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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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90/008,555 04/30/2007 5922695 8170

25000 7590 07/13/2007

GILEAD SCIENCES INC
333 LAKESIDE DR
FOSTER CITY, CA 94404

EXAMINER

Gary L. Kunz

ART UNIT PAPER NUMBER

3991 IFW

DATE MAILED: 07/13/2007

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



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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

DANIEL B. RAVICHER
PUBLIC PATENT FOUNDATION, INC.
1375 BROADWAY, SUITE 600
NEW YORK, NEW YORK 10018

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/008,555.

PATENT NO. 5922695.

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)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No. 90/008,555	Patent Under Reexamination 5922695	
	Examiner Gary L. Kunz	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 30 April 2007 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.

2. The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within **ONE MONTH** from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) by Treasury check or,
b) by credit to Deposit Account No. _____, or
c) by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

***Ex Parte* Reexamination**

Detailed Action: Granting of Request

Procedural Posture

The Third Party Request of 30 April 2007 for an *ex parte* reexamination of claims 1 - 31 of United States Patent Number 5,922,695 (Arimilli '695) is acknowledged.

Decision

A substantial new question of patentability affecting claims 1 - 31 of United States Patent Number 5,992,695 (Arimilli '695) is raised by this request for reexamination.

Information Disclosure Statement

The information disclosure statement (PTO/SB/08A) filed 23 March 2007 has been considered. An initialed, signed copy of this document is provided with this action.

Ongoing Duty to Disclose

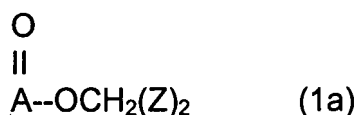
The patent owner is reminded of the continuing responsibility under 37 CFR §1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,922,695 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282, and 2286.

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The Arimilli 5,922,659 Patented Inventions

In the Arimilli '695 patent 31 claims are present and claim 1 is the sole independent claim.

Claim 1. 1A compound having formula (1a)



wherein

Z is independently $\text{---OC(R}^2\text{)}_2\text{OC(O)X(R)}_a$, an ester, an amidate or --H , but at least one Z is $\text{---OC(R}^2\text{)}_2\text{OC(O)X(R)}_a$;

A is the residue of an antiviral phosphonmethoxy nucleotide analog;

X is N or O;

R_2 independently is --H , $\text{C}_1\text{--C}_{12}$ alkyl, $\text{C}_5\text{--C}_{12}$ aryl, $\text{C}_2\text{--C}_{12}$ alkenyl, $\text{C}_2\text{--C}_{12}$ alkynyl, $\text{C}_7\text{--C}_{12}$ alkenylaryl, $\text{C}_7\text{--C}_{12}$ alkynylaryl, or $\text{C}_6\text{--C}_{12}$ alkaryl, any one of which is unsubstituted or is substituted with 1 or 2 halo, cyano, azido, nitro or ---OR^3 in which R^3 is $\text{C}_1\text{--C}_{12}$ alkyl, $\text{C}_2\text{--C}_{12}$ alkenyl, $\text{C}_2\text{--C}_{12}$ alkynyl or $\text{C}_5\text{--C}_{12}$ aryl;

R is independently --H , $\text{C}_1\text{--C}_{12}$ alkyl, $\text{C}_5\text{--C}_{12}$ aryl, $\text{C}_2\text{--C}_{12}$ alkenyl, $\text{C}_2\text{--C}_{12}$ alkynyl, $\text{C}_7\text{--C}_{12}$ alkenylaryl, $\text{C}_7\text{--C}_{12}$ alkynylaryl, or $\text{C}_6\text{--C}_{12}$ alkaryl, any one of which is unsubstituted or is substituted with 1 or 2 halo, cyano, azido, nitro, $\text{--N(R}^4\text{)}_2$ or ---OR^3 , where R^4 independently is --H or $\text{C}_1\text{--C}_8$ alkyl, provided that at least one R is not H; and

a is 1 when X is O, or 1 or 2 when X is N;

with the proviso that when a is 2 and X is N, (a) two N-linked R groups can be taken together to form a carbocycle or oxygen-containing heterocycle, (b) one N-linked R additionally can be ---OR_3 or (c) both N-linked R groups can be --H ;

and the salts, hydrates, tautomers and solvates thereof.

