



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,209	09/17/2004	5969156		3367

7590 06/13/2005
Francis J. Tinney
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action in Ex Parte Reexamination	Control No. 90/007,209	Patent Under Reexamination 5969156	
	Examiner Deborah C. Lambkin	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

- a Responsive to the communication(s) filed on 4/11/05 b This action is made FINAL.
c A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 3 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 3. <input type="checkbox"/> Interview Summary, PTO-474. |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statement, PTO-1449. | 4. <input type="checkbox"/> _____. |

Part II SUMMARY OF ACTION

- 1a. Claims 1-44 are subject to reexamination.
1b. Claims _____ are not subject to reexamination.
2. Claims _____ have been canceled in the present reexamination proceeding.
3. Claims _____ are patentable and/or confirmed.
4. Claims 1-44 are rejected.
5. Claims _____ are objected to.
6. The drawings, filed on _____ are acceptable.
7. The proposed drawing correction, filed on _____ has been (7a) approved (7b) disapproved.
8. Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of the certified copies have
1 been received.
2 not been received.
3 been filed in Application No. _____.
4 been filed in reexamination Control No. _____.
5 been received by the International Bureau in PCT application No. _____.
* See the attached detailed Office action for a list of the certified copies not received.
9. Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. Other: _____

cc: Requester (if third party requester)

Claim 1-44 are under reexam.

The instant reexam is claiming various crystalline forms, I, II and IV, of the anti-cholesterol drug, Atorvastatin or Lipitor.

The question is whether the prior art compounds of Roth and Mills et al teach amorphous or crystalline forms of atorvastatin, and if it is the latter (since a showing was already made over the amorphous form during prosecution of the patent in question), then a prima facie case of obviousness exists and applicant must then come in with a showing that the new crystalline forms possess unobvious or unexpected results over their obvious variant counterparts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,273,995 (Roth) and/or US 5,686,104(Mills et al).

The instant reexam is claiming various crystalline forms of atorvastatin or Lipitor, namely, Forms I, II and IV.

Roth teaches a specific enantiomer of the racemic compound, atorvastatin or Lipitor. It is not absolutely clear if the compound disclosed in Roth is amorphous or crystalline, however, in col. 15, line 51, the word "recrystallized" is recited. This implies

that the compound was initially crystallized. On this basis, it is assumed that the compound in Roth existed in a crystalline form unless applicant can show otherwise. Hence, if this is the case, then the instant crystalline forms of Lipitor are prima facie obvious variants of the known crystalline form of Roth. In other words, different crystalline forms of the same compound are obvious variants to the ordinary skilled artisan, absent some unobvious or unexpected result.


Likewise, Mills et al teach essentially the same compound of Roth et al (col. 2, lines 60-63), however in a more stable ORAL pharmaceutical composition. Mills is silent to the crystallinity of the atorvastatin compound used and hence may be redundant of Roth (this is why and/or is used above). If the compound in Mills et al is different from that of Roth et al in terms of amorphism or crystallinity, applicant is requested to disclose this; however the more pertinent question is whether or not the compounds of Mills et al and/or Roth are different crystalline forms of atorvastatin compared to those of the instant reexam patent. If the former is true then applicant needs to make a showing over both the compounds of Roth and Mills et al (provided that they are crystalline, if they are amorphous, no showing is needed), alternatively, if the latter is true then only one showing is needed.

Note: Applicant's attention is drawn to US patent 6,605,636, where the compound in US patent 5,273,995 (Roth referred to here in the instant 103 rejection) is referred to as crystallized (col. 2, lines 21-26). Applicant is requested to comment on this statement.

Art Unit: 1626

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 571-272-0698.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699.


DEBORAH C. LAMBKIN
PRIMARY EXAMINER
Deborah C. Lambkin
Primary Patent Examiner
Art Unit 1626



DO NOT USE IN PALM PRINTER

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

PUBLIC PATENT FOUNDATION
1375 BROADWAY, SUITE 600
NEW YORK, NY 10018

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/007,209.

PATENT NO. 5969156.

ART UNIT 1600.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).