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REQUEST FOR EX PARTE REEXAMINATION TRANSMITTAL FORM

Address to:

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Commissioner for Patents
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Attorney Docket No.: _____

Date: August 25, 2010

1. This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 5,674,882 issued October 7, 1997. The request is made by:
 patent owner. third party requester.
2. The name and address of the person requesting reexamination is:
Public Patent Foundation
55 Fifth Avenue, Suite 928
New York, NY 10003
3. a. A check in the amount of \$ _____ is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(1);
 b. The Director is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(1) to Deposit Account No. _____; or
 c. Payment by credit card. Form PTO-2038 is attached.
4. Any refund should be made by check or credit to Deposit Account No. _____ 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.
5. A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4)
6. CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
 Landscape Table on CD
7. Nucleotide and/or Amino Acid Sequence Submission
If applicable, items a. - c. are required.
a. Computer Readable Form (CRF)
b. Specification Sequence Listing on:
i. CD-ROM (2 copies) or CD-R (2 copies); or
ii. paper
c. Statements verifying identity of above copies
8. A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.
9. Reexamination of claim(s) 1-3 is requested.
10. A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO/SB/08, PTO-1449, or equivalent.
11. An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.510. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Mall Stop Ex Parte Reexam, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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12. The attached detailed request includes at least the following items:
- a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.510(b)(1)
- b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2).
13. A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e)
14. a. It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c).
The name and address of the party served and the date of service are:
Paul D. Yasger, Abbott Laboratories
100 Abbott Park Road, Dept. 377/AP6A
Abbott Park, IL 60064-6008
Date of Service: August 25, 2010; or
- b. A duplicate copy is enclosed because service on patent owner was not possible. An explanation of the efforts made to serve patent owner is attached. See MPEP 2220.

15. Correspondence Address: Direct all communications about the reexamination to:

 The address associated with Customer Number:

OR

 Firm or Individual Name Public Patent Foundation

Address

55 Fifth Avenue, Suite 928City New YorkState NYZip 10003Country USATelephone (212) 790-0442Email info@pubpat.org16. The patent is currently the subject of the following concurrent proceeding(s):

- a. Copending reissue Application No. _____
- b. Copending reexamination Control No. _____
- c. Copending Interference No. _____
- d. Copending litigation styled: _____

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Daniel B. Ravicher
Authorized SignatureDaniel B. Ravicher
Typed/Printed NameAugust 25, 2010

Date

47,015 For Patent Owner Requester
Registration No. For Third Party Requester

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO.: 5,674,882
ISSUED: Oct. 7, 1997
TO: Kempf et al.
FOR: RETROVIRAL PROTEASE INHIBITING COMPOUNDS

**ATTACHMENT TO FORM PTO/SB/57,
REQUEST FOR *EX PARTE* REEXAMINATION**

SIR:

The Public Patent Foundation (“PUBPAT”), a not-for-profit public service organization that works to protect the public from the harms caused by undeserved patents and unsound patent policy, respectfully requests *ex parte* reexamination under 35 U.S.C. §§ 302-307 and 37 C.F.R. § 1.510 of every claim of United States Patent No. 5,674,882 issued October 7, 1997, to Kempf et al. and assigned to Abbott Laboratories (“the ‘882 patent”) because they are all invalid under 35 U.S.C. §§ 102 and 103 and their existence is causing significant public harm.¹

THE ‘882 PATENT IS CAUSING SIGNIFICANT PUBLIC HARM

HIV/AIDS is one of the greatest threats to public health faced by the world today. As of the end of 2008, over 33 million people worldwide were living with HIV/AIDS,² including more

¹ A copy of the ‘882 patent is attached hereto as Appendix A.

² <http://www.avert.org/worldstats.htm>, last visited August 3, 2010.

than one million Americans.³ Every person afflicted with HIV/AIDS has the right to obtain the best medical treatment available without any improper obstacles placed in their way. More specifically, American men, women, and children suffering from HIV/AIDS are entitled to access the best pharmaceutical treatments available without undeserved patents making those treatments either too expensive or too limited in supply.

