



UNITED STATES PATENT AND TRADEMARK OFFICE

BEST PRACTICES IN REISSUES PART II

Addressing specific 35 USC 251 issues in depth

- 1) **Amendments to the claims**
- 2) **Amendments to the specification**
- 3) **Amendments to the drawings**
- 4) **Certificate of correction**
- 5) **Proper format for oath/declaration**
- 6) **Amendments to a reissue of a reissue**

Part I can be found at <http://www.cablc.com/bcp/090209>



UNDERSTANDING CLAIM AMENDMENTS

A copy of a claim set from a patented reissue

1. A [pharmaceutical] composition comprising [an active ingredient which is] *an analogue of* sulforaphane ((-)-1-isothiocyanato-(4R)-(methylsulfinyl)butane) [(CAS 4478-93-7) or an analogue thereof], said analogue being selected from the group consisting of: 6-isothiocyanato-2-hexanone [(GHP 1105)]; *exo*-2-acetyl-6-isothiocyanatonorbornane [(GHP 1066)]; *exo*-2-isothiocyanato-6-methylsulfonylnorbornane [(GHP 1068)]; 6-isothiocyanato-2-hexanol [(GHP 1106)]; 1-isothiocyanato-4-dimethylphosphonylbutane [(GHP 1078)]; *exo*-2-(1'-hydroxyethyl)-5-isothiocyanatonorbornane [(GHP 1075)]; *exo*-2-acetyl-5-isothiocyanatonorbornane [(GHP 1067)]; 1-isothiocyanato-5-methylsulfonylpentane [(GHP 1003)]; and *cis*- or *trans*-3-(methylsulfonyl)cyclohexylmethylisothiocyanate [(GHP 1079 or 1080)].

[2. The pharmaceutical composition of claim 1 wherein said active ingredient is sulforaphane.]

15. *A composition comprising an active ingredient which is sulforaphane ((-)-1-isothiocyanato-(4R)-(methylsulfinyl)butane) or an analogue thereof, said analogue being selected from the group consisting of: 6-isothiocyanato-2-hexanone; exo-2-acetyl-6-isothiocyanatonorbornane; exo-2-isothiocyanato-6-methylsulfonylnorbornane; 6-isothiocyanato-2-hexanol; 1-isothiocyanato-4-dimethylphosphonylbutane; exo-2-(1'-hydroxyethyl)-5-isothiocyanatonorbornane; exo-2-acetyl-5-isothiocyanatonorbornane; 1-isothiocyanato-5-methylsulfonylpentane; and cis- or trans-3-(methylsulfonyl)cyclohexylmethylisothiocyanate, and a suitable excipient.*



AMENDMENT TO CLAIMS

When amending reissue claims one uses markings in comparison with the existing patent claims each time there is an amendment.

One does not use the markings from the previous amendment.

The amendment must be made in accordance with 37 CFR 1.173.

Claims - An amendment paper must include the entire text of each claim being changed by such amendment paper and of each claim being added by such amendment paper. For any claim changed by the amendment paper, a parenthetical expression "amended," "twice amended," etc., should follow the claim number. Each changed patent claim and each added claim must include markings pursuant to paragraph (d) of this section, except that a patent claim or added claim should be canceled by a statement canceling the claim without presentation of the text of the claim.



AMENDMENT TO CLAIMS

(d) Changes shown by markings. “Any changes relative to the patent being issued which are made to the specification, including the claims, upon filing, or by an amendment paper in the reissue application must include the following markings: (1) The matter to be omitted by reissue must be enclosed in brackets; and (2) The matter to be added by reissue must be underlined except for amendments submitted on compact discs”.

Examples Amendment to original issued claim:

1. (Original) A composition comprising acetylsalicylic acid, 95% ethanol and distilled water.
1. (Amended) A composition [comprising] consisting essentially of acetylsalicylic acid, 95% ethanol and distilled water.

Amendment to an amended claim.

1. (Twice Amended) A composition [comprising] consisting essentially of acetylsalicylic acid, 95% ethanol and [distilled] water.



AMENDMENT TO THE CLAIMS

Examples (cont.)

5. (New) A composition of claim 1 which also includes a pharmaceutical carrier .

5. (New-amended) A composition of claim 1 which includes a pharmaceutical carrier, and an additional headache medicament other than acetylsalicylic acid.



