PTO/SB/57 (02-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also referred to as FORM PTO-1465)

REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

Address to:
Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attorney Docket No.: _____

Date: August 25, 2010

1. [x] This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 5,648,497 issued July 15, 1997. The request is made by:
   [ ] patent owner. [x] third party requester.

2. [x] 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**
   [x] c. Payment by credit card. Form PTO-2038 is attached.

4. [x] 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. [x] 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. [x] A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.

9. [x] Reexamination of claim(s) 1-8 is requested.

10. [x] 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.

12. [x] 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. [x] 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

[x] Firm or Individual Name Public Patent Foundation

Address

55 Fifth Avenue, Suite 928

City New York	State NY	Zip 10003
Country USA		
Telephone (212) 790-0442	Email info@pubpat.org	

16. [ ] 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 Signature

August 25, 2010
Date

Daniel B. Ravicher
Typed/Printed Name

47,015
Registration No.

[ ] For Patent Owner Requester
[x] For Third Party Requester

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO.: 5,648,497

ISSUED: Jul. 15, 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. 5,648,497 issued July 15, 1997, to Kempf et al. and assigned to Abbott Laboratories ("the '497 patent") because they are all invalid under 35 U.S.C. §§ 102 and 103 and their existence is causing significant public harm.[1]

THE '497 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 '497 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 '497 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 ' 497 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 '497 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 ' 497 patent merits review by your office.

THE SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

1. Whether claims 1-8 of the '497 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 1-8 of the '497 patent were anticipated or rendered obvious by EP 337714A2, to Sigal et al. published on October 18, 1989 ("Sigal"); and
3. Whether claims 1-8 of the '497 patent were anticipated or 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").

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 '497 patent is set forth below.[5]

THE '056 PATENT ANTICIPATED OR RENDERED OBVIOUS THE '497 PATENT

The '497 patent application was filed March 24, 1995. The applicants claimed priority to a series of applications, including application no. 08/270,210 (filed August 23, 1994) and application number 08/121,673 (filed September 14, 1993). However, the claims of the ' 497 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 eight claims of the ' 497 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 article[6] 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 '497 patent is not entitled to claim priority to those earlier applications. Thus, the effective filing date of the ' 497 patent is its specific filing date, March 24, 1995.

The '056 patent issued on August 25, 1992. Accordingly, the '056 patent is 102(b) prior art to the '497 patent. As explained below, the '056 patent renders each claim of the '497 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

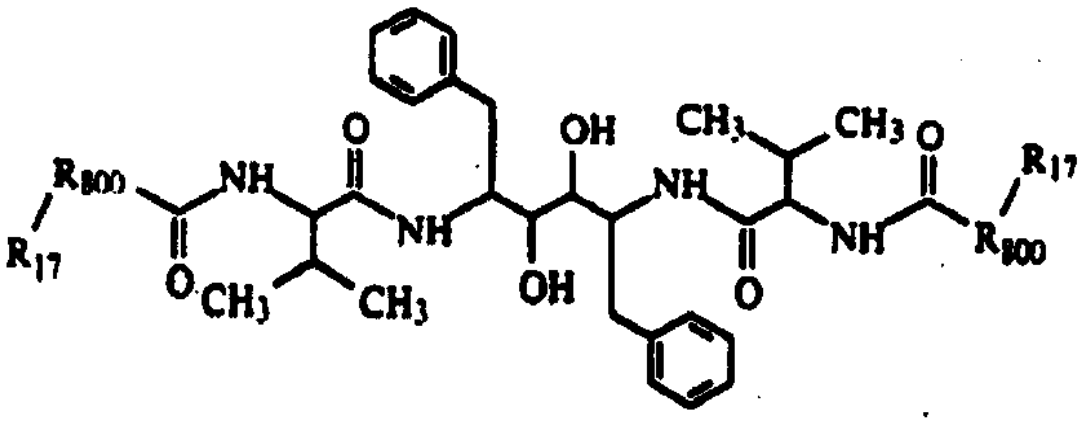
6 Sandstrom et al., "Antiviral Therapy In AIDS: Clinical Pharmacological Properties and Therapeutic Experience to Date," Drugs 34: 373-390 (1987).

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 '497 patent over the '056 patent.

The '497 patent contains eight claims, two of which are independent. Each one recites a compound. The first is the broadest claim and purports to cover variations in the compound's functional groups. Claims 2 through 7 purport to cover subsets of the variations described in claim 1. Claim 8, the second independent claim, recites a compound that is a single iteration of the category of compounds described in claim 1. It reads as follows:

> 8. The compound (2S,3S,5S)-2-(N-(N-((N-Methyl-N-((2-amino-4-thiazolyl)methyl)amino)carbonyl)valinyl)amino)-5-(N-((5-thiazolyl)-methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane; or a pharmaceutically acceptable salt thereof.

