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

mail

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/008,550	04/30/2007	5977089		8068

7590 07/13/2007

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

EXAMINER	
Dwayne C. Jones	
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.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DO NOT USE IN PALM PRINTER

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Daniel B. Ravicher, Esq.
Public Patent Foundation, INC.
1375 Broadway, Suite 600
New York, NY 10018

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/008,550*.

PATENT NO. *5977089*.

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.	Patent Under Reexamination	
	90/008,550	5977089	
	Examiner	Art Unit	
	Dwayne C. Jones	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)).

Dwayne C Jones
Primary Examiner
Art Unit: 3991

cc:Requester (if third party requester)

DETAILED ACTION

Order Request for Ex Parte Reexamination by Third Party Requester

Procedural Posture

On 03/23/2007:	An Incomplete Request for *Ex Parte* Reexamination by a Third Party Requester was filed.
On 04/03/2007:	A Notice of Failure to Comply with *Ex Parte* Reexamination Request Filing Requirements (37 CFR 1.510(c)) was mailed.
On 04/30/2007:	A Corrected Request for *Ex Parte* Reexamination by a Third Party Requester was filed for U.S. Patent No. 5,977,089 ('089 Patent) now assigned control number 90/008,550.

Priority

1. The '089 Patent issued to Arimilli et al. on 11/02/1999, which was filed on 11/06/1998 as U.S. Serial No. 09/187,763, which is a continuation of U.S. Patent No. 08/900,746, which was filed on 07/25/1997, which is further based on U.S. Provisional Application No. 60/022,708, which was filed on 07/26/1996. The Third Party Requester asserts that the three (3) claims of the '089 Patent (patent undergoing reexamination), which are directed to (R)-bis(POC)PMPA, are not entitled to claim priority to the provisional application of 60/022,708 because the 60/022,708 specification did not describe the invention in sufficient detail to show one of ordinary skill in the art that the '089 Patent possessed the claimed invention at the time of filing 60/022,708 (See pages 4-7 of the Request). Accordingly, the Third Party Requester asserts that the written description requirement was not satisfied until 07/25/1997, the filing date of 08/900,746.

These assertions regarding the priority date are not found persuasive for the following reasons. First, 60/022,708 lists a synthetic method to yield the compound of formula (I), which is the generic compound that embraces the bis(POC)PMPA compound and its enantiomers (See

pages 2, 3, 8, and 9). Second, Example 7 is specifically directed to the synthesis of bis-isopropyl oxymethyl carbonate of PMPA (See pages 23 and 24). Third, Table 1 specifically lists the prodrug carbonate compound of bis-isopropylCOM PMPA (See page 34). Fourth, 60/022,708 describes that "The compounds of this invention are optionally enriched or resolved at the carbon atom chiral center linked to R^1 in accordance with prior findings associating optimal antiviral activity with the configuration at this site. Thus, where R^1 is methyl, the center will be in (R) configuration" (See page 6). Fifth, 60/022,708 describes that the compounds and compositions with pharmaceutically acceptable carriers of this invention are useful in the treatment or prophylaxis of one or more viral infections in a variety modes of administration, in particular oral administration (See pages 9-14).

In view of the sundry descriptions and examples provided in 60/022,708, there is adequate written support and description under 35 USC 112, 1st paragraph for (R)-bis(POC)PMPA as claimed in '089 Patent (patent undergoing reexamination). Accordingly, the Third Party Requester's allegations regarding the lack of written description in 60/022,708 are not convincing. Therefore, the earliest effective filing date possible for the '089 Patent (patent undergoing reexamination) is 07/26/1996, which is the filing date of provisional 60/022,708.

Information Disclosure Statement

2. The information disclosure statement filed 03/23/2007 (2 sheets) has been reviewed and considered, see enclosed copy of PTO/SB/08A form.

The Invention of U.S. Patent No. 5,977,089 (Arimilli et al.)

3. The Arimilli et al. invention has three (3) claims each of which are independent. Claim 1 is directed to a compound. Claim 2 is directed to a composition. Claim 3 is directed to a method of use.

The claims are:

Claim 1.	(R)-bis(POC)PMPA.
Claim 2.	A composition comprising (R)-bis(POC)PMPA and a pharmaceutically acceptable carrier.
Claim 3.	A method comprising orally administering to a patient infected with virus or at risk to viral infection a therapeutically effective amount of (R)-bis(POC)PMPA.

Substantial New Question (SNQ) of Patentability

4. 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 question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and

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, (I).

It is not necessary that a "prima facie" case of unpatentability exist as to the claim in order for "a substantial new question of patentability" to be present as to the claim. Thus, "a substantial new question of patentability" as to a patent claim could be present even if the

examiner would not necessarily reject the claim as either fully anticipated by, or obvious in view of, the prior art patents or printed publications.

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 the 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. Determinations on 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, see MPEP 2258.01.

References Cited by the Third Party Requester

New References Cited:

1. **Bischofberger et al.**,"Bis(POC)PMPA, an Orally Bioavailable Prodrug of the Antiretroviral agent PMPA," *Conference on Retroviruses and Opportunistic Infections*, 4th:104 (abstract no. 214, January 22-26, 1997, (hereinafter referred to as **Bischofberger et al.**).
2. **Holy et al.** of EP 0206459 B1, published on 12/30/1986, (hereinafter referred to as **Holy et al.**).
3. **Notari, R. E.**, "Prodrug Design," *Pharmaceutical Therapy*, 14:25-53, 1981. (hereinafter referred to as **Notari**).