AMENDMENT TO CLAIMS

15.(amended) A method for preparing products selected from cosmetics and toiletries [compositions] which provide antimicrobial or fluorescent whitening properties comprising the step of: incorporating into said products [one of these compositions] a compound of Formula I: ABCR1 wherein R1 is selected from: a C10-C30 hydrocarbon which may be saturated, unsaturated, straight, branched, alicyclic or [an] aromatic [C10 -C30 hydrocarbon residue] , [;] [or] nonyl, 3,5,5-trimethyl-hexanyl, cis-6-nonenyl, 2-nonenyl, 2-ethoxy-4-formylphenyl, and 2-phenyl- propyl, ...

THE RED IS THE ISSUED CLAIM-WHAT IS WRONG?



AMENDMENT TO THE CLAIMS

15.(amended) A method for preparing products selected from cosmetics and toiletries [compositions] which provide antimicrobial or fluorescent whitening properties **comprising** the step of: incorporating into said products [one of these compositions] a compound of Formula I: ABCR1 wherein R1 is **selected from: a C10-C30 hydrocarbon which may be saturated, unsaturated, straight, branched, alicyclic or [an] aromatic [C10 -C30 hydrocarbon residue] , [;] [or] nonyl, 3,5,5-trimethyl-hexanyl, cis-6-nonenyl, 2-nonenyl,2-ethoxy-4-formylphenyl,and 2-phenyl- propyl, ...**

- 1) The “comprising” was in the issued claim - Why is it underlined?
- 2) The “selected from:” was not in the issued claim - Why isn't it underlined
- 3) The “comma” was in the issued claim - Why is it underlined?
- 4) The “;” and the “or” was not in the issued claim but in a previous amendment to the issued claim - Why are they bracketed?
- 5) If there was a previous amendment, why does the status identifier say amended and not (twice amended) or (four times amended)?



AMENDMENT TO SPECIFICATION

- (1) Specification other than the claims . Changes to the specification, other than to the claims, must be made by submission of the entire text of an added or rewritten paragraph, including markings pursuant to paragraph (d) of this section, except that an entire paragraph may be deleted by a statement deleting the paragraph without presentation of the text of the paragraph. The precise point in the specification must be identified where any added or rewritten paragraph is located. This applies whether the amendment is submitted on paper or compact disc (see §§1.52(e)(1) and 1.821(c), but not for discs submitted under §1.821(e)).



AMENDMENT TO SPECIFICATION EXAMPLES IMPROPER FORMAT

Add the following paragraph in column 1, line 32.

- The present invention is directed to a method of regulating type II collagen gene expression in cartilage cells via the application of specific and selective fields generated by--: specific and selective electric and electromagnetic signals for the treatment of injured or diseased articular cartilage, as well as a device for generating signals. --

37 CFR 1.73 d (1), (2) The matter to be omitted by reissue must be enclosed in brackets; and the matter to be added by reissue must be underlined.

The markings "--" are not used in reissue, and the added matter should be underlined.



AMENDMENT TO SPECIFICATION EXAMPLES IMPROPER FORMAT

Delete line 22 in column 2 and replace with:

Osteoarthritis is the most common form of arthritis.

37 CFR 1.173(b)(1) - Changes to the specification must be made by submission of the entire text of an added or rewritten paragraph.

37 CFR 1.173(d)(1)(2) - The matter to be omitted by reissue must be enclosed in brackets; and the matter to be added by reissue must be underlined.

Amend the paragraph in column 2 line 22-24 with:

Osteoarthritis is [a] the most common form of arthritis. It is wide spread among all age groups and has been viewed as on of the fastest growing arthritis forms in the country.



AMENDMENT TO THE SPECIFICATION PROPER FORMAT

Amend the paragraph at column 3, line 5 to line 11 as follows:

The present invention is directed to a method of [regulation] regulating [tybe] type II collagen gene expression in cartilage cells via the application of specific and selective [fileds] fields generated by specific and selective electric and electromagnetic signals for the treatment of injured or diseased articular cartilage.

Insert new paragraph in column 3, line 5 :

The present invention is directed to a method of regulating type II collagen gene expression in cartilage cells via the application of specific and selective fields generated by specific and selective electric and electromagnetic signals for the treatment of injured or diseased articular cartilage.