Ritonavir is a retroviral protease inhibitor that is a significant treatment for HIV/AIDS patients. Today it is widely used as a booster for other protease inhibitors. Abbott Laboratories is the sole distributor of ritonavir in the United States (under the brand name Norvir) and is using the '882 patent – and seven other patents for which requests for reexamination are being filed concurrently herewith – to prevent anyone else from offering ritonavir to HIV/AIDS patients in the United States.⁴ Not only is the '882 patent being used to deny American HIV/AIDS patients fair access to the medical treatment that they need and deserve; it is also a barrier to further research on ritonavir here in the United States because there is no exception to patent infringement for such research. In these ways, the '882 patent is unquestionably causing significant public harm to the American people. Although these issues are not grounds to grant this request for reexamination, PUBPAT respectfully requests that they be considered when determining whether the validity of the '882 patent merits review by your office.

THE SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

1. Whether claims 1-3 of the '882 patent were anticipated or rendered obvious by U.S.

Patent No. 5,142,056 to Kempf et al. issued on August 25, 1992 (“’056 patent”);

³ <http://www.avert.org/usa-statistics.htm>, last visited August 3, 2010.

⁴ Approved Drug Products with Therapeutic Equivalence Evaluations, Food and Drug Administration (“Orange Book”), Application Number. N022417 (Approval Date February 10, 2010).

2. Whether claims 1-3 of the '882 patent were anticipated or rendered obvious by EP 337714A2, to Sigal et al. published on October 18, 1989 (“Sigal”); and
3. Whether claims 1-3 of the '882 patent were rendered obvious by Ho et al., Nature vol. 375 Jan. 12, 1995 “Rapid Turnover of Plasma Virions and CD4 Lymphocytes in HIV-1 Infection” (“Ho”) in light of the '056 patent and/or Sigal.

These are new questions because neither the '056, Sigal nor Ho were cited as references, much less applied, during prosecution. A detailed explanation of the pertinency and manner of applying the cited patents and publications to the claims of the '882 patent is set forth below.⁵

THE '056 PATENT ANTICIPATED OR RENDERED OBVIOUS THE '882 PATENT

The '882 patent application was filed March 29, 1995. The applicants claimed priority to a series of applications, including application no. 07/998,114 (filed December 29, 1992) and application number 08/158,587 (filed December 2, 1993). However, the claims of the '882 patent are not entitled to those claims of priority because the specifications of those earlier applications were not sufficient to satisfy the written description requirement of 35 U.S.C. § 112 with respect to the three claims of the '882 patent.

The Federal Circuit recently confirmed that the written description requirement is a separate statutory requirement from the best mode and enablement requirements. Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). To satisfy the written description requirement, a specification must describe the claimed invention so that one of ordinary skill in the art can recognize what is claimed. Further, sufficient detail must be included in the specification to show one of ordinary skill in the art that the applicant possessed

⁵ Appendix B contains a copy of the cited patents and publications.

the claimed invention at the time of the filing of the application.

In this case, the inventors did not possess the claimed invention at the time of filing of the claimed priority applications because the specifications lacked evidence that the claimed methods were effective *in vivo*. The only evidence of efficacy was *in vitro*, and no evidence of the correlation between the *in vitro* results and successful treatment in humans was provided. Many antiviral agents that provide exceptional results *in vitro* are ineffective *in vivo*. This principle is substantiated by a 1987 review article⁶ indicating that *in vitro* testing performed on anti-viral compounds is useful as a screening tool but is not predictive of *in vivo* efficacy. The specifications of the purported priority applications lacked *in vivo* data supporting the efficacy of the claimed methods, which thus renders them insufficient to satisfy the written description requirement. Therefore, the '882 patent is not entitled to claim priority to those earlier applications. Thus, the effective filing date of the '882 patent is its specific filing date, March 29, 1995.

The '056 patent issued on August 25, 1992. Accordingly, the '056 patent is 102(b) prior art to the '882 patent. As explained below, the '056 patent renders each claim of the '882 patent invalid.

