PTO/SB/58 (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 *INTER PARTES* REEXAMINATION TRANSMITTAL FORM

Address to:
Mail Stop *Inter Partes* 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 *inter partes* reexamination pursuant to 37 CFR 1.913 of patent number 7,364,752 issued April 29, 2008. The request is made by a third party requester, identified herein below.

2. [X] a. The name and address of the person requesting reexamination is:

Public Patent Foundation
55 Fifth Avenue, Suite 928
New York, NY 10003

b. The real party in interest (37 CFR 1.915(b)(8)) is: _____

3. [ ] a. A check in the amount of $_____ is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(2);

[ ] b. The Director is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(2) 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 1.915(b)(5)

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) 1-10 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 1.915(b)(3)
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 1.915(b)(1) & (3).

13. [x] It is certified that the estoppel provisions of 37 CFR 1.907 do not prohibit this reexamination. 37 CFR 1.915(b)(7)

14. [x] a. It is certified that a copy of this request 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 2620.

15. Third Party Requester 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	State	Zip
New York	NY	10003

Country USA

Telephone	Email
(212) 790-0442	info@pubpat.org

16. [x] 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. _____
[x] d. Copending litigation styled:
Abbott Laboratories v. Matrix Laboratories, et al.,
09-cv-1586 (N.D. Ill.).

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., if applicable

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO.: 7,364,752

ISSUED: Apr. 29, 2008

TO: Fort et al.

FOR: SOLID DISPERSION PHARMACEUTICAL FORMULATIONS

ATTACHMENT TO FORM PTO/SB/58,
REQUEST FOR *INTER PARTES* 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 *inter partes* reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. § 1.913 of every claim of United States Patent No. 7,364,752 issued April 29, 2008 to Fort et al. and assigned to Abbott Laboratories ("the '752 patent") because they are all invalid under 35 U.S.C. §§ 102 and 103 and their existence is causing significant public harm.[1]

THE '752 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 than one million Americans.[3] Every person afflicted with HIV/AIDS has the right to obtain the

1 A copy of the '752 patent is attached hereto as Appendix A.
2 http://www.avert.org/worldstats.htm, last visited August 3, 2010.
3 http://www.avert.org/usa-statistics.htm, last visited August 3, 2010.

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 '752 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 '752 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 '752 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 '752 patent merits review by your office.

Additionally, PUBPAT points out that the application leading to the '752 patent was abandoned by applicants during prosecution due to what appears to have been pure negligence. On January 17, 2003, a Final Office Action was mailed rejecting the claims of the application. On September 30, 2003, a Notice of Abandonment was issued for applicants' failure to timely

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

file a reply to the January 2003 Final Office Action. Some two years later, applicants filed a petition to revive the application, arguing that the abandonment was "unintentional." However, it is clear from the reason given by applicants in their petition that this was not the case. Rather, it was pure negligence on the part of the applicants that caused at least a substantial portion of the two year period of abandonment.

Specifically, the applicants conceded that, "Applicant's representative first discovered that this application became abandoned when the present application was included in her docket after the previous Applicant's representative left the Company in May 2005." Petition to Revive Application Abandoned Unintentionally (September 9, 2005). Thus, the excuse given by applicants for the delay appears to be that there was a change in personnel responsible for the application. However, that change in personnel did not occur until May 2005, well over a year after the January Final Office Action was mailed. Thus, this explanation gives no reason for why the January 2003 Final Office Action wasn't responded to prior to the previous representative's departure from the company in 2005. The delay from January 2003 to May 2005 is entirely unexplained, and PUBPAT cannot fathom a reason that would justify such delay being held unintentional. As such, the granting of the petition by your office seems to have been in error. Again, although this issue is not grounds to grant this request for reexamination, PUBPAT respectfully requests that it be considered when determining whether the validity of the '752 patent merits review.