AMENDMENT TO THE DRAWINGS

AMENDMENT OF DRAWINGS

37 CFR 1.173. Reissue specification, drawings, and amendments. (b)

(3) Drawings. One or more patent drawings shall be amended in the following manner: Any changes to a patent drawing must be submitted as a replacement sheet of drawings which shall be an attachment to the amendment document. Any replacement sheet of drawings must be in compliance with § 1.84 and shall include all of the figures appearing on the original version of the sheet, even if only one figure is amended. Amended figures must be identified as “Amended, ” and any added figure must be identified as “New”. In the event that a figure is canceled, the figure must be surrounded by brackets and identified as “Canceled”. All changes to the drawing(s) shall be explained, in detail, beginning on a separate sheet accompanying the papers including the amendment to the drawings.



AMENDMENT TO THE DRAWING IMPROPER NOT LABELED AMENDED, NOT A REPLACEMENT SHEET

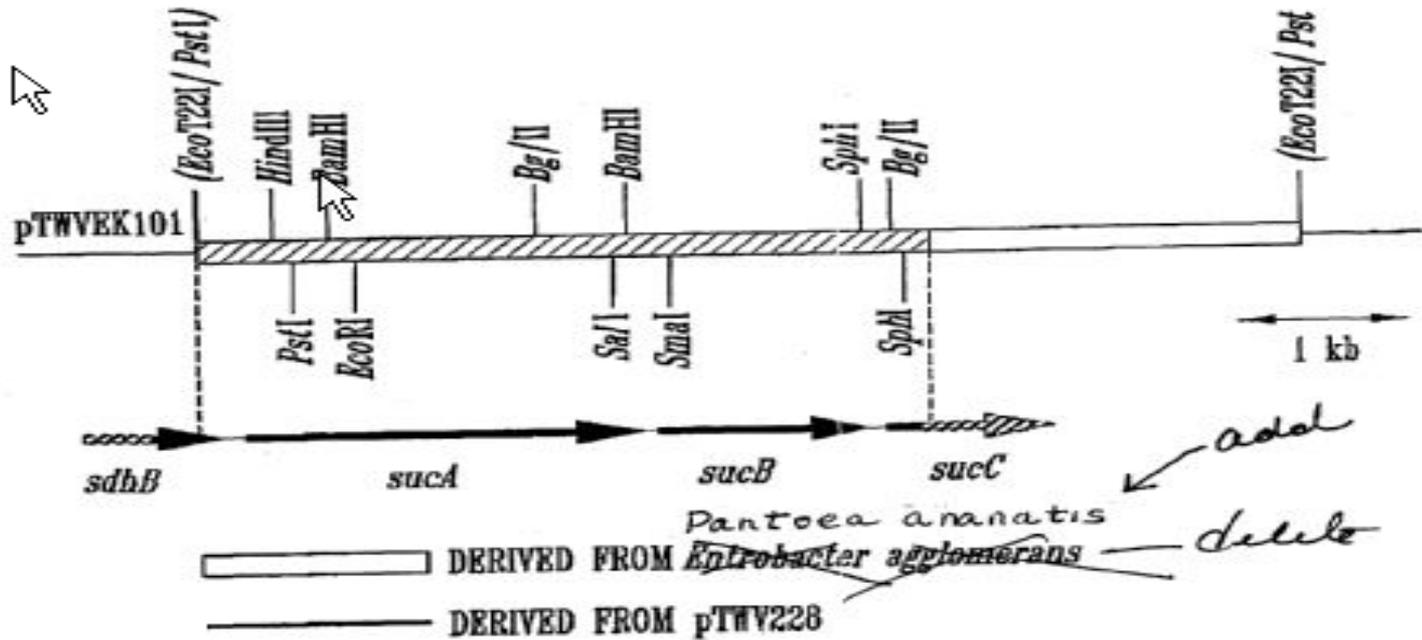


FIG. 1



PROPER AMENDMENT TO DRAWING

REPLACEMENT SHEET
1/4

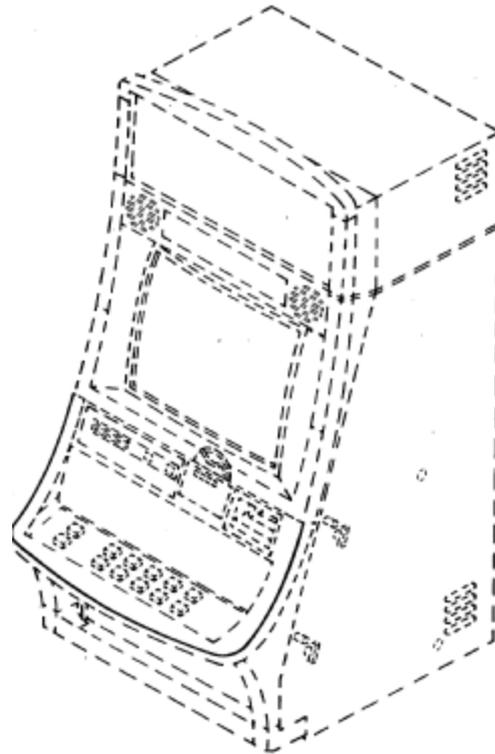


Fig. 1
(Amended)



PROPER AMENDMENT TO DRAWING

REPLACEMENT SHEET

2/4

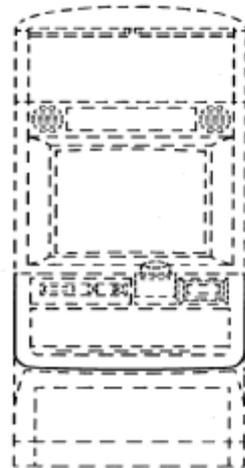


Fig. 2
(Amended)

Fig. 3
(Cancelled)





CERTIFICATE OF CORRECTION

If a certificate of correction has been granted in the original patent then the certificate changes are considered part of the patent as issued.

As such, the certificate changes must be made to the patent in the specification, abstract, or claims without underlining or bracketing (See section of MPEP 1411.01)

The examiner should make certain that all Certificate of Correction changes in the patent have been properly incorporated into the reissue application.



CERTIFICATE OF CORRECTION

