



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.
90/008,556	04/30/2007	5935946		8460 <i>mas</i>

25000 7590 07/13/2007

GILEAD SCIENCES INC  
333 LAKESIDE DR  
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.



**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. 90/008,556.

PATENT NO. 5935946.

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)).

<b>Order Granting / Denying Request For Ex Parte Reexamination</b>	Control No. 90/008,556	Patent Under Reexamination 5935946	
	Examiner Dwayne C. Jones	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)).

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. 5,935,946 ('946 Patent) now assigned control number 90/008,556.

#### *Priority*

1. The '946 Patent issued to Munger, Jr. et al. on 08/10/1999, which was filed on 07/25/1997 as U.S. Serial No. 08/900,752. Therefore, the earliest effective filing date possible for the '946 Patent (patent undergoing reexamination) is 07/25/1997.

#### *Information Disclosure Statement*

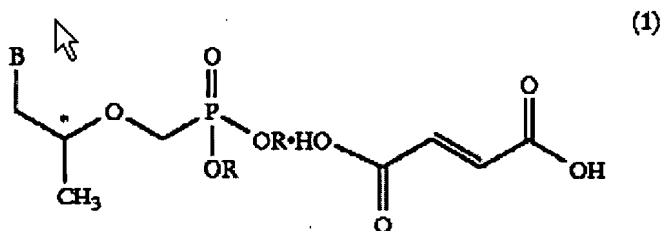
2. The information disclosure statement filed 03/23/2007 (2 sheets) has been reviewed and considered, see enclosed copy of PTO/SB/08A form.

#### *The Invention of U.S. Patent No. 5,935,946 (Munger, Jr. et al.)*

3. The Munger, Jr. et al. invention has twenty claims, eight (8) of which are independent claims. Claims 1, 7, 8, 16, and 19 are directed to compositions. Claims 10, 12, and 15 are directed to a method of producing. The independent claims are listed as follows.

Art Unit: 3991

## 1. A composition of formula (1)



wherein B is adenin-9-yl and R independently is —H or —CH<sub>2</sub>—O—C(O)—O—CH(CH<sub>3</sub>)<sub>2</sub>, but at least one R is —CH<sub>2</sub>—O—C(O)—O—CH(CH<sub>3</sub>)<sub>2</sub>.

7. A composition comprising a lithium alkoxide and a 9-(2-hydroxypropyl)adenine solution.

8. A composition comprising an (R,S)-PMPA solution at a pH of about 2.7–3.5 wherein the solution has less than about 0.1 g/mL (R,S)-PMPA and wherein about 90–94% of the PMPA is in the (R) configuration.

10. A method comprising contacting bis(POC)PMPA with fumaric acid.

12. A method comprising mixing a lithium alkoxide with a 9-(2-hydroxypropyl)adenine solution.

15. A method comprising adjusting the pH of a solution comprising less than about 0.08 g/mL (R,S)-PMPA wherein about 90–94% of the PMPA is in the (R) configuration to a pH of about 2.7–3.5.

16. A composition comprising a tablet containing 9-[2-(R)-[[bis[[isopropoxycarbonyl]oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine.fumaric acid (1:1), pregelatinized starch, croscarmellose sodium, lactose monohydrate and magnesium stearate.

19. A product produced by the process of preparing wet granules from a mixture comprising a liquid, 9-[2-(R)-[[bis[[isopropoxycarbonyl]oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine.fumaric acid (1:1) and a pharmaceutically acceptable excipient.

*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*

Art Unit: 3991

*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. **Arimilli et al.** of U.S. Patent No. 5,922,695 issued on 07/13/1999, which has priority to 07/26/1996, (hereinafter referred to as **Arimilli et al.**).
2. **Bischofberger et al.**, "Bis(POC)PMPA, an Orally Bioavailable Prodrug of the Antiretroviral agent PMPA," *Conference on Retroviruses and Opportunistic Infections*, 4<sup>th</sup>:104 (abstract no. 214, January 22-26, 1997, (hereinafter referred to as **Bischofberger et al.**).
3. **Gould, P. L.** "Salt Selection for Basic Drugs," *International Journal of Pharmaceutics*, 33:201-271, 1986. (hereinafter referred to as **Gould**).
4. **Takashima et al.** of EP 0206459 B1, published on 01/04/1985, (hereinafter referred to as **Takashima et al.**).