THE SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

1. Whether claims 1-10 of the '752 patent were anticipated by U.S. Patent No. 5,635,523 to Kempf et al. issued on June 3, 1997 ("the '523 patent");and,
2. Whether claims 1-10 of the '752 patent were rendered obvious by the '523 patent in view of Hancock, B., et al., "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems", *Journal of Pharmaceutical Sciences*, 86(1):1-12 (1997) ("Hancock"), and/or Royall, P., et al., "Characteristics of the Glass Transition of an Amorphous Drug Using Modulated DSC", *Pharmaceutical Research*, 15(7):1117-1121 (1998) ("Royall") in further view of U.S. Patent No. 5,955,475 to Krape et al. issued on September 21, 1999 ("Krape") or International Publication WO 97/21685 to Sham et al. published on June 19, 1997 ("Sham").

These are new questions because none of these references were of record during prosecution. A detailed explanation of the pertinency and manner of applying the cited patents and publications to the claims of the '752 patent is set forth below.[5]

THE '523 PATENT ANTICIPATED THE '752 PATENT

The '752 patent application was filed November 10, 2000. The applicants claimed priority to a provisional application, number 60/165,018 filed November 12, 1999. Therefore, the earliest possible priority date for the '752 patent is November 12, 1999. The '523 patent issued on June 3, 1997. Accordingly, the '523 patent is 102(b) prior art to the '752 patent. As explained below, the '523 patent anticipates each claim of the '752 patent.

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

The Federal Circuit set forth the appropriate standard for anticipation, and in particular inherent anticipation in the pharmaceutical arts, in Schering Corp. v. Geneva Pharms., 339 F.3d 1373 (Fed. Cir. 2003). There, the Federal Circuit said that anticipation requires, "a single prior art reference [that] discloses each and every limitation of the claimed invention." Id. at 1377. However, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. " Id. Further, the court rejected "the contention that inherent anticipation requires recognition in the prior art," and reconfirmed, "[t]he patent law principle 'that which would literally infringe if later in time anticipates if earlier.'" Id. at 1377, 1379 (citing Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed. Cir. 2001)).

With respect to inherency, the court confirmed that it has broad and unlimited scope, saying:

> Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art.

Id. at 1379.

Applying these principles in Schering, the court held that a later patent claiming a metabolite formed in a patient's body upon ingestion of a pharmaceutical was anticipated by a prior art reference disclosing the pharmaceutical itself despite the fact that it was conceded that the formation of the metabolite in a patient's body was not known or recognized by those of skill in the art prior to the filing of the application leading to the patent on the metabolite. The court

held that such recognition was not required to qualify for inherent anticipation. Id. at 1377 ("Other precedents of this court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. E.g., In re Cruciferous Sprout Litig., 301 F.3d 1343, 1351 (Fed. Cir. 2002); Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where ... the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results."); Atlas Powder, 190 F.3d at 1348-49 ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention. ... An inherent structure, composition, or function is not necessarily known.")")

Here, the claims of the '752 patent are directed to pharmaceutical compositions comprising amorphous ritonavir. There are no limitations or requirements as to the quantity (by volume, or otherwise) of amorphous ritonavir. Therefore, a composition containing a very small amount of amorphous ritonavir is covered by the claims, and this is regardless of whether that amount of amorphous ritonavir is combined in mixture with crystalline ritonavir. In fact, those of skill in the art readily understood that, "[p]harmaceutical solids rarely exist as 100% crystalline or 100% amorphous." Hancock, 5. A single body of ritonavir can be (and actually would be expected to be) made of parts that are crystalline and parts that are amorphous. Those amorphous parts are themselves amorphous ritonavir. Therefore, a prior art teaching of compositions containing ritonavir that is not expressly 100% crystalline, inherently includes compositions containing amorphous ritonavir.