This slide applies for a certificate of correction dated during the pendency of the reissue application.

As to the certificate either before or during the pendency, its changes are retroactively a part of the original patent and are thus part of the original patent; accordingly they must show up in the printed reissue patent document as part of the original patent, i.e., not in italics or bracketed. If the changes are submitted improperly with underlining and brackets, the examiner will require correction by the applicant in the form of a replacement paragraph (or paragraphs) without such markings.



CERTIFICATE OF CORRECTION

If the changes are extensive a clean copy of the specification with the Certificate of Correction change maybe required by the examiner. For the clean copy of the specification to be entered, a petition must be filed under 37 CFR 1.183 for waiver of 37 CFR 1.125(d) and 37 CFR 1.173(a)(1). The examiner's requirement for the clean copy will generally serve as sufficient basis for granting the petition.

Note-Applicant is required to include a copy of any certificate of correction (37 CFR 1.322 – 1.324) issued in the patent for which the reissue is requested. (MPEP 1410 Content of reissue)



CERTIFICATE OF CORRECTION

Not corrected

Example

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,683,156 B1 Page 3 of 3
DATED : January 27, 2004
INVENTOR(S) : Siamak Tabibzadeh

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13, SEQ ID NO: 1, Column 6 of Sequence Listing.
Line 19, "TTTAGCTA 1920" should read -- TTTAGCTAAA 1920 --

CTGGGCTTCA GCTCTAAGAA CTCATTGCC CTGGGGATCA GACAGCCCCT ACCTACCC 1800
GCCACTCCT CTGGAGACTG AGCCTTGCCC GTGCATATTT AGGCATTTC CCACACTG 1860
TTAGAGAACT TGCACCAGA AACCACATGT ATTTGCATGT TTTTGTAA **TTTAGCTA** 1920
GCAATTGAAT GTAGATACTC AGAAGAAATA AAAAATGATG TT 1962

Column 13 above. It has not been changed per certificate of correction.