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The other 30 claims depend from claim 1 and are directed to more specific compounds or methods of preparing such compounds, except claim 25, which is directed to a method of orally administering to a patient infected with a virus, a compound of claim 1.

Priority

U.S. Patent Number 5,922,695 issued from application 08/900,746, filed 25 July 1997, claims the benefit under 35 USC 119(e) of provisional application number 60/022,708 filed 26 July 1996.

In order for a patent to gain the benefit of priority under 35 USC §119(e), the provisional application must fully comply with 35 USC §112, first paragraph. This means that the provisional application must provide enablement and adequate written description for all 31 claims of the Arimilli '695 patent. In this instance, the provisional application 60/022,708 fails to provide adequate written description for claims 1 - 31 of the Arimilli '695 patent. (See *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 922 (Fed. Cir. 2004). To satisfy the written description requirement, a specification must describe the claimed invention so that one of ordinary skill in the art at the time of the invention would have recognized what is claimed. In addition, the provisional application must provide sufficient detail in the specification to show one of ordinary skill in the art that the Patent Owner possessed the claimed invention at the time of the filing of the application. The provisional application 60/022,708 fails to provide the necessary written description of the claimed inventions of Arimilli '695 for the following reasons.

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The following table provides a variable by variable comparison of claims 1 & 2 of the Arimilli '695 patent and the '708 provisional application.

VARIABLE	PROVISIONAL '708	'230 PATENT Claim 1
Formula 1a	A(Z) _n	$A-O-CH_2-P(=O)(Z)_2$
A	<p>"A" is the residue of an antiviral phosphonmethoxy nucleotide analog."</p> <p>Therefore "A" represents</p> $\text{Base} - W - O - CH_2 - P(=O) - O$ <p>Where "W" is an unspecified linkage between phosphono-methoxy and the base</p>	<p>"A" is the residue of an antiviral phosphono-methoxy nucleotide analogue."</p> <p>Therefore, "A" represents</p> <p>Base --W --</p> <p>Where "W" is an unspecified linkage between phosphono-methoxy and the base</p>
X	O or N	O or N
R ²	<p>--H, C1-C12 alkyl, aryl, alkenyl, alkynyl, alkyenylaryl, alkynylaryl, alkaryl, arylalkynyl, arylalkenyl or arylalkyl, which is unsubstituted or substituted with halo, azido, nitro, or -OR₃,</p> <p>page 2, lines 4 - 6; page 6, lines 5 - 8; and page 36, lines 12 - 14.</p>	<p>Independently is --H, C1-C12 alkyl, C2-C12 alkenyl, C2-C12 alkynyl, C7-C12 alkenylaryl, C7-C12 alkynylaryl, or C6-C12 alkaryl, any one of which is unsubstituted or substituted with 1 or 2 halo, cyano, azido, nitro, or --OR₃</p>

