyl, pyrrolyl, pyrazolyl, imidazolyl, oxazolyl, cinnolinyl, isoxazolyl, thiazolyl, isothiazolyl, 1H-tetrazolyl, oxadiazolyl, triazolyl, **pyridyl**, pyrimidinyl, **pyrazinyl**, pyridazinyl, benzoxazolyl, benzisoxazolyl, benzothiazolyl, benzofuranyl, benzothienyl, benzotriazinyl, benzimidazolyl, indolyl, isoindolyl, indazolyl, quinolinyl, isoquinolinyl, quinazolinyl, quinoxalinyl, purinyl, pteridinyl, α-carboline, indolizinyl, benzoisothiazolyl, benzoxazolyl, pyrrolopyridyl, pyrazolopyrimidyl, furopyridinyl, benzothiadiazolyl, benzooxadiazolyl, benzotriazolyl, benzotriadiazolyl and the like. Preferably "heteroaryl" refers to 5- to 6-membered ring selected from the group consisting of furanyl, thienyl, pyrrolyl, pyrazolyl, imidazolyl, oxazolyl, cinnolinyl, isoxazolyl, thiazolyl, isothiazolyl, 1H-tetrazolyl, oxadiazolyl, triazolyl, pyridyl, pyrimidinyl, pyrazinyl and pyridazinyl. More preferably, pyrazolyl, pyridyl, oxazolyl, furanyl or benzimidazolyl. All heteroaryls are optionally substituted by one or more groups selected from alkyl, halogen, hydroxyl, carboxylic acid, alkoxycarbonyl, formyl, acyl, thiocarbonyl, thioester,

thioacetate, thioformate, alkoxyl, oxo, phosphoryl, a phosphate, phosphonate, phosphinate, amino, amido, amidine, imine, cyano, nitro, azido, sulfhydryl, alkylthio, sulfate, sulfonate, sulfamoyl, sulfonamido and sulfonyl group.

Accordingly, it would have been obvious to one of ordinary skill in the art to have selected bipyridinyl, bipyrazinyl, tripyridinyl or pyrazinyl-pyridyl for the heteroaryl of "A" in the compound of formula (IB) in claims 10-12 of the '205 patent so as to fully practice the scope of claims 10-12 as the '205 patent specifies that heteroaryl for "A" can be a bicyclic or polycyclic heteroaryl, e.g., bipyridinyl, bipyrazinyl, tripyridinyl or pyrazinyl-pyridyl.

With respect to the pharmaceutical composition and treatment method in instant claims 19-24, the '205 patent teaches that the compound of formula (IB) in claims 10-12 of the '205 patent has the same utility as the instant compound, i.e., treatment of diseases mediated by PRMT5, in particular the same diseases as here claimed (see Abstract, col. 1, lines 15-20, and col. 67, line 32 through col. 68, line 41).

It would have been obvious to one of ordinary skill in the art to have administered the compound of formula (IB) in claims 10-12 of the '205 patent in a pharmaceutical composition further containing a conventional pharmaceutically acceptable carrier or excipient because the '205 patent specification contemplates the utility of the compound for treatment of diseases mediated by PRMT5, in particular the same diseases as here claimed.

Duty to Disclose

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No.

11,542,275 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation. Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application. These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALAN D DIAMOND whose telephone number is (571)272-1338. The examiner can normally be reached Monday through Thursday 5:30 am to 3:00 pm, and Fridays from 5:30 am to 9:30 am.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Engle can be reached on 571-272-6660. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Signed:

/ALAN D DIAMOND/
Patent Reexamination Specialist
Central Reexamination Unit 3991

Conferees:

/JOSEPH R KOSACK/
Patent Reexamination Specialist
Central Reexamination Unit 3991

/Patricia L Engle/
SPRS, Art Unit 3991