CERTIFICATE OF CORRECTION

Correct Submission

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,683,156 B1 Page 3 of 3
DATED : January 27, 2004
INVENTOR(S) : Siamak Tabibzadeh

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13, SEQ ID NO: 1, Column 6 of Sequence Listing.
Line 19, "TTAGCTA 1920" should read -- TTAGCTAAA 1920 --

CTGGGCTTCA GCTCTAAGAA CTCATTGCC CTGGGGATCA GACAGCCCCT ACCTACCC 1800
GCCCACTCCT CTGGAGACTG AGCCTTGCCC GTGCATATT AGGCATTTC CCACACTG 1860
TTAGAGAACT TGCACCAGA AACCATGT ATTTGCATGT TTTTGTAA TTAGCTAAA 1920
GCAATTGAAT GTAGATACTC AGAAGAAATA AAAAATGATG TT 1962



OATH/DECLARATION

Two types of first or full oath in reissue:

INVENTOR OATH- PTO/SB/51 (05-08)

ASSIGNEE OATH – PTO/SB/52 (05-08)

Inventor oath must be used for broadening reissue

Assignee oath can be used for narrowing reissue or reissue not broadening the claims (e.g., inventorship change)

We will go through the parts of the two oaths, the differences between them, and what to double check before submission.

We will also discuss the reissue error and what is required.



OATH/DECLARATION

An applicant for reissue is required to file a reissue oath or declaration which, in addition to complying with 37 CFR 1.63, must comply with 37 CFR 1.175.

37 CFR 1.63 requires same information as a non reissue oath except if it is an assignee oath the inventors signatures are not required. (e.g., original and first inventor or inventors).

37 CFR 1.175 has additional requirements for a reissue oath. (e.g., All errors being corrected in the reissue application up to the time of filing of the oath or declaration under this paragraph (i.e.,1.175) arose without deceptive intent on the part of the applicant)



INVENTOR OATH/DECLARATION 37 CFR 1.63 YELLOW, 37CFR1.175 RED

PTO/SB/51 (05-08)

Approved for use through 08/31/2010. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

REISSUE APPLICATION DECLARATION BY THE INVENTOR	Docket Number (Optional)
<p>I hereby declare that: Each inventor's residence, mailing address and citizenship are stated below next to their name. I believe the inventors named below to be the original and first inventor(s) of the subject matter which is described and claimed in patent number _____, granted _____ and for which a reissue patent is sought on the invention entitled _____, _____ the specification of which <input type="checkbox"/> is attached hereto. <input type="checkbox"/> was filed on _____ as reissue application number _____ and was amended on _____ (If applicable)</p> <p>I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.</p> <p><input type="checkbox"/> I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b). Attached is form PTO/SB/02B (or equivalent) listing the foreign applications.</p>	



INVENTOR OATH/DECLARATION 37CFR 1.63 YELLOW, 37 CFR 1.175 RED

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

by reason of a defective specification or drawing.

by reason of the patentee claiming more or less than he had the right to claim in the patent.

by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening:



INVENTOR OATH/DECLARATION 37CFR 1.63 YELLOW, 37CFR 1.175 RED

PTO/SB/51 (05-08)

Approved for use through 08/31/2010. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)		Docket Number (Optional)	
<div style="border: 1px solid red; padding: 2px;">All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant.</div>			
<p>Note: To appoint a power of attorney, use form PTO/SB/81.</p> <p>Correspondence Address: Direct all communications about the application to:</p> <p><input type="checkbox"/> The address associated with Customer Number: <input style="width: 300px;" type="text"/></p> <p>OR</p>			
<input type="checkbox"/> Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone		Email	



INVENTOR OATH/DECLARATION 1.63 YELLOW 1.175 RED

false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Full name of sole or first inventor (given name, family name)

Inventor's signature

Date

Residence

Citizenship

Mailing Address

Full name of second joint inventor (given name, family name)

Inventor's signature

Date

Residence

Citizenship

Mailing Address



OATH/DECLARATION REISSUE ERROR

- Not all errors can be used as the basis of a reissue. One cannot recapture claims or limitations in claims that one gave up in the patent application. Nor can one obtain a restricted group that was non-elected in the patent application and not pursued before patent issued.
- Other errors that cannot be corrected by a reissue include
 - 1) Reissue filed just to add citations
 - 2) Error with spelling, punctuation, etc (use certificate of correction)
 - 3) No defect. Applicant seeking a patentability determination via reissue rather than reexam



OATH/DECLARATION REISSUE ERROR

Other errors that can be grounds for a reissue include,

- 1) Change of inventorship,
- 2) failure to file a certified copy of the original foreign application to obtain the right of foreign priority,
- 3) a substantive drawing error,
- 4) a substantive specification error,
- 5) failure to adequately claim benefit under 35 USC 120 in earlier-filed copending US patent application,
- 6) claim less than they had a right to claim (2 year limitation), and
- 7) correction of problem with patent oath.