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R ³	C1-C12 alkyl, C1-C3 alkyl, Page 2, line 6; page 5, line 13; page 6, line 9; page 36, line 14	C1-C12 alkyl, C2-C12 alkyenyl, C2-C12 alkynyl, C5-C12 aryl
R	Independently H, C1-C12 alkyl, aryl, alkenyl, alkynyl, alkyenylaryl, alkynylaryl, alkaryl, arylalkynyl, arylalkenyl or arylalkyl which is unsubstituted or substituted with halo, azido, nitro, or OR ₃ , provided that at least one R is not H; Page 2 lines 7 - 9; page 5, lines 7 - 33; page 36, lines 15 - 17	Independently --H, C1-C12 alkyl, C5 - 12 aryl, C2-C12 alkenyl, C2- C12 alkynyl, C7-C12 alkyenylaryl, C7-C12 alkynylaryl, or C7-C12 alkaryl, any one of which is unsub- stituted or substituted with 1 or 2 halo, cyano , azido, nitro, --N(R₄)₂, --OR₃
R ⁴	R ₄ is not mentioned in the '708 provisional specification	where R₄ is independently --H or C1-C12 alkyl, provided that at least one R is not H;
A	1 or 2	1 or 2
X	O or N	O or N
n	1 or 2	"n" not present
Proviso	With the proviso that then a is 2 and X is N, (a) two R groups can be taken together to form a carbocycle or oxygen-containing heterocycle, or (b) one R additionally can be --OR ₃ page 2, lines 12 - 14; page 36, lines 20 - 22	With the proviso that when a is 2 and X is N, (a) two N-linked R groups can be taken together to form a carbocycle or oxygen- containing heterocycle; (b) one N- linked R additional can be --OR ₃ ; or (c) both N-linked R-groups can be --H.

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VARIABLE	PROVISIONAL '708	'695 PATENT Claim 2
R	--H, C1-C12 alkyl, aryl, alkenyl, alkynyl, alkyenylaryl, alkynylaryl, alkaryl, arylalkynyl, arylalkenyl or arylalkyl, which is unsubstituted or substituted with halo, azido, nitro, or -OR ₃ , page 2, lines 4 - 6; page 6, lines 5 - 8; and page 36, lines 12 - 14.	Independently is --H, C1-C12 alkyl, C2-C12 alkenyl, C2-C12 alkynyl, C7-C12 alkenylaryl, C7-C12 alkynylaryl, or C6-C12 alkaryl, any one of which is unsubstituted or substituted with 1 or 2 halo, cyano, azido, nitro, or --OR₃
R ³	C1-C12 alkyl, C1-C3 alkyl, page 2, line 6; page 5, line 13; page 6, line 9; page 36, line 14	C1-C12 alkyl, C2-C12 alkenyl, C2-C12 alkynyl, C5-C12 aryl.

The Third Party Requester asserts at pages 6 - 7 that claims 1 - 31 of Arimilli '695 should not receive benefit of the filing date of the provisional '708 application because the '708 application does not provide adequate written description for the inventions of claims 1 - 31 since Formula 1a in the provisional and Formula 1a in claim 1 of Arimilli '695 are different. Furthermore, the Third Party Requester points out that the Arimilli '695 patent has added about 26 columns to the specification, from column 6, line 55 to column 32, line 45. Finally, the Third Party Requester argues indicates that the '708 provisional application does not provide written description for the following limitation in claim 1: "and the salts, hydrates, tautomers, and solvates thereof."

Based upon a detail analysis of the specification of the '708 provisional application, the examiner agrees with the Third Party Requester that claims 1 - 25 are not fully supported by the specification of the provision '708 application.

The following parts of claim 1 of the 'Arimilli '695 represent unsupported new matter.

(1) Regarding the definition of variable "Z," there is new matter in the second R^2 attached at the carbon atom. The '708 application only describes Formula 1A wherein there is only a single R^2 attached to this carbon atom. See page 1, last two lines and page 36, lines 7 - 8 of the '708 application. Additionally, the general terms of an "ester" and an "amidate" in the definition of variable "Z" are also new matter.

(2) Regarding the definition of variable R^2 , the specific carbon limits of the alkenyl, alkynyl, alkenylaryl, alkynylaryl, and alkaryl are not described in the '708 application. The '708 application fails to describe cyano as a substitute in R^2 . Finally, the '708 application fails to teach that R^2 can be "--N(R^4)₂". See page 2, lines 4 - 6 and 28 and page 36, lines 12 - 14 of the '708 application.

(3) Regarding the definition of variable R^3 , C2-C12 alkenyl, C2-C12 alkynyl, and C5-C12 aryl represent new matter.