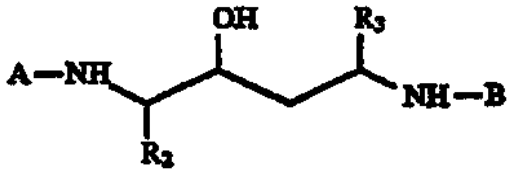
A compound disclosed in the '056 patent is represented as follows:



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 '497 patent. The additional hydroxyl group described in the '497 patent is inherent in or obvious in light of the '056 patent compound.

The chart below sets forth a comparison of all eight claims of the '497 patent to the teaching of the '056 patent. In essence, the compounds claimed in the '497 patent represent a genus of or are rendered obvious by the class of compounds disclosed in the '056 patent. Although the '056 patent may not have explicitly disclosed the exact compounds recited in the '497 patent, each element of the '497 patent's claims is either inherent in or rendered obvious by the '056 patent's teachings. Therefore each claim of the '497 patent is invalid and should be canceled.

'497 patent	'056 patent
1. A compound of the formula:  wherein R_2 and R_3 are independently selected from C_3-to-C_7-cycloalkyl-C_1-to-C_6-alkyl and (C_6-monocyclic or C_9-or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl; and (a) A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9-- C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH—C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 1, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.

'497 patent	'056 patent
C_1-to-C_6-alkyl-NH—C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and $-SO_3H$; or (b) A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH--C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and B is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9C(O)--NH--CH(R5)C(O)-- wherein R9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6- loweralkyl and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and $-SO_3H$; or a pharmaceutically acceptable salt thereof.	
2. The compound of claim 1 wherein A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9-- C(O)--NH--CH(R_5)--C(O)--	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 2, save one

'497 patent	'056 patent
wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH—C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H.	additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.
3. The compound of claim 2 wherein R_2 and R_3 are benzyl, A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O-- or –N(CH_3)-- and R_5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- or (substituted-thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- and wherein at each occurrence substituted-thiazolyl is as defined therein.	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 3, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.
4. The compound of claim 3 wherein R_5 is isopropyl and at each occurrence substituted -thiazolyl is independently amino-substituted thiazolyl or C_1-to-C_6-loweralkyl-substituted thiazolyl.	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 4, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.
5. The compound of claim 1 wherein A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH--C(O)--, thiazolyl-C_1-to-C_6-	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent

'497 patent	'056 patent
alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and B is thiazolyl-C_1-to-C_6- alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9--C(O)--NH--CH(R5)C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R_5 is C_1-to-C_6- loweralkyl and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H.	as the compound of claim 5, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.
6. The compound of claim 5 wherein R_2 and R_3 are benzyl, A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)-- and B is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6- alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O-- or –N(CH_3)-- and R_5 is C_1-to-C_6-loweralkyl and wherein at each occurrence substituted-thiazolyl is as defined therein.	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 6, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.
7. The compound of claim 6 wherein R_5 is isopropyl and at each occurrence substituted-thiazolyl is independently amino-substituted thiazolyl or C_1-to-C_6-loweralkyl-substituted thiazolyl.	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent as the compound of claim 7, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.
8. The compound (2S,3S,5S)-2-(N-(N-((N-Methyl-N-((2-amino-4-thiazolyl)methyl)amino)carbonyl)valinyl)amin	The '056 patent claims compounds and pharmaceutically acceptable salts of compounds having the same central substituent

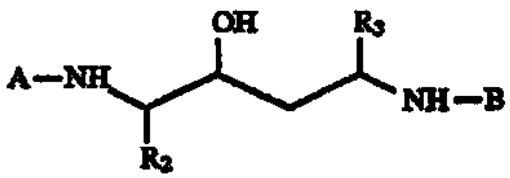
'497 patent	'056 patent
o)-5-(N-((5-thiazolyl)-methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane; or a pharmaceutically acceptable salt thereof.	as the compound of claim 8, save one additional hydroxyl group. The equivalence of the central substituent having an additional hydroxyl group was known in the art.

SIGAL ANTICIPATED OR RENDERED OBVIOUS THE '497 PATENT

In addition to being anticipated or rendered obvious by the '056 patent, the '497 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 '497 patent which has an effective filing date of March 24, 1995 as explained above. Pfizer v. Apotex is again instructive as to why the '497 patent is invalid over Sigal.