Further, there are no limitations or requirements in the claims of the '752 patent that it be

known or recognized that the compositions containing ritonavir produced includes amorphous ritonavir. Referring to the "patent law principle" cited above, compositions containing ritonavir in amorphous form (either by itself or in combination with ritonavir in crystalline form) would infringe the claims of the '752 patent, regardless of whether anyone was aware of the fact that it was in that form. Thus, a prior art teaching of compositions containing ritonavir in any state other than 100% pure crystalline form anticipates the claims of the '752 patent even if that prior art reference does not disclose that the ritonavir would be partially (or completely) amorphous. The fact that it wasn't expressly recognized that ritonavir compositions would be partially crystalline and partially amorphous does not defeat this anticipatory effect.

The '523 patent is precisely such a reference. It discloses compositions containing ritonavir and it is not expressly shown that each and every disclosed composition contained ritonavir that existed in 100% crystalline form. '523 patent, 107:13-51 ("One preferred dosage form for the compounds of the invention comprises a solid dosage form for oral administration"). Therefore, one of ordinary skill in the art would inherently understand that at least some of the '523 patent's compositions containing ritonavir contained ritonavir that was partially or perhaps even completely amorphous. It is impossible to fathom that the entirety of teachings of the '523 patent are completely void of any inherent existence of amorphous ritonavir.

The '523 patent also taught compositions containing amorphous ritonavir (i) in the form of gelatin capsules (106:49; 107:26-51), (ii) in the form of tables (106:49), (iii) comprising propylene glycol, which is a petroleum derivative that acts as a solvent, surfactant, and wetting agent, like PEG (107:27), (iv) in combination with other retroviral protease inhibitors, and

specifically HIV protease inhibitors, (107:52-67, 109:21-26), (v) comprising diluents (106:49-51), and (vi) for use in treating HIV (105:58-67). These are the additional limitations of the dependent claims of the '752 patent, and therefore provide no patentable distinction over the '523 patent.

The chart below compares all of the claims of the '752 patent to the teaching of the '523 patent. In essence, each claim of the '752 patent was inherently anticipated by the teaching of the '523 patent. Therefore each claim of the '752 patent is invalid and should be canceled.

'752 patent	**'523 patent**
1. A pharmaceutical composition comprising ritonavir, wherein ritonavir in said composition is formulated as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer.	The '523 patent disclosed compositions containing ritonavir in a matrix including a water soluble polymer and it is not expressly proven that each and every composition contained ritonavir that existed in 100% crystalline form. Therefore, one of ordinary skill in the art would inherently understand that at least some of the '523 patent's compositions containing ritonavir contained ritonavir that was partially or perhaps even completely amorphous. Further, since there are no limitations or requirements as to the quantity (by volume, or otherwise) of amorphous ritonavir in the compositions, compositions containing a very small amount of amorphous ritonavir are covered by this claim, and this is regardless of whether the compositions also contain crystalline ritonavir. A single body of ritonavir can be (and actually would be expected to be) made of parts that are crystalline and parts that are amorphous. Those amorphous parts are themselves substantially pure amorphous ritonavir as claimed here. Therefore, a prior art teaching of compositions containing ritonavir

'752 patent	'523 patent
	that is not expressly 100% crystalline, inherently includes compositions containing amorphous ritonavir.
2. A pharmaceutical composition of claim 1, comprising a gelatin capsule which encapsulates said solid dispersion.	The '523 patent expressly taught its compositions could comprise a gelatin capsule which encapsulates the solid dispersion. 106:49; 107:26-51.
3. A pharmaceutical composition of claim 1 which is a tablet comprising said solid dispersion.	The '523 patent expressly taught its compositions could comprise a tablet comprising the solid dispersion. 106:49
4. The pharmaceutical composition of claim 1, wherein said water soluble polymer is PEG.	The '523 patent expressly taught its compositions could comprise a petroleum derivative that acts as a solvent, surfactant, and wetting agent, like PEG. 107:27.
5. The pharmaceutical composition of claim 1, wherein said water soluble polymer is PEG 8000.	The '523 patent expressly taught its compositions could comprise a petroleum derivative that acts as a solvent, surfactant, and wetting agent, like PEG 8000. 107:27.
6. The pharmaceutical composition of claim 1, wherein said solid dispersion further comprises (2S,3S,5S)-2-(2,6-dimethylphenoxyacetyl)amino-3-hydroxy-5-[2S-(1-tetrahydro-pyrimid-2-onyl)-3-methylbutanoyl]amino-1,6-diphenylhexane (ABT-378).	The '523 patent expressly taught its compositions could be administered in combination with other retroviral protease inhibitors, and specifically HIV protease inhibitors. 107:52-67, 109:21-26.
7. The pharmaceutical composition of claim 1, further comprising a pharmaceutically-acceptable filler, diluent, lubricant or disintegrant.	The '523 patent expressly taught its compositions could comprise diluents. 106:49-51.
8. The pharmaceutical composition of claim 1, wherein said solid dispersion is ground and formulated into a delivery system.	The '523 patent inherently taught its compositions could contain solid dispersion that is ground and formulated into a delivery system, as such was well known within the pharmaceutical arts at the time.
9. A method of treating an HIV infection comprising administering a pharmaceutical	The '523 patent expressly taught its compositions were useful to treat HIV. 105:58-

