

UNITED STATES PATENT AND TRADEMARK OFFICE

BEST PRACTICES IN REISSUE

ADDRESSING 35 USC 251 ISSUES 1.AMENDMENTS 2. CERTIFICATE OF CORRECTION 3. OATHS 4. CONSENT 5. OWNERSHIP 6. SEQ ID COMPLIANCE



A copy of a claim set from a patented reissue

1. A [pharmaceutical] composition comprising [an active ingredient which is] an analogue of sulforaphane ((-)1isothiocyanato-(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-isothiocyanato-2-hexanone [(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)-5isothiocyanatonorbornane [(GHP 1075)]; exo-2-acetyl-5isothiocyanatonorbornane [(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-2hexanone; exo-2-acetyl-6-isothiocyanatonorbornane; exo-2-isothiocyanato-6-methylsulfonylnorbornane; 6-isothiocyanato-2-hexanol; 1-isothiocyanato-4dimethylphosphonylbutane; exo-2-(1'-hydroxyethyl)-5isothiocyanatonorbornane; exo-2-acetyl-5isothiocyanatonorbornane; 1-isothiocyanato-5methylsulfonylpentane; and cis- or trans-3-(methylsulfonyl) cvclohexvlmethvlisothiocvanate. and a suitable excipient.



AMENDMENTS TO CLAIMS

When amending reissue claims one uses markings in comparison with the existing patent claims each time there is an amendment.
One does <u>not</u> 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.



AMENDMENTS TO THE CLAIMS

- (d) Changes shown by markings . Any changes relative to the patent being reissued 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:
- 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 (§§ 1.96 and 1.821(c)). Matter added by reissue on compact discs must be
- preceded with "<U > " and end with "</U > " to properly identify the material being added.



AMENDMENT TO THE CLAIMS

Examples

Amendment to original issued claim:

- (Original) A composition comprising acetylsalicylic acid, 95% ethanol and distilled water.
- (Amended) A composition [comprising] <u>consisting essentially</u> of acetylsalicylic acid, 95% ethanol and distilled water.
 Amendment to an amended claim.
- (Twice Amended) A composition [comprising] <u>consisting</u> <u>essentially of</u> acetylsalicylic acid, 95% ethanol and [distilled] water.



AMENDMENTS TO THE CLAIMS

- Examples (cont.)
- 5. (New) <u>A composition of claim 1 which also includes a</u> <u>pharmaceutical carrier</u>.
- 5. (New-amended) <u>A composition of claim 1 which, besides</u> <u>including a pharmaceutical carrier, also includes an</u> <u>additional headache medicament besides acetylsalicylic</u> <u>acid.</u>



AMENDMENT TO THE SPECIFICATION

Specification other than the claims . Changes to the (1)specification 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 paragraph 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 \S 1.821(e)).



AMENDMENT TO THE DRAWINGS

- (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.
- (i) A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be included. The marked-up copy must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change to the drawings.
- (ii) A marked-up copy of any amended drawing figure, including annotations indicating

the changes made, must be provided when required by the examiner.



- 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 <u>without</u> 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.



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.



- 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 37CFR 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)



Example

PATENT AND TRADEMARK OFFICE CATE OF CORRECTION
Page 3 of 3
i in the above-identified patent and that said Letters Patent is low:
. <u>Column 6 of Sequence Listing.</u> 0" should read TTTAGCTAAA 1920

CTGGGCTTCA GCTCTAAGAA CTTCATTGCC CTGGGGATCA GACAGCCCCT ACCTACCC 1800 GCCCACTCCT CTGGAGACTG AGCCTTGCCC GTGCATATTT AGGTCATTTC CCACACTG 1860 TTAGAGAACT TGTCACCAGA AACCACATGT ATTTGCATGT TTTTTGTTAA TTTAGCTA 1920 GCAATTGAAT GTAGATACTC AGAAGAAATA AAAAATGATG TT 1962

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



Two type 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)



- 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)



Applicant is not required to use the PTO forms but should review the language in the forms to avoid a defective oath due to improper language in a modified form.

