64660 U.S.PTO
09/17/04

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(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: 09-14-2004

1. ☑ This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 5,969,156 issued Oct. 19, 1999. The request is made by:

   ☐ patent owner. ☑ third party requester.

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2. ☑ The name and address of the person requesting reexamination is:

   Public Patent Foundation
   1375 Broadway, Suite 600
   New York, NY 10018

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. _____ (submit duplicate of this form for fee processing); 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

7. ☐ Nucleotide and/or Amino Acid Sequence Submission
   If applicable, all of the following are necessary.

   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) 1-44 is requested.

10. ☑ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO-1449 or equivalent.

11. ☑ An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

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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 1.14. 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: Mail 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.

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:

_____

_____

_____

Date of Service: _____; or

☑ b. A duplicate copy is enclosed since service on patent owner was not possible.

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

☐ Customer Number:

OR

☑ Firm or Individual Name	Public Patent Foundation				
Address (line 1)	1375 Broadway, Suite 600				
Address (line 2)					
City	New York	State	NY	Zip	10018
Country	USA				
Telephone	(212) 545-5337	Fax	(212) 591-6038		

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:
There are too many cases to list them all in this space.
Please see attached Appendix C to this request.

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.

[redacted] 09-14-2004
Authorized Signature *Date*

DANIEL B. RAVICHER 47,015
Typed/Printed Name *Registration No., if applicable*

☐ *For Patent Owner Requester*
☑ *For Third Party Requester*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO.: 5,969,156

ISSUED: October 19, 1999

FOR: CRYSTALLINE [R- (R*,R*)]-2-(4-DFLUOROPHENYL)-. BETA.,.DELTA.-DIHYDROXY-5-(1-METHYLETHYL)- 3-PHENYL-4-[(PHENYLAMINO)CARBONYL]-1H-PYRROLE-1-HEPTANOIC ACID HEMI CALCIUM SALT (ATORVASTATIN)

ATTACHMENT TO FORM PTO-1465,
REQUEST FOR *EX PARTE* REEXAMINATION

SIR:

The Public Patent Foundation ("PUBPAT"), a not-for-profit public service organization working to protect the public from the harms caused by wrongly issued 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 all claims of United States Patent No. 5,969,156 issued October 19, 1999 to Briggs et al. ("'156 patent") because they are each invalid under 35 U.S.C. § 102 and their existence is causing significant public harm.[1]

THE '156 PATENT IS CAUSING SIGNIFICANT PUBLIC HARM

The '156 patent claims crystalline forms of atorvastatin, a cholesterol-lowering pharmaceutical product marketed by Pfizer Inc. ("Pfizer") under the trade name Lipitor® ("Lipitor"). According to Pfizer's most recent Quarterly Report filed with the Securities and

1 Appendix A contains a copy of the '156 patent.

Exchange Commission, "Lipitor is the best-selling treatment for lowering cholesterol and the best-selling pharmaceutical product of any kind in the world."[2] More specifically, in just the second quarter of 2004 alone, Pfizer made $2.4B from the sale of Lipitor.

Lipitor's success is due to the substantial health benefits provided by atorvastatin. As Pfizer stated in its Quarterly Report, "Lipitor continues to gain wide physician and patient acceptance based on its ability to bring the vast majority of patients to target cholesterol goals across the full dosing range, with an excellent safety profile." Yet, millions of Americans are not receiving the substantial health benefits offered by atorvastatin. As Pfizer concedes in its Quarterly Report, "of the tens of millions of Americans that are in need of medical therapy for high cholesterol, only one third are actually receiving treatment." A primary reason why millions of Americans are not getting the cholesterol lowering treatment they need and deserve is that the price for Lipitor is too high. A one-month supply of Lipitor can cost up to $132 and, to make things worse, Pfizer recently ended its discount program for the elderly.[3]

Pfizer is able to charge such a high price for Lipitor because the '156 patent stands as an impediment to the marketing of a generic atorvastatin pharmaceutical product. In just the past few months, Pfizer sued no less than two dozen different distributors of generic atorvastatin for patent infringement.[4] In each case, the only basis asserted by Pfizer for preventing the marketing of generic atorvastatin in the United States is the '156 patent. As such, the '156 patent is causing significant public harm by impeding the marketing of generic atorvastatin to Americans. Pfizer's patent-provided monopoly over atorvastatin not only injures the economy by

2 Pfizer Inc., Quarterly Report, August 6, 2004.

3 Price data available from www.NYAGRx.org; Pfizer Ends Discount Card for the Elderly, CNNMoney, September 1, 2004, available at http://money.cnn.com/2004/09/01/news/fortune500/pfizer/ ("Newspaper reports 536,000 low-income seniors will lose access to discounted drugs").

4 Appendix C contains a list of copending litigation; Pfizer Sues False Lipitor Web Sites, September 2, 2004, available at http://www.forbes.com/technology/ sciences/feeds/ap/2004/09/02/ap1529371.html.

forcing Americans to pay supra-competitive prices for atorvastatin, it also causes significant harm to the public health by denying millions of Americans the medical treatment they need and deserve. Although these issues are not grounds to grant this request for reexamination, PUBPAT respectfully requests they be considered in determining whether or not a substantial new question of patentability exists and, ultimately, whether the '156 patent should be revoked in its entirety.