In 2007 the Federal Circuit specifically addressed the standard for obviousness in another case involving a pharmaceutical composition. In that case, Pfizer v. Apotex, the patented besylate salt of the compound amlodipine was held obvious over a prior art patent that claimed a genus of pharmaceutically acceptable salts of amlodipine even though it did not disclose the besylate salt. 480 F.3d 1348 (Fed. Cir. 2007). The besylate salt was found obvious despite the

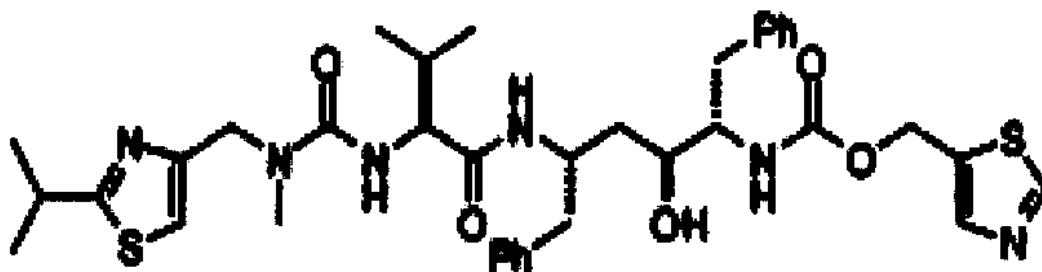
⁶ Sandstrom et al., "Antiviral Therapy In AIDS: Clinical Pharmacological Properties and Therapeutic Experience to Date," *Drugs* 34: 373-390 (1987).

fact that none of the anions listed in the prior art patent had a cyclic structure as does besylate and it was undisputed that one cannot reliably predict the influence of a particular salt species on the behavior of a parent compound. The Federal Circuit's obviousness decision was based on the skilled artisan's motivation to combine prior art teachings to achieve the claimed invention and reasonable expectation of success. *Id.* at 1361. The Pfizer v. Apotex case is instructive as to the obviousness of the '882 patent over the '056 patent.

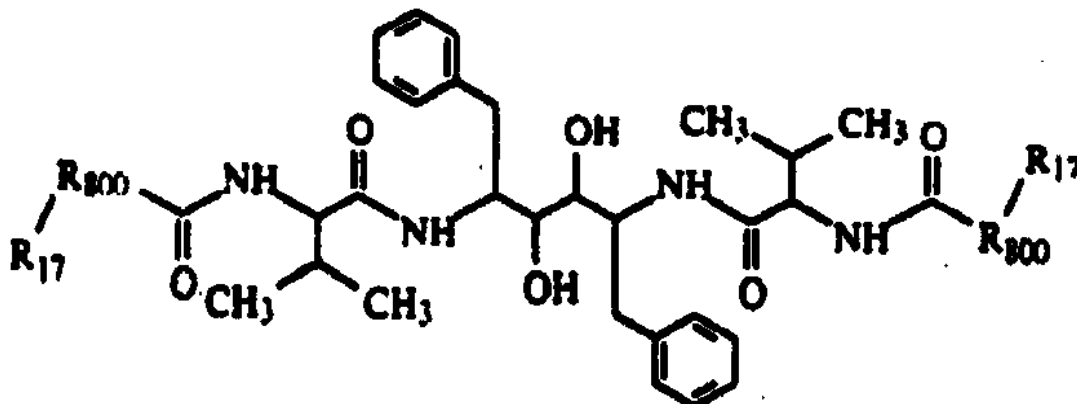
The '882 patent contains three claims. Each one recites a method of inhibiting an HIV infection using a particular retroviral protease inhibiting compound along with another HIV protease inhibiting compound. Claim 1 is the broadest claim and reads as follows:

1. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-((N-Methyl-N-((2-isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound.

The remaining claims vary only in the selection of HIV protease inhibiting compound used with the named compound. The compound having the formula recited in the claims is depicted as follows:



A compound disclosed in the '056 patent is depicted as follows:



The claimed compound and the compound taught by the '056 patent have the same central substituent. Therefore, the '056 patent anticipates the claims of the '882 patent. The additional hydroxyl group described in the '882 patent is inherent in or obvious in light of the '056 patent compound.