Old Reference Cited:

4. **Jones et al.**, "Minireview: Nucleotide Prodrugs," *Antiviral Research*, 27:1-17, 1995, (hereinafter referred to as **Jones et al.**).

Existence of a SNQ of Patentability

Reference Not Deemed as Valid Prior Art

SNQ 1: The Third Party Requester asserts that a substantial new question of patentability of claims 1-3 is raised by **Bischofberger et al.**

5. **Bischofberger et al.** is discussed on pages 6-7 of the Request.

Bischofberger et al., which is a newly cited reference, teach bis(POC)PMPA and the oral administration of this compound. **Bischofberger et al.** also teach that bis(POC)PMPA has antiviral activity (See abstract).

The teachings of bis(POC)PMPA, its oral administration, and further its use as antiviral, which were raised by the Request for *Ex Parte* Reexamination, were not present in a prior examination of the patent being reexamined.

However, no substantial new question of patentability is raised by the request for reexamination and prior art cited therein for the reasons set forth below. **Bischofberger et al.** is not available against the claims of U.S. Patent No. 5,977,089. **Bischofberger et al.** is not available as prior art because of its earlier date (January 22-26, 1997) versus the effective filing date of U.S. Patent No. 5,977,089 (patent undergoing reexamination) (July 26, 1996). Please refer to the **Priority** Section of this Office Action for a detailed discussion of the adequate written description in 60/022,708.

The **Bischofberger et al.** reference is not deemed as valid prior art, thus a rejection based on **Bischofberger et al.** alone or in view of another reference **does not** create a substantial new question of patentability with respect to claims 1-3 of U.S. Patent No. 5,977,089.

Existence of a SNQ of Patentability

References Deemed as Valid Prior Art

SNQ 2: Third Party Requester asserts that a substantial new question of patentability of claims 1-3 is raised by **Holy et al.** in view of **Notari** and in view of **Jones et al.**

6. **Holy et al.** is discussed on pages 9-12 of the Request.

Holy et al., which is a newly cited reference, teach anti-viral treatments made from 9-(phosphonomethoxyalkyl)adenines (a.k.a. PMPA) (See pages 2, lines 23-38; page 5, line 29 of Example 2; page 8, line 20).

Notari is discussed on pages 9-12 of the Request.

Notari, which is a newly cited reference, teaches that prodrugs (enzyme-reversible prodrugs) can be made to improve the stability or solubility of a drug. **Notari** also teaches that '[b]y far the most widely used prodrug linkage is that of an ester wherein the original drug provides either the carboxylic acid or the hydroxyl group . . . carbonates" (See pages 26 and 27). **Notari** also teaches that prodrugs are orally administered (See page 26).

Jones et al. is discussed on page 9-12 of the Request.

Jones et al. was previously cited on the face of U.S. Patent No. 5,977,089, however this reference was not previously applied in a rejection.

Jones et al. teach that nucleoside and nucleotide analogues have great therapeutic antiviral activity. **Jones et al.** teach that "the negative charge(s) on the phosphorous entail(s) nucleotides with short comings (low permeability and bioavailability), increasing work in the literature is focusing on overcoming these difficulties with nucleotide prodrugs (See page 2). **Jones et al.** teach oral administration (See page 4).

Although the **Jones et al.** reference was previously cited during the prosecution of the application that became the '089 Patent, it was not discussed in combination with the newly cited references of **Holy et al.** and **Notari**. Thus, **Jones et al.** is now being considered in a new light and a different way as compared with its use in an earlier concluded examination. Accordingly, **Jones et al.** in combination with **Holy et al.** and further in combination with **Notari** raise a substantial new question of patentability as to claims 1-3 which has not been decided in a previous examination of the '089 Patent.

Conclusion

7. Request for *Ex Parte* Reexamination by a Third Party Requester for U.S. Patent No. 5,977,089 (control no. 90/008,550) for claims 1-3 is hereby **GRANTED**.

Extensions of Time

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).

Future 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 particular, 37 CFR 1.530(i) states: "All amendments must be made relative to the patent specification, including the claims, and drawings, which are in effect as of the date of filing the request for reexamination." As a result each amendment to the claims should be made relative to the originally patented claims and not to the previous amendment. Any changes must include brackets (not strikethroughs) for the matter to be omitted and underlining fro added matter (See 37 CFR 1.530(f)(1)(2)). The Patent Owner is directed to MPEP 2250 (IV) containing examples of claim amendments in reexamination proceedings.

Please provide a complete listing of all pending claims and their respective status (i.e., original, cancelled, amended, new) undergoing reexamination that complies with 37 CFR 1.530(d)-(j).

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. 5,977,089 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.

Waiver of Right to File Patent Owner's Statement

In a reexamination proceeding, the Patent Owner may waive the right under 37 CFR 1.530 to file a Patent Owner's 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's 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)).

Service of Papers

After the filing of a request for reexamination by a third 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 are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248 (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 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

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays-Thursdays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, may be reached at (571) 272-1535. The official fax No. for the organization where this application is assigned is (571)-273-9900. For status inquires of a general nature refer to the customer service line at (571) 272-7705.

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 may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

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

By Mail to:	Mail Stop *Ex Parte* Reexam Central Reexamination Unit Commissioner for Patents United States Patent & Trademark Office 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 Street Alexandria, VA 22314

July 6, 2007

DWAYNE JONES
PRIMARY EXAMINER

Dwayne C. Jones
Primary Examiner
Art Unit 3991

Conferee:

GARY L. KUNZ
CRU EXAMINER - AU 3991

JERRY D. JOHNSON
CRU EXAMINER-AU 3991