The chart below sets forth an element-by-element comparison of all eight claims of the '497 patent to the teaching of Sigal. In essence, the compounds claimed in the '497 patent represent a genus of or are rendered obvious by the class of compounds disclosed in Sigal. Sigal discloses compounds useful in the treatment of HIV and AIDS which have the identical central substituent as that of the compounds named in the claims of the '497 patent and pharmaceutically acceptable salts thereof. Sigal at 42. Although Sigal may not have explicitly disclosed the exact compounds recited in the '497 patent, each element of the '497 patent's claims is either inherent in or rendered obvious by Sigal's teachings. Therefore each claim of the '497 patent is invalid and should be canceled.

'497 patent	Sigal
1. A compound of the formula:	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 1.

'497 patent	Sigal
 wherein R_2 and R_3 are independently selected from C_3-to-C_7-cycloalkyl-C_1-to-C_6-alkyl and (C_6-monocyclic or C_9-or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl; and (a) A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9-- C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH—C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H; or (b) A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH--C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and B	

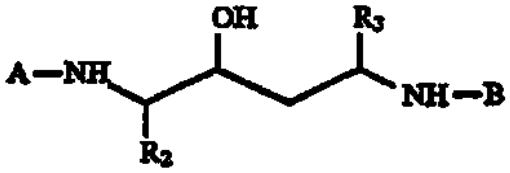
'497 patent	Sigal
is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9C(O)--NH--CH(R5)C(O)-- wherein R9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6- loweralkyl and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H; or a pharmaceutically acceptable salt thereof.	
2. The compound of claim 1 wherein A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9-- C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH—C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 2.

'497 patent	Sigal
3. The compound of claim 2 wherein R_2 and R_3 are benzyl, A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl-C_1-to-C_6-alkyl-R_9—O(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O-- or –N(CH_3)-- and R_5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- or (substituted-thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- and wherein at each occurrence substituted-thiazolyl is as defined therein.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 3.
4. The compound of claim 3 wherein R_5 is isopropyl and at each occurrence substituted -thiazolyl is independently amino-substituted thiazolyl or C_1-to-C_6-loweralkyl-substituted thiazolyl.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 4.
5. The compound of claim 1 wherein A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH--C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and B is thiazolyl-C_1-to-C_6- alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9--C(O)--NH--CH(R5)C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R_5 is C_1-to-C_6- loweralkyl and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 5.
6. The compound of claim 5 wherein R_2 and R_3 are benzyl, A is thiazolyl-C_1-to-C_6-alkyl-O—	Sigal discloses compounds and pharmaceutically acceptable salts of

'497 patent	Sigal
C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)-- and B is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6- alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O-- or –N(CH_3)-- and R_5 is C_1-to-C_6-loweralkyl and wherein at each occurrence substituted-thiazolyl is as defined therein.	compounds having the identical central substituent as the compound of claim 6.
7. The compound of claim 6 wherein R_5 is isopropyl and at each occurrence substituted-thiazolyl is independently amino-substituted thiazolyl or C_1-to-C_6-loweralkyl-substituted thiazolyl.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 7.
8. The compound (2S,3S,5S)-2-(N-(N-((N-Methyl-N-((2-amino-4-thiazolyl)methyl)amino)carbonyl)valinyl)amino)-5-(N-((5-thiazolyl)-methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane; or a pharmaceutically acceptable salt thereof.	Sigal discloses compounds and pharmaceutically acceptable salts of compounds having the identical central substituent as the compound of claim 8.

THE '497 PATENT WAS ANTICIPATED OR RENDERED OBVIOUS BY HO

Ho, published in January of 1995, predates the March 1995 filing of the '497 application and is thus prior art to the '497 patent under 102(a). Ho provides *in vivo* evidence that a compound nearly identical to that claimed in the '497 patent, referred to as ABT-538 in the article, was effective in treating HIV when administered to humans. Ho at 123. Ho thus anticipated the invention claimed in the '497 patent. The chart below sets forth an element-by-element comparison of all eight claims of the '497 patent to the teaching of Ho. Because Ho disclosed a method of treatment using almost the exact compound recited in the '497 patent, each element of the '497 patent's claims is either inherent in or rendered obvious by Ho's teachings. Therefore each claim of the '497 patent is invalid and should be canceled.

'497 patent	Ho
1. A compound of the formula:  wherein R_2 and R_3 are independently selected from C_3-to-C_7-cycloalkyl-C_1-to-C_6-alkyl and (C_6-monocyclic or C_9-or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl; and (a) A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9-- C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH—C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H; or (b) A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH--C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 1.