'752 patent	'523 patent
composition of claim 1 to a mammal in need of such treatment.	67.
10. A method of treating an HIV infection comprising administering the pharmaceutical composition of claim 6 to a mammal in need of such treatment.	The '523 patent expressly taught its compositions were useful to treat HIV. 105:58-67.

THE '523 PATENT IN VIEW OF HANCOCK AND/OR ROYALL IN FURTHER VIEW OF KRAPE OR SHAM RENDERED THE '752 PATENT OBVIOUS

As discussed above, the earliest possible priority date for the '752 patent is November 12, 1999. Hancock is a publication that was published in January 1997, and is therefore 102(b) prior art to the '752 patent. Royall is a publication that was received for publication in November 1997, and is therefore 102(b) prior art to the '752 patent. Krape was applied for on June 30, 1997, and is therefore 102(e) prior art to the '752 patent. Sham was published on June 19, 1997, and is therefore 102(b) prior art to the '752 patent. As explained below, the combined teachings of the '523 patent in view of Hancock and/or Royall in further view of Krape or Sham rendered obvious each claim of the '752 patent.

The Supreme Court set forth the appropriate standard for obviousness in KSR v. Teleflex, 127 S.Ct. 1727 (2007). In KSR, the Supreme Court reaffirmed its holding in Graham v. John Deere that obviousness is principally a three-prong analysis whereby "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." Id. at 1734 (citing

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966)). Since the KSR decision, the Federal Circuit has restated that the obviousness inquiry also requires a showing that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention and that the skilled artisan would have had a reasonable expectation of success in doing so. Pfizer v. Apotex, 480 F. 3d 1348, 1361 (Fed. Cir. 2007).

However, although the Federal Circuit may have in the past implemented a rigid rule that a patent claim cannot be rendered obvious merely because it was "obvious to try," the Supreme Court in KSR expressly reversed that rule, saying:

> The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." ... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

127 S. Ct. at 1742. Further, as the Federal Circuit has stated post-KSR, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." Pfizer v. Apotex, 480 F. 3d at 1364. Thus, under binding recent Federal Circuit case law, there is a reasonable expectation of success and the claims are thus obvious if, (i) one of ordinary still in the art would have been motivated to combine the teachings in the prior art, (ii) it was in fact obvious-to-try to do that, and (iii) there was only a limited number of parameters that one of ordinary skill in the art would have to try in order to

successfully achieve the claimed invention. Pfizer v. Apotex, 480 F. 3d at 1366.

Here, the '523 patent taught compositions comprising ritonavir and their use as an HIV protease inhibitor. The '523 patent also taught compositions containing ritonavir (i) in the form of gelatin capsules (106:49; 107:26-51), (ii) in the form of tables (106:49), (iii) comprising propylene glycol, which is a petroleum derivative that acts as a solvent, surfactant, and wetting agent, like PEG (107:27), (iv) in combination with other retroviral protease inhibitors, and specifically HIV protease inhibitors, (107:52-67, 109:21-26), (v) comprising diluents (106:49-51), and (vi) for use in treating HIV (105:58-67).