OATH/DECLARATION REISSUE ERROR

There needs to be “at least one error” to support the reissue. It is not sufficient for an oath /declaration to merely state, “this application is being filed to correct errors in the patent which may be noted from the changes made in the disclosure.” Rather, the oath /declaration must specifically identify an error. In addition, it is not sufficient to merely reproduce the claims with brackets and underlining and state that such will identify the error. See *In re Constant*, 827 F.2d 728, 729, 3 USPQ2d 1479 (Fed. Cir.), cert. denied, 484 U.S. 894 (1987).



OATH/DECLARATION REISSUE ERROR

Any error in the claims must be identified by reference to the specific claim(s) and the specific claim language wherein lies the error. A statement of "... failure to include a claim directed to ..." and then presenting a newly-added claim, would not be considered a sufficient "error" statement. Applicant has not pointed out what the other claims lacked that the newly added claim has, or vice versa. Such a statement would be no better than saying in the reissue oath or declaration that "this application is being filed to correct errors in the patent which may be noted from the change made by adding new claim 10." In both cases, the error has not been identified.



OATH/DECLARATION REISSUE ERROR

Likewise, a statement of the error as " ... the inclusion of claims 3-5 which were unduly broad ..." and then canceling claims 3-5, would not be considered a sufficient "error" statement because applicant has not pointed out what the canceled claims lacked that the remaining claims contain. The statement of what the remaining claims contain need not identify specific limitations, but rather may provide a general identification, such as "Claims 3-5 did not provide for any of the tracking mechanisms of claims 6-12, nor did they provide an attachment mechanism such as those in claims 1-2 and 9-16."



OATH/DECLARATION REISSUE ERROR

Please note that the filing of additional claims narrower than the broadest claim(s) of a patent, without cancellation of such broader patent claim(s), is not an error that will support reissue. See MPEP, 1402 and www.uspto.gov/web/offices/pac/dapp/opla/documents/reissue_narrower_claims_11152007.pdf (Ex Parte Tanaka, BPAI Precedential <http://www.uspto.gov/ip/boards/bpai/decisions/prec/fd09000234.pdf>)



OATH/DECLARATION ERROR EXAMPLES

- 1) I believe the original U.S. Patent No. A,000,000 as issued to be partly or wholly inoperative or invalid by reason of the patentee claiming less than the patentee had the right to claim in the patent and based on an error with the wording of claim 4 as issued. (IS THIS OKAY?)
- 2) One error being relied upon as the basis for reissue is that the patent failed to claim the following, and in this respect, this reissue is a broadening reissue: A pharmaceutical composition comprising a salt of losartan; the pharmaceutical composition further comprising a material selected from the group consisting of one or more of colloidal silicon microcrystalline cellulose, and polyethylene glycol. (HINT: THIS ERROR IS IDENTICAL WITH NEW CLAIM 6. IS THIS OKAY?).



OATH/DECLARATION REISSUE ERROR EXAMPLES

In 1) on the previous slide, the error is based on patentee claiming less than the patentee had the right to claim in the patent and based on an error with the wording of claim 4 as issued.

The alleged error has not complied with the MPEP 1414(II)(C)– “ the oath/declaracion must **specifically** identify an error” and “Any error in the claims must be identified by **reference to the specific claim(s)** and **the specific claim language** wherein lies the error.”

The error on the previous slide has only identified the claim number. It does not say why the wording in the claim renders it partially or wholly inoperative or invalid. Thus it is not sufficient reissue error.



OATH/DECLARATION REISSUE ERROR EXAMPLES

For example 2) on previous slide 34 the error is cited as : A pharmaceutical composition comprising a salt of losartan; the pharmaceutical composition further comprising a material selected from the group consisting of one or more of colloidal silicon microcrystalline cellulose, and polyethylene glycol.

If one looks at claim 6 . It is word for word the same as the error cited. MPEP 1414(II)(C) states that a statement of **“failure to include a claim directed to ...” and then presenting a newly added claim, would not be considered a sufficient error statement.** Applicant has not pointed out what the other claims lacked that the newly added claim has, or vice versa. Thus this is not considered sufficient reissue error.