'497 patent	Ho
C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and B is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9C(O)--NH--CH(R5)C(O)-- wherein R9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6- loweralkyl and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and –SO_3H; or a pharmaceutically acceptable salt thereof.	
2. The compound of claim 1 wherein A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9-- C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH—C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 2.

'497 patent	Ho
C_6-alkyl, --COOH and $-SO_3H$.	
3. The compound of claim 2 wherein R_2 and R_3 are benzyl, A is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl-C_1-to-C_6-alkyl-R_9—O(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O-- or –N(CH_3)-- and R_5 is C_1-to-C_6-loweralkyl and B is thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- or (substituted-thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- and wherein at each occurrence substituted-thiazolyl is as defined therein.	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 3.
4. The compound of claim 3 wherein R_5 is isopropyl and at each occurrence substituted -thiazolyl is independently amino-substituted thiazolyl or C_1-to-C_6-loweralkyl-substituted thiazolyl.	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 4.
5. The compound of claim 1 wherein A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)--, thiazolyl-C_1-to-C_6-alkyl-NH--C(O)--, thiazolyl-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl)-C(O)--, (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)--, (substituted thiazolyl)-C_1-to-C_6-alkyl-NH—C(O)-- or (substituted thiazolyl)-C_1-to-C_6-alkyl-N(C_1-to-C_6-loweralkyl-C(O)-- and B is thiazolyl-C_1-to-C_6- alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-R_9--C(O)--NH--CH(R5)C(O)-- wherein R_9 is –O--, --NH-- or –N(C_1-to-C_6-loweralkyl)- and R_5 is C_1-to-C_6- loweralkyl and wherein at each occurrence substituted-thiazolyl is independently selected from a thiazolyl ring substituted with one or two substituents independently selected from C_1-to-C_6-loweralkyl, hydroxy, halo, amino, C_1-to-C_6-alkylamino, di-C_1-to-C_6-alkylamino, C_1-to-C_6-alkoxy, halo-C_1-to-C_6-alkyl, unsubstituted C_3-to-C_7-cycloalkyl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl, unsubstituted (C_6-monocyclic or C_9- or C_{10}-bicyclic)aryl-C_1-to-C_6-alkyl, --COOH and $-SO_3H$.	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 5.
6. The compound of claim 5 wherein R_2 and R_3	Ho taught the efficacy in AIDS/HIV treatment

'497 patent	Ho
are benzyl, A is thiazolyl-C_1-to-C_6-alkyl-O—C(O)-- or (substituted-thiazolyl)-C_1-to-C_6-alkyl-O—C(O)-- and B is thiazolyl-C_1-to-C_6-alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- or (substituted-thiazolyl)-C_1-to-C_6- alkyl-R_9—C(O)--NH--CH(R_5)--C(O)-- wherein R_9 is –O-- or –N(CH_3)-- and R_5 is C_1-to-C_6-loweralkyl and wherein at each occurrence substituted-thiazolyl is as defined therein.	of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 6.
7. The compound of claim 6 wherein R_5 is isopropyl and at each occurrence substituted-thiazolyl is independently amino-substituted thiazolyl or C_1-to-C_6-loweralkyl-substituted thiazolyl.	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 7.
8. The compound (2S,3S,5S)-2-(N-(N-((N-Methyl-N-((2-amino-4-thiazolyl)methyl)amino)carbonyl)valinyl)amino)-5-(N-((5-thiazolyl)-methoxycarbonyl)amino)-1,6-diphenyl-3-hydroxyhexane; or a pharmaceutically acceptable salt thereof.	Ho taught the efficacy in AIDS/HIV treatment of a compound having the identical central substituent and nearly identical side groups as a compound claimed in claim 8. The differences between the molecules consist merely of the movement of one hydroxyl group to the adjacent carbon atom and the substitution of an isopropyl group with an amine.

CONCLUSION

For the reasons set forth above, each of the claims of the '497 patent is invalid. Accordingly, PUBPAT respectfully requests that they be examined *ex parte* and subsequently canceled.

August 25, 2010

Date

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APPENDIX A

APPENDIX B

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	90/ ,
Filing Date	
First Named Inventor	Kempf, Dale J.
Art Unit	
Examiner Name	
Attorney Docket Number	

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5,142,056	08-25-1992	Kempf, et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	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]
		EP 0 337 714 A2	10-18-1989	Merck & Co. Inc.		

Examiner Signature		Date Considered	

*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] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

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

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	

*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.