***Existence of a SNQ of Patentability***

**SNQ 1:** The Third Party Requester asserts that a substantial new question of patentability of claims 1-20 is raised by **Arimilli et al.**

5. **Arimilli et al.** are discussed on pages 4-8 of the Request.

**Arimilli et al.**, which is a newly cited reference, teach the composition of "bis(POC)PMPA fumarate (See column 1, lines 29-45; column 45, line 64; column 35, lines 37-44) as a crystal from about 97.0 to 99.5% purity (See column 45, lines 50-65). **Arimilli et al.** also teach that compounds are enriched or resolved at the carbon atom chiral center, in particular at least about 90% of the compound is in the (R) configuration (See claim 12).

The teachings of bis(POC)PMPA fumarate composition, especially in the claimed purity levels, which were raised by the Request for *Ex Parte* Reexamination, was not present in a prior examination of the patent being reexamined, and there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding the patentability of

Art Unit: 3991

claims 1-20. Accordingly, the prior art reference of **Arimilli et al.** raises a substantial new question of patentability as to claims 1-20, which question has not been decided in a previous examination of the '946 Patent.

**SNQ 2:** The Third Party Requester asserts that a substantial new question of patentability of claims 1-20 is raised by **Bischofberger et al.** in view of **Gould** and in view of **Takashima et al.**

6. **Bischofberger et al.** are discussed on pages 3 and 8-20 of the Request.

**Bischofberger et al.**, which are 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).

**Gould** is discussed on pages 3 and 8-20 of the Request.

**Gould**, which is a newly cited reference, teaches that any acid relating to normal metabolism, or present in food and drink can be regarded as a suitable candidate for preparing salts (See page 202, 1<sup>st</sup> column). **Gould** lists a variety of suitable acids, in particular fumarate (See Table 1, page 215).

**Takashima et al.** are discussed on pages 3 and 8-20 of the Request.

**Takashima et al.**, which is a newly cited reference, teach the formation of pharmaceutically acceptable acid salts for phosphonate-nucleotide esters that have effective anti-HIV activity (See page 2, lines 1-16; page 76, lines 53-58). **Takashima et al.** teach the use of fumarate in the formation of such salts in order to achieve superior oral administration characteristics (See page 4, lines 40-47; page 77, lines 1-3).

It is agreed that consideration of **Bischofberger et al.** in view of **Gould** and in view of



Art Unit: 3991

**Takashima et al.** raise a substantial new question of patentability that has not been decided in a previous examination of the '946 Patent. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding the patentability of claims 1-20.

Accordingly, the combination of **Bischofberger et al.** in view of **Gould** and in view of

**Takashima et al.** raises a substantial new question of patentability as to claims 1-20, which question has not been decided in a previous examination of the of the '946 Patent.

### *Conclusion*

7. Request for *Ex Parte* Reexamination by a Third Party Requester for U.S. Patent No. 5,935,946 (control no. 90/008,556) for claims 1-20 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 for 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).

Art Unit: 3991

***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)).

***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.

***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.

Art Unit: 3991

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 inquiries 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).

Art Unit: 3991

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

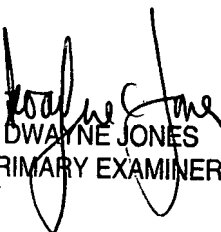
By Mail to: Mail Stop *Ex Parte* Reexam  
Central Reexamination Unit  
Commissioner for Patents  
United States Patent & Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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

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

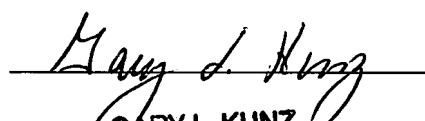
July 8, 2007

Dwayne C. Jones  
Primary Examiner  
Art Unit 3991

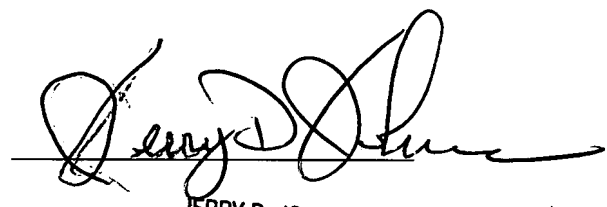


DWAYNE JONES  
PRIMARY EXAMINER

Conferee:



GARY L. KUNZ  
CRU EXAMINER - AU 3991



JERRY D. JOHNSON  
CRU EXAMINER-AU 3991