The chart below sets forth an element-by-element comparison of all three claims of the '882 patent to the teaching of the '056 patent. In essence, the formula recited in the method claims of the '882 patent represents a genus of or is rendered obvious by the class of compounds disclosed in the '056 patent. The method of combining the compound with another HIV protease inhibiting compound is explicitly disclosed in the '056 specification. Although the '056 patent may not have explicitly disclosed the exact compound recited in the '882 patent, each element of the '882 patent's claims is either inherent in or rendered obvious by the '056 patent's teachings. Therefore each claim of the '882 patent is invalid and should be canceled.

'882 patent	'056 patent
1. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-(N-Methyl-N-(2-	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 1, save one

'882 patent	'056 patent
isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound.	additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art. The '056 specification teaches the utility of the disclosed compounds for the treatment of AIDS/HIV when administered in combination with one or more other immunomodulators, antiviral agents, other antiinfective agents or vaccines (col. 220). The '056 specification also teaches that agents which can be combined with the disclosed compounds include any agents useful for the treatment or prophylaxis of AIDS or an HIV infection.
2. The method of claim 1 wherein the other HIV inhibiting is selected from the group of Ro 31-8959 SC-52151 KIN-227 and KNI-272.	As discussed above, the '056 patent disclosed a method of inhibiting HIV infection which included one or more other antiinfective agents and did not limit such agents to those listed in the specification.
3. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-((N-Methyl-N-((2-isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of Ro 31-8959.	As discussed above, the '056 patent disclosed a method of inhibiting HIV infection which included one or more other antiinfective agents and did not limit such agents to those listed in the specification.

SIGAL ANTICIPATED OR RENDERED OBVIOUS THE '882 PATENT

In addition to being anticipated or rendered obvious by the '056 patent, the '882 patent was also anticipated or rendered obvious by Sigal. The Sigal application was published October 18, 1989. Accordingly, it is 102(b) prior art to the '882 patent which has an effective filing date of March 29, 1995 as explained above. Pfizer v. Apotex is again instructive as to why the '882 patent is invalid over Sigal.

The chart below sets forth an element-by-element comparison of all three claims of the '882 patent to the teaching of Sigal. In essence, the formula recited in the method claims of the '882 patent represents a genus of or is rendered obvious by the class of compounds disclosed in Sigal. Sigal discloses compounds having the identical central substituent as that of the compound named in the claims of the '882 patent and pharmaceutically acceptable salts thereof. Sigal at 42. It teaches the utility of such compounds in the inhibition of HIV protease, the prevention or treatment of infection by the human immunodeficiency virus (HIV) and the treatment of consequent pathological conditions such as AIDS. *Id.* Its invention is directed toward the combination of the disclosed compounds with other agents useful in the treatment of AIDS. *Id.* at 42-44. Although Sigal may not have explicitly disclosed the exact compound recited in the '882 patent, each element of the '882 patent's claims is either inherent in or rendered obvious by Sigal's teachings. Therefore each claim of the '882 patent is invalid and should be canceled.

'882 patent	Sigal
<p>1. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-((N-Methyl-N-((2-isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound.</p>	<p>Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 1. Sigal teaches the utility of the disclosed compounds for the treatment of AIDS/HIV when administered in combination with one or more other agents useful in the treatment of AIDS. pp.42-44. Sigal does not limit the other agents to those listed in the specification.</p>
<p>2. The method of claim 1 wherein the other HIV inhibiting is selected from the group of Ro 31-8959 SC-52151 KIN-227 and KNI-272.</p>	<p>Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 1. Sigal</p>

'882 patent	Sigal
	teaches the utility of the disclosed compounds for the treatment of AIDS/HIV when administered in combination with one or more other agents useful in the treatment of AIDS. pp.42-44. Sigal does not limit the other agents to those listed in the specification.
3. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-((N-Methyl-N-((2-isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of Ro 31-8959.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 3. Sigal teaches the utility of the disclosed compounds for the treatment of AIDS/HIV when administered in combination with one or more other agents useful in the treatment of AIDS. pp.42-44. Sigal does not limit the other agents to those listed in the specification.