THE SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

The substantial new questions of patentability raised by this request are (1) whether all claims of the '156 patent were anticipated by U.S. Patent No. 5,273,995 to Roth ("Roth") and (2) whether all claims of the '156 patent were anticipated by U.S. Patent No. 5,686,104 to Mills et al. ("Mills") (Roth and Mills are, collectively, "the Cited Prior Art").[5] These are substantial new questions of patentability because neither of the Cited Prior Art were applied during prosecution of the '156 patent and they each individually disclose the purported invention of the '156 patent, while the prior art that was applied during prosecution of the '156 patent did not. A detailed explanation of the pertinency and manner of applying each of the Cited Prior Art to every claim of the '156 patent is set forth below.

THE CITED PRIOR ART EACH ANTICIPATE EVERY CLAIM OF THE '156 PATENT

The '156 patent application date is July 17, 1995. As such, since Roth issued on December 28, 1993, more than a year before the application date of the '156 patent, it is prior art to the '156 patent under 35 U.S.C. § 102(b), and since Mills' effective application date is January 19, 1993, prior to the application date of the '156 patent, it is prior art to the '156 patent under 35 U.S.C. § 102(e).

Each of the 44 claims of the '156 patent claim crystalline atorvastatin. '156 patent,

5 Appendix B contains a copy of the Cited Prior Art.

column 15, line 41 – column 18, line 33. Atorvastatin is identified by the specification of the '156 patent as being "known by the chemical name [R-(R*,R*)]-2-(4-fluorophenyl)-.beta.,.delta.-dihydroxy-5-(1-methylethyl)- 3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid hemi calcium salt." '156 patent, column 1, lines 13 – 16. The claims of the '156 patent differ only in having limitations regarding either (a) X-ray powder diffraction values, (b) solid-state ^{13}C nuclear magnetic resonance chemical shift differences, or (c) moles of water. '156 patent, column 15, line 41 – column 18, line 34. However, these limitations are merely physical properties that help differentiate between purported different crystalline forms of atorvastatin. As such, they do not change the fact that each claim of the '156 patent claims crystalline atorvastatin.

Long before the '156 patent application was filed, Roth disclosed crystalline atorvastatin. Specifically, Roth's Example 10 taught "[]crystallized" atorvastatin and claim 6 claimed "[t]he hemicalcium salt of [[R-(R*R*)]-2-(4-fluorophenyl)-.beta.-.delta.-dihydroxy-5-(1-methylethyl)-3 -phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid]," the chemical name identified by the '156 patent for atorvastatin. Roth, column 14, line 64 – column 16, line 14, column 16, line 67 – column 17, line 2, and column 17, line 12. Therefore, each of the claims of the '156 patent are invalid under 35 U.S.C. § 102(b) as being anticipated by Roth.

Likewise, prior to the filing of the '156 patent application, Mills disclosed crystalline atorvastatin, labeled by Mills as "CI-981". Mills, column 4, line 64 – column 5, line 1 ("[t]he most preferred compound of the present invention, CI-981 (structural Formula IA), is ... [R-(R*R*)]-2-(4-fluorophenyl)-.beta.,.delta.-dihydroxy-5-(1-methylethyl)-3 -phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, hemicalcium salt," the chemical name identified by the '156 patent for atorvastatin). Specifically, Mills' Example A taught "[]

crystallized" atorvastatin and claim 4 claimed "[a] stable pharmaceutical composition ... wherein the active ingredient is CI-981 Hemi-Calcium of Formula (IA) ... and wherein the stabilizing pharmaceutically acceptable metal salt additive is calcium carbonate." Mills, column 8, line 61 – column 9, line 30 and column 15, lines 40 – 58. Further, note that Mills incorporated the teachings of Roth discussed above. Mills, column 4, lines 54 – 55. Therefore, each of the claims of the '156 patent are invalid under 35 U.S.C. § 102(e) as being anticipated by Mills.

The '156 patent attempts to distinguish itself over certain identified prior art patents by stating they only "disclose amorphous atorvastatin." '156 patent, column 1, lines 62 – 63. And, indeed, the single prior art reference applied in the prosecution of the '156 patent was believed by the Examiner to only disclose amorphous atorvastatin. However, as discussed above, both Roth and Mills both disclose crystalline atorvastatin. Therefore, this argument cannot distinguish the '156 patent claims from Roth and Mills.

Further, the '156 patent attempts to distinguish itself over the prior art by stating it discloses "atorvastatin in a pure and crystalline form to enable formulations to meet exacting pharmaceutical requirements and specifications." '156 patent, column 1, lines 52 – 54. However, none of the claims of the '156 patent contain any limitation regarding pharmaceutical requirements or specifications, and both Roth and Mills taught atorvastatin in the form of a pharmaceutical product. Roth, column 2, lines 39 – 40 ("The present invention also relates to a pharmaceutical composition") and Mills, column 11, lines 20 – 43 (disclosing a "Method of Preparation of [Atorvastatin] Pharmaceutical Composition"). Therefore, this argument cannot distinguish the '156 patent claims from Roth and Mills.

CONCLUSION

For the reasons set forth above, each of the claims of the '156 patent are invalid in light of the Cited Prior Art. PUBPAT respectfully requests that they be reexamined ex parte.

09-14-2004

Date

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