Hancock taught that, "[t]he amorphous state is critical in determining the solid-state physical and chemical properties of many pharmaceutical dosage forms," and "[t]he high internal energy and specific volume of the amorphous state relative to the crystalline state can lead to enhanced dissolution and bioavailability." Hancock, Abstract and 2. Hancock further taught the four most common ways in which amorphous character can be induced in pharmaceutical systems, namely (i) vapor condensation, (ii) precipitation from solution, (iii) supercoolng of melt, and (iv) milling and compaction of crystals. Hancock, 1.

Royall taught that, "[t]he significance of the amorphous state in pharmaceutical systems has been widely discussed" and then continued to specifically investigate the amorphous state of the HIV protease inhibitor saquinavir. 1117-1118. Therefore, Hancock and Royall expressly taught, suggested and motivated the creation and investigation of amorphous forms of pharmaceuticals and specifically HIV protease inhibitors like ritonavir.

This is not the case where there would be an unlimited number of parameters to try in

order to achieve amorphous ritonavir, as Hancock teaches the four well known methods for doing so. Therefore, one of ordinary skill in the art was expressly motivated to derive amorphous ritonavir in order to determine its pharmacological characteristics and was expressly taught how to do so. As such, the claims of the '752 patent were obvious in light of the combined teachings of the '523 patent in view of Hancock and/or Royall in further view of Krape or Sham.

Krape taught a process for manufacturing solid dispersions of poorly soluble pharmaceuticals. Specifically of relevance to the '752, Krape taught solid dispersions in the form of gelatin capsules or tables (9:28, 12:7-8) and comprising PEG 8000 (9:42 – 11:50). Krape also taught solid dispersions that could be made by grinding or milling product to an acceptable particle size. 10:21-22.

Sham disclosed ABT-378 and expressly taught co-administering ritonavir with ABT-378 to treat HIV. 126-127 ("In a most preferred combination, a compound of this invention is administered in combination with ritonavir").

The chart below compares all of the claims of the '752 patent to the teachings of the '523 patent in view of Hancock and/or Royall and further in view of Krape or Sham. In essence, each claim of the '752 patent was obvious in light of the teachings of the '523 patent in view of Hancock and/or Royall and further in view of Krape or Sham. Therefore each claim of the '752 patent is invalid and should be canceled.

'752 patent	**'523 patent in view of Hancock and/or Royall in further view of Krape or Sham**
1. A pharmaceutical composition comprising	The '523 patent disclosed compositions

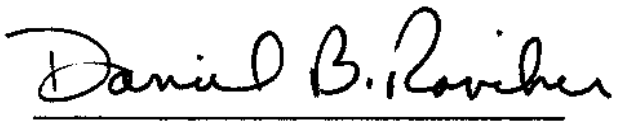
'752 patent	'523 patent in view of Hancock and/or Royall in further view of Krape or Sham
ritonavir, wherein ritonavir in said composition is formulated as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer.	containing ritonavir in a matrix including a water soluble polymer. Hancock taught, motivated and suggested that the amorphous form of pharmaceutical compounds be derived and analyzed, and Royall taught, motivated and suggested investigation into the amorphous forms of specifically HIV protease inhibitors, like ritonavir. Therefore, one of ordinary skill in the art would have pursued the creation of compositions containing amorphous ritonavir as claimed here.
2. A pharmaceutical composition of claim 1, comprising a gelatin capsule which encapsulates said solid dispersion.	The '523 patent expressly taught its compositions could comprise a gelatin capsule which encapsulates the solid dispersion. 106:49; 107:26-51. Krape expressly taught solid dispersions of poorly soluble pharmaceuticals being made into tablets. 9:28, 12:7-8
3. A pharmaceutical composition of claim 1 which is a tablet comprising said solid dispersion.	The '523 patent expressly taught its compositions could comprise a tablet comprising the solid dispersion. 106:49. Krape expressly taught solid dispersions of poorly soluble pharmaceuticals being made into tablets. 9:28, 12:7-8
4. The pharmaceutical composition of claim 1, wherein said water soluble polymer is PEG.	The '523 patent expressly taught its compositions could comprise a petroleum derivative that acts as a solvent, surfactant, and wetting agent, like PEG. 107:27. Krape expressly taught the use of PEG in solid dispersions of poorly soluble pharmaceuticals. 9:42 – 11:50
5. The pharmaceutical composition of claim 1, wherein said water soluble polymer is PEG 8000.	The '523 patent expressly taught its compositions could comprise a petroleum derivative that acts as a solvent, surfactant, and wetting agent, like PEG 8000. 107:27. Krape expressly taught the use of PEG 8000 in solid dispersions of poorly soluble pharmaceuticals. 9:42 – 11:50