**THE '882 PATENT WAS RENDERED OBVIOUS BY HO
IN VIEW OF THE '056 PATENT AND/OR SIGAL**

Ho, published in January of 1995, predates the March 1995 filing of the '882 application and is thus prior art to the '882 patent under 102(a). Ho provides *in vivo* evidence that the compound recited in the claims of the '882 patent, referred to as ABT-538 in the article, was effective in treating HIV when administered to humans. Ho at 123. Ho thus rendered obvious the invention claimed in the '882 patent. The chart below sets forth an element-by-element comparison of all three claims of the '882 patent to the teaching of Ho. Because Ho disclosed a method of treatment using the exact compound recited in the '882 patent, the '882 patent's claims are rendered obvious in light thereof. Although Ho did not explicitly disclose the combination of the compound with another HIV protease inhibiting compound, this element of the invention was rendered obvious in light of the '056 patent and/or Sigal, both discussed above. Therefore each

claim of the '882 patent is invalid and should be canceled.

'882 patent	Ho in view of the '056 Patent and/or Sigal
<p>1. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-((N-Methyl-N-((2-isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound.</p>	<p>Ho taught the efficacy of a method in which the claimed compound was administered to humans in need thereof. Although Ho did not specifically disclose the combination of the compound with another HIV protease inhibiting compound, such combinations were obvious in light of prior art, including the '056 patent and Sigal, discussed above. One of ordinary skill in the art would have been motivated to combine the teachings of these references because they each relate to the same field and problem.</p>
<p>2. The method of claim 1 wherein the other HIV inhibiting is selected from the group of Ro 31-8959 SC-52151 KIN-227 and KNI-272.</p>	<p>Ho taught the efficacy of a method in which the claimed compound was administered to humans in need thereof. Although Ho did not specifically disclose the combination of the compound with another HIV protease inhibiting compound, such combinations were obvious in light of prior art, including the '056 patent and Sigal, discussed above. One of ordinary skill in the art would have been motivated to combine the teachings of these references because they each relate to the same field and problem.</p>
<p>3. A method for inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of (2S,3S,5S)-5-(N-(N-((N-Methyl-N-((2-isopropyl-4-thiazolyl)methyl)-amino)carbonyl)valinyl)amino)-2-(N-((5-thiazolyl)methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of Ro 31-8959.</p>	<p>Ho taught the efficacy of a method in which the claimed compound was administered to humans in need thereof. Although Ho did not specifically disclose the combination of the compound with another HIV protease inhibiting compound, such combinations were obvious in light of prior art, including the '056 patent and Sigal, discussed above. One of ordinary skill in the art would have been motivated to combine the teachings of these references because they each relate to the same field and problem.</p>

CONCLUSION

For the reasons set forth above, each of the claims of the '882 patent is invalid. Accordingly, PUBPAT respectfully requests that they be examined *ex parte* and subsequently canceled.

August 25, 2010

Date

Daniel B. Ravicher

Daniel B. Ravicher, Esq.
U.S.P.T.O. Reg. No. 47,015
PUBLIC PATENT FOUNDATION, INC.
55 Fifth Avenue, Suite 928
New York, NY 10003
Tel: (212) 790-0442
Fax: (212) 591-6038
www.pubpat.org

APPENDIX A

APPENDIX B

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substituta for form 1448/PTO <h2 style="margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="margin: 0;">(Use as many sheets as necessary)</p>			Complete if Known	
Application Number	90/			
Filing Date				
First Named Inventor	Kempf, Dale J.			
Art Unit				
Examiner Name				
Attorney Docket Number				
Sheet 1	of		2	

U. S. PATENT DOCUMENTS					
Examiner Initials ^a	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 5,142,056	08-25-1992	Kempf, et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials ^a	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		EP 0 337 714 A2	10-18-1989	Merck & Co. Inc.		

Examiner Signature		Date Considered	
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^aEXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***(Use as many sheets as necessary)***Complete if Known**

Application Number	09/____
Filing Date	
First Named Inventor	Kempf, Dale J.
Art Unit	
Examiner Name	
Attorney Docket Number	

Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		HO et al., Rapid Turnover of Plasma Virions and CD4 Lymphocytes in HIV-1 Infection, Nature, 373: 123-126, January 1995.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.