Example: Forms state: "duty to disclose information which is material to **patentability...** in **37CFR 1.56**."

Submitted non form oath "duty to disclose information which is material to **examination** ... in **37CFR 1.56(a)**

Note- Chapter 0200- The term "information" as used in 37 CFR 1.56 means all of the kinds of information required to be disclosed and includes any information which is <u>"material to patentability."</u>



Reissue oath must contain a SPECIFIC error and an error upon which the reissue can be based.

Not all errors can be corrected under reissue practice(e.g. no recapture) See MPEP 1402 for what may constitute the "error" required by 35 USC 251.

For the specific error in the claims - 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.



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 because 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.



Likewise, a statement of the error as " ... the inclusion of claims 3-5 which were unduly broad ..." and then canceling claims 3-5, would <u>not be</u> considered a <u>sufficient</u> 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 claims1-2 and 9-16."



EXAMPLE OF NON SPECIFIC ERROR- The patent claims more than applicant had a right to claim in view of U.S. Patent No. 2,222,222.

EXAMPLE OF SPECIFIC ERROR- in second oath submission -The patent claims more than applicant had a right to claim In view of U.S. Patent No. 2,222,222 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 2,222,222, Example 12. Claim1 of the patent is amended in this reissue application to exclude that subject matter of the 222' patent.



Other errors that can be grounds for a reissue include,

- change of inventorship, failure to file a certified copy of the original foreign application to obtain the right of foreign priority, a substantive drawing error, a substantive specification error, failure to adequately claim benefit under 35 USC 120 in earlier filed copending US patent application, and correction of problem with patent oath.
- **Example non specific error** The inventorship is being changed
- **Example of specific error-** The inventorship is being change to include two additional inventors, John Smith and Jane Doe.



SUPPLEMENTAL OATH

If additional defects or errors are corrected in the reissue after the filing of the application and the original reissue oath or declaration, a supplemental reissue oath/declaration must be filed, unless all additional defects and errors corrected are spelling, grammar, typographical, editorial or clerical errors which are not errors under 35 U.S.C. 251 (see MPEP §1402).



- Where the patent has been assigned, the reissue applicant must also provide a consent of assignee to the reissue and evidence of ownership. Where the patent has not been assigned, the <u>reissue applicant should affirmatively state</u> <u>that the patent is not assigned.</u>
 - CONSENT FORM PTO/SB/53 (09-07) There is a place to check on the form if the patent is not assigned.
- 1. Filed herein is a statement under 37 CFR 3.73(b). (Form PTO/SB/96)
- 2. Ownership of the patent is in the inventor(s), and no assignment of the patent is in effect.



Or applicant can check the "NO" box of item 7 of Form PTO/SB/50 (08-

08) REISSUE PATENT APPLICATION TRANSMITTAL			
APPLICATION FOR REISSUE OF: (Check applicable box) Utility Patent	Design Patent Plant Patent		
APPLICATION ELEMENTS (37 CFR 1.173)	ACCOMPANYING APPLICATION PARTS		
1. Fee Transmittal Form (PTO/SB/56) 2. Applicant claims small entity status. See 37 CFR 1.27. 3. Specification and Claims in double column copy of patent format (amended, if appropriate) 4. Drawing(s) (proposed amendments, if appropriate) 5. Reissue Oath/Declaration (original or copy) (37 C.F.R. 1.175) (PTO/SB/51 or 52) 6. Power of Attomey 7. Original U.S. Patent currently assigned? Yes 9. Written Consent of all Assignees (PTO/SB/53) 9. 37 CFR 3.73(b) Statement (PTO/SB/96) 8. CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table 9. Nucleotide and/or Amino Acid Sequence Submission (if appl/cable, items a c. are required)) a. Computer Readable Form (CRF)	10. Statement of status and support for all changes to the claims. See 37 CFR 1.173(c). 11. Foreign Priority Claim (35 U.S.C. 119) (if applicable) 12. Information Disclosure Statement (IDS) PTO/SB/06 or PTO-1449 Copies of foreign patent documents, publications & other information 13. English Translation of Reissue Oath/Declaration (if applicable) 14. Preliminary Amendment 15. Return Receipt Postcard (MPEP 503) (Should be specifically Itemized) 16. Other:		
b. Specification Sequence Listing on: I CD-ROM (2 copies) or CD-R (2 copies); or II paper Statements verticion identity of above copies	ι		



IF there are multiple assignees that own part of the patent then consents from each assignee are required (e.g. ABC corporation and XYZ corporation).