OATH/DECLARATION ERROR EXAMPLES

EXAMPLE OF NON SPECIFIC ERROR - The patent claims more than applicant had a right to claim in view of U.S. Patent No. A,222,222.

EXAMPLE OF SPECIFIC ERROR - The second oath submission states “The patent claims more than applicant had a right to claim In view of U.S. Patent No. A,222,222 which describes a plant having integrated into its genome a DNA construct containing a delta-five desaturase, wherein the plant reportedly produces dodecaenoic acid. See, U.S. Patent No. A,222,222, Example 12. Claim1 of the patent is amended in this reissue application to exclude that subject matter of the ‘222 patent.”



OATH/DECLARATION ERROR EXAMPLES

Example nonspecific error - The inventorship is being changed

Example of specific error - The inventorship is being changed to include two additional inventors, John Smith and Jane Doe

(HINT: If the inventorship is the only thing you want to correct, then you can also file a petition under 1.324 for correction of inventorship in an issued patent)



ASSIGNEE OATH 37CFR I.63 YELLOW, 37CFR 1.175 RED

PTO/SB/52 (05-08)

Approved for use through 08/31/2010. OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

REISSUE APPLICATION DECLARATION BY THE ASSIGNEE	Docket Number (optional)
<p>I hereby declare that:</p> <p>The residence, mailing address and citizenship of the inventors are stated below.</p> <p>I am authorized to act on behalf of the following assignee: _____</p> <p>and the title of my position with said assignee is: _____</p> <p>The entire title to the patent identified below is vested in said assignee.</p>	
Inventor	Citizenship
Residence/Mailing Address	
Inventor	Citizenship
Residence/Mailing Address	
<input type="checkbox"/> Additional Inventors are named on separately numbered sheets attached hereto.	



ASSIGNEE OATH 37CFR I.63 YELLOW, 37CRF 1.175 RED

I believe said inventor(s) to be the original and first inventor(s) of the subject matter which is described and claimed in said patent, for which a reissue patent is sought on the invention entitled:

the specification of which

is attached hereto.

was filed on _____ as reissue application number _____ / _____

and was amended on _____
(If applicable)

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b). Attached is form PTO/SB/02B (or equivalent) listing the foreign applications.



ASSIGNEE OATH 37CFR I.63 YELLOW, 37CFR 1.175 RED

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

by reason of a defective specification or drawing.

by reason of the patentee claiming more or less than he had the right to claim in the patent.

by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, such must be stated with an explanation as to the nature of the broadening:



ASSIGNEE OATH

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Signature

Date

Full name of person signing (given name, family name)

Address of Assignee

[Page 2 of 2]



SUPPLEMENTAL OATH

1.173(b)(1) For any error corrected, which is not covered by the oath or declaration submitted under paragraph (a) of this section, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant. Any supplemental oath or declaration required by this paragraph must be submitted before allowance and may be submitted:

- (i) With any amendment prior to allowance; or
- (ii) In order to overcome a rejection under 35 U.S.C. 251 made by the examiner where it is indicated that the submission of a supplemental oath or declaration as required by this paragraph will overcome the rejection.



FORMS THAT ARE HELPFUL

Forms found on the www.uspto.gov website.

PTO/SB/53 - CONSENT FORM (cannot be allowed without consent).

PTO/SB/96 - 3.73(b)FORM (statement to show ownership)

PTO/SB/51 - INVENTOR OATH

PTO/SB/52 - ASSIGNEE OATH

PTO/SB/51s - SUPPLEMENTAL OATH



REISSUE QAS TC1600

REISSUE/REEXAM HELP LINE 571-272-7703

JEAN F. VOLLANO 571-272-0648 General questions, etc.

BENNETT CELSA 571-272-0807 Recapture



AMENDMENT IN A REISSUE OF A REISSUE

MPEP 1411- Double underlining and double bracketing are used in the second reissue application, while bold-faced type and double bracketing appear in the printed patent (the second reissue patent) to indicate further insertions and deletions, respectively, in the second reissue patent.

When a copy of a first reissue patent is used as the specification of a second reissue application (filed as a reissue of a reissue), additions made by the first reissue will already be printed in italics, and should remain in such format. Thus, applicants need only present additions to the specification/claims in the second reissue application as double underlined text. Subject matter to be deleted from the first reissue patent should be presented in the second reissue application within sets of double brackets.