(4) Regarding the definition of variable R^4 , this variable does not even appear in the '708 provisional application.

The following parts of claim 2 of the Arimilli '695 patent represent unsupported new matter.

(1) Regarding the definition of variable "R" in claim 2, the specific carbon ranges

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for alkenyl, alkynyl, alkenylaryl, alkynylaryl, and alkaryl in the definition of "R" is deemed to be new matter because there is a lack of support for this invention in the '708 provisional application. In addition, there is no support for "cyano" as a possible substituent of these hydrocarbon structures.

Regarding the definition of variable R³ in claim 2, there is no support in the '708 application for C2-C12 alkenyl, C2-C12 alkynyl, or C5-C12 aryl.

Thus, formula (1a) in claim 1 and Formula 1 in claim 2 of Arimilli '695 are different from formulas (1a) and formula 1 in the provisional application '708. This impacts all of instant claims 2 - 25 which depend from claim 1 directly or indirectly.

The '695 patent specification does contain significant discussion of salts at column 3, lines 33 - 63 that does not appear in the '708 application. However, the last limitation of claim 1 of the Arimilli '695 patent, "and salts, hydrates, tautomers, and solvates thereof" is fully supported by the '708 provisional application at see page 2, lines 15 - 16; page 10, lines 10 - 11; and page 36, lines 23 - 24,

There are over 26 columns of additional specification detail in the '695 patent that is absent in the '708 provisional application specification. Compare column 6, line 53 through column 32, line 52 in Arimilli '695 to '708 application.

For all of these reasons, the '708 provisional application does not provide adequate written description for claims 1 - 25 of the Arimilli '695 patent. Thus, Claims 1 - 25 of the Arimilli '695 patent are not granted benefit of priority under 35 USC 119(e) with respect to the provisional application 60/022,708. Consequently, the earliest priority date for claims 1 - 25 of the Arimilla '695 patent is the filing date of said

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patent: 25 July 1997. Claim 26 - 31 are fully supported by the '708 provisional application and are, accordingly, given the benefit of the filing date of this provisional under 35 USC §119(e): 26 July 1996.

Documents Cited by the Requester

Old Reference: Previously Cited in 08/900,746 Application:

1. **Jones et al.**, "Minireview : Nucleotide Prodrugs," *Antiviral Research*, 27 : 1 - 17, 1995.

Newly Cited References:

2. **Bischofberger et al.**, "Bis(POC)PMPA, an Orally Bioavailable Prodrug of the Antiretroviral Agent PMPA," *Conferences on Retroviruses and Opportunistic Infections*, 4th: 104 (abstract no. 214) (January 22 - 26, 1997).
3. **Holy et al.**, EP 0 206 249 B1, 30 December 1986.
4. **Notari, Robert E.**, "Prodrug Design," *Pharmaceutical Therapy*, 14 : 25 - 53, 1981.

Criteria for Raising a Substantial New Question of Patentability

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 regarding at least one claim, i.e., the prior art teaching is such that there is a substantial likelihood that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and it is not necessary that the prior art establish a *prima facie* case of patentability and;

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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 in a decision on the merits involving the claim. See MPEP § 2242.

For a reexamination that was ordered on or after November 2, 2002 (the date of enactment of Public Law 107-273); see Section 13105, of the Patent and Trademark Office Authorization Act of 2002), reliance *solely* on old art (as basis for a rejection) does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. The determination of whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. For example, a SNQ may be based 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 the earlier concluded examination(s), in view of a material new argument or interpretation presented in the request. MPEP § 2258.01.

Discussion of the Cited Documents and as SNQ

The request indicates that Requester considers that claims 1 - 31 are unpatentable over Bischofberger. It is agreed that consideration of Bischofberger raises a substantial new question of patentability. Page 4, line 4 to page 16, remaining part of table, of the request for reexamination are hereby incorporated by reference for their explanation of the teaching provided in Bischofberger that was not present in the prosecution of the application that became the '695 patent. There is a substantial

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likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1 - 31 were patentable. Accordingly, Bischofberger raises a substantial new question of patentability as to claims 1 - 31.