'752 patent	'523 patent in view of Hancock and/or Royall in further view of Krape or Sham
6. The pharmaceutical composition of claim 1, wherein said solid dispersion further comprises (2S,3S,5S)-2-(2,6-dimethylphenoxyacetyl)amino-3-hydroxy-5-[2S-(1-tetrahydro-pyrimid-2-onyl)-3-methylbutanoyl]amino-1,6-diphenylhexane (ABT-378).	The '523 patent expressly taught its compositions could be administered in combination with other retroviral protease inhibitors, and specifically HIV protease inhibitors. 107:52-67, 109:21-26. Sham expressly taught co-administering ritonavir with ABT-378 to treat HIV. 126-127.
7. The pharmaceutical composition of claim 1, further comprising a pharmaceutically-acceptable filler, diluent, lubricant or disintegrant.	The '523 patent expressly taught its compositions could comprise diluents. 106:49-51.
8. The pharmaceutical composition of claim 1, wherein said solid dispersion is ground and formulated into a delivery system.	The '523 patent inherently taught its compositions could contain solid dispersion that is ground and formulated into a delivery system, as such was well known within the pharmaceutical arts at the time. Krape expressly taught solid dispersions that were ground and formulated into a delivery system. 10:21-22.
9. A method of treating an HIV infection comprising administering a pharmaceutical composition of claim 1 to a mammal in need of such treatment.	The '523 patent expressly taught its compositions were useful to treat HIV. 105:58-67.
10. A method of treating an HIV infection comprising administering the pharmaceutical composition of claim 6 to a mammal in need of such treatment.	The '523 patent expressly taught its compositions were useful to treat HIV. 105:58-67. Sham expressly taught co-administering ritonavir with ABT-378 to treat HIV. 126-127.

CONCLUSION

For the reasons set forth above, each of the claims of the '752 patent is invalid. Accordingly, PUBPAT respectfully requests that they be reexamined *inter partes* and subsequently canceled.

August 25, 2010
Date



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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of this Request for Inter Partes Reexamination in its entirety, including all accompanying documents, is being deposited with the U.S. Postal Service as First Class Mail on the date of the signature below in an envelope addressed to the attorney of record for the assignee of U.S. Patent No. 7,364,752 as provided for in 37 C.F.R. § 1.33(c):

PAUL D. YASGER
ABBOTT LABORATORIES
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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	95/
Filing Date	
First Named Inventor	Fort
Art Unit	
Examiner Name	
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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- 5,635,523	06-03-1997	Kempf et al.	
		US- 5,955,475	09-21-1999	Krape et al.	
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FOREIGN PATENT DOCUMENTS

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		WO 97/21685	06-19-1997	Abbott Laboratories		

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Sheet 2 of 2

Complete if Known	
Application Number	95/___,___
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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]
		Hancock, B., et al., "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems", Journal of Pharmaceutical Sciences, 86(1):1-12 (1997)	
		Royall, P., et al., "Characteristics of the Glass Transition of an Amorphous Drug Using Modulated DSC", Pharmaceutical Research, 15(7):1117-1121 (1998)	

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.

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