AMENDMENT IN REISSUE OF REISSUE

Claim 27 was issued in the first reissue and was a claim not amended from the original issued patent claim.

27. The composition of claim 26, where in the pharmaceutical acceptable salt of the ring-opened 7-substituted 3,5-dihydroxy heptanoic acid salt is pravastatin sodium.

Claim 27 below is now the amendment in the reissue of the first issued reissue. Note the double underlining for the addition and double bracketing for deletion.

27 (Amended). The composition of claim 26, wherein the pharmaceutically acceptable salt of the ring-opened [[7-substituted 3,5-dihydroxy heptanoic]] 7-substituted 3,5-dihydroxyheptanoic acid [[salt]] is pravastatin sodium.



AMENDMENT IN A REISSUE OF A REISSUE

Claim 1 is a amendment in the reissue of a reissue where the patent claim issued had been amended in the first reissue solely by adding HMG-CoA reductase inhibiting to the claim (italics from published first reissue) and the double bracketing and double underlining from the current amendment

- 1 (Amended). A stabilized pharmaceutical composition for the treatment of dyslipidemia, comprising
- an active component consisting essentially of one or more compounds selected from the group consisting of
 - (i) an *HMG-CoA reductase inhibiting* ring-opened [[7-substituted-3,5-dihydroxyheptafluoric]] 7-substituted-3,5-dihydroxyheptanoic acid or a pharmaceutically acceptable [[acid]] salt thereof, and
 - (ii) an *HMG-CoA reductase inhibiting* ring-opened 7-substituted-3,5-dihydroxyheptenoic acid or a pharmaceutically acceptable [[acid]] salt thereof,
- and



AMENDMENT IN A REISSUE OF A REISSUE

In the first reissue, claim 5 was amended such that C1-C6 and O were deleted from the claim and C2-C8 was added. Now in the present reissue application of the first reissue they want to take out the C2-C8 from claim 5 below and add some new limitations for an alkylene group encompassed by C2-C8. What do they do?

L^2 is $[C_1-C_6]C_2-C_8$ saturated alkylene or $[C_2-C_6]C_2-C_8$ alkenylene, wherein the alkylene or alkenylene optionally may be substituted, provided that L^2 is not $-C(\text{O})-$, and wherein one of the carbon atoms of the alkylene optionally may be replaced by a heteroatom moiety selected from the group consisting of $[O;]NR'$; R' being alkyl, acyl, or hydrogen; S; S(O); or S(O)₂;



AMENDMENT OF A REISSUE OF A REISSUE

As shown below, use double bracketing to take out the C₂-C₈ limitation that was added in the first reissue patent and use double underlining for the addition of specific alkylenes added in this reissue of a reissue application.

L² is [C₁-C₆] [[C₂-C₈]] saturated alkylene selected from ethylene, propylene, butylene, pentylene and hexylene, or C₂-C₈ [C₂-C₆] alkenylene, wherein the alkylene or alkenylene optionally may be substituted, provided that L₂ is not -C(O)-, and wherein one of the carbon atoms of the alkylene optionally may be replaced by a heteroatom moiety selected from the group consisting of [O;] S; S(O); or S(O)₂;



AMENDMENT IN A REISSUE OF A REISSUE

Here is an example of a claim that was new in the first reissue patent and not amended in the second reissue application.

46. The stable solid pharmaceutical composition of claim 42, wherein the composition does not contain a buffering agent.

Below is an example of a claim which is new in this reissue

58. (New) The composition of claim 57, wherein the at least one amido-group containing polymeric compound comprises between about 30 and about 80 percent by weight of the composition.



AMENDMENT IN A REISSUE OF A REISSUE

Here is claim 54 as issued in the first reissue. Note the claim is completely italicized which means it was a newly added claim in the first reissue.

54. The composition of claim 52, wherein the active component consists essentially of one or more compounds selected from the group consisting of atorvastatin, pravastatin, fluvastatin, cerivastatin and pharmaceutically acceptable acid salts thereof.

Claim 54 is amended by adding, Itavastin which is not italicized.

54 (Amended). The composition of claim 52, wherein the active component consists essentially of one or more compounds selected from the group consisting of atorvastatin, pravastatin, fluvastatin, cerivastatin, itavastatin, and pharmaceutically acceptable `[[acid]]` salts thereof.