The request indicates that Requester considers that claim 1 is unpatentable over Holy in view of Notari and Jones. It is agreed that consideration of Holy in view of Notari and Jones raises a substantial new question of patentability. Page 16, last 8 lines through page 29 of the request for reexamination are hereby incorporated by reference for their explanation of the teaching provided in Holy, Notari and Jones that was not present in the prosecution of the application that became the '695 patent. There is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1 - 31 were patentable. Accordingly, Holy in view of Notari and Jones raises a substantial new question of patentability as to claims 1 - 31.

Conclusion

In view of the above, the request for reexamination is **GRANTED**.
Claims 1 - 31 of United States Patent Number 5,922,695 will be examined.

Extensions of Time

Extensions of time under 37 CFR §1.136(a) will not be permitted in these proceedings because of the provisions of 37 CFR §1.136 apply only to an applicant and not to parties in a reexamination proceeding. Additionally, 35 USC §305 requires that

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ex parte reexamination proceedings “will be concluded 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).

Service on the Other Party (3rd Party Request)

After the filing of a request for reexamination by 3rd party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings have been merged) in the reexamination proceedings in the manner provided in 37 CFR §1.248. See 37 CFR §1.530(f).

Patent Owner Amendment

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). In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, will be governed by requirements of 37 CFR §1.116, after final rejection and 37 CFR §41.33 after appeal, which will be strictly enforced.

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Waiver of Right to File Patent Owner Statement

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

NOTICE RE PATENT OWNER'S CORRESPONDENCE ADDRESS

Effective May 16, 2007, 37 CFR 1.33(c) has been revised to provide that:

The patent owner's correspondence address for all communications in an *ex parte* reexamination or an *inter partes* reexamination is designated as the correspondence address of the patent.

Revisions and Technical Corrections Affecting Requirements for Ex Parte and Inter Partes Reexamination, 72 FR 18892 (April 16, 2007)(Final Rule)

The correspondence address for any pending reexamination proceeding not having the same correspondence address as that of the patent is, by way of this revision to 37 CFR 1.33(c), automatically changed to that of the patent file as of the effective date.

This change is effective for any reexamination proceeding which is pending before the Office as of May 16, 2007, including the present reexamination proceeding, and to any reexamination proceeding which is filed after that date.

Parties are to take this change into account when filing papers, and direct communications accordingly.

In the event the patent owner's correspondence address listed in the papers (record) for the present proceeding is different from the correspondence address of the patent, it is strongly encouraged that the patent owner affirmatively file a Notification of Change of Correspondence Address in the reexamination proceeding and/or the patent (depending on which address patent owner desires), to conform the address of the proceeding with

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that of the patent and to clarify the record as to which address should be used for correspondence.

Telephone Numbers for reexamination inquiries:

Reexamination and Amendment Practice	(571) 272-7703
Central Reexam Unit (CRU)	(571) 272-7705
Reexamination Facsimile Transmission No.	(571) 273-9900

Further Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary L. Kunz, whose telephone number is 571-272-0887. The examiner can normally be reached on Monday through Friday (with alternative Fridays off) between 7:00 AM and 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached at 571-272-1535. The fax phone number for the organization where this application or proceeding 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 unpublished 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 about access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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All correspondence relating to this Ex parte Reexamination proceeding should be directed to:

By Mail to:

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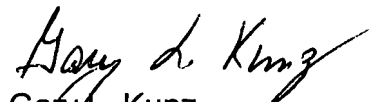
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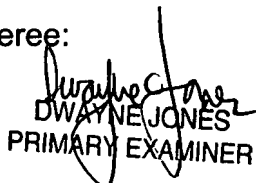
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Primary Examiner
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