Often overlooked on the consent form is the typed or printed name and the TITLE of the person signing for the assignee

Signature	Date		
Typed or printed name and title of person signing for assignee (if assigned)			



- Where a continuation reissue application is filed with a copy of the assignee consent from the parent reissue application, and the parent reissue application <u>is not to be abandoned</u>, the copy of the consent should <u>not</u> be accepted.
- In a voluntary divisional reissue a copy of the consent from the parent reissue application should <u>not</u> be accepted <u>whether</u> <u>or not the parent reissue is to be abandoned.</u>
- In a divisional reissue based on a restriction made in the parent reissue application, the assignee need not file a consent because the consent has already been provided in the parent reissue. MPEP 1410.01



The assignee may establish ownership by

- 1) Documentary evidence of a chain from the original owner to the assignee (e.g. Copy of an executed assignment)
- 2) A statement specifying where the documentary evidence of a chain of title from the original owner to the assignee is recorded in the assignment records of the Office (e.g. reel and frame). (PTO/SB/96 (07-09)
 - If there are multiple assignees each assignee must file a 3.73(b) statement establishing ownership .



In PTO/SB/96 applicant must state he is either the assignee of the entire interest or an assignee of less than the entire right, title... and then give the **percentage** of ownership or state entire interest of one of the inventors(see boxes 1-3 below). Note this if not using a PTO form.

STATEMENT UNDER 37 CFR 3.73(b)					
Applicant/Patent Owner:					
Application No./Patent No.:	Filed/Issue Date:				
Titled:					
, a					
(Name of Assignee)	(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.				
states that it is:					
1. the assignee of the entire right, title, and interest in;					
	an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is%); or				
3. The assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)					
the patent application/patent identified above, by virtue of either:					



Also required is the reel and frame of the assignment(s) as found in either box A or B

A.	the Unite	nment from the inventor(s) of th d States Patent and Trademark refore is attached.	e patent application/pate Office at Reel	nt identi	fied above. The assignment was recorded in , Frame, or for which a		
В.	A chain o	chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:					
	1. From	:		To:			
		The document was recorded in	n the United States Pater	nt and T	rademark Office at		
		Reel	Frame		or for which a copy thereof is attached.		
	2. From	:		To:			
		The document was recorded in	n the United States Pater	nt and T	rademark Office at		
		Reel	Frame		or for which a copy thereof is attached.		
	3. From			To:			
	The document was recorded in the United States Patent and Trademark Office at				rademark Office at		
		Reel	Frame		or for which a copy thereof is attached.		



If one makes a statement that they are authorized act on behalf of the assignee the office will accept such statement absent evidence in the record that cast doubt on the authorization. "On the PTO/SB/96 form it states

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

-y--

Signature	Date	
Typed or printed name and title of person signing for assignee (if assigned)		



- The submission establishing ownership must show that the person signing the submission is a person authorized to act on behalf of the assignee by:
- (i) Including a statement that the person signing the submission is authorized to act on behalf of the assignee; or
- (ii) Being signed by a person having apparent authority to sign on behalf of the assignee, e.g., an officer of the assignee.
- (iii) Organization resolution (e.g. corporate resolution) giving authority to the person signing to bind the organization.



MPEP 324 (V) PARTY WHO MUST SIGN

(A) The submission may be signed by a person in the organization having apparent authority to sign on behalf of the organization. 37 CFR 3.73(b)(2)(ii). An officer (chief executive officer, president, vicepresident, secretary, or treasurer) is presumed to have authority to sign on behalf of the organization. The signature of the chairman of the board of directors is acceptable, but not the signature of an individual director. Modifications of these basic titles are accept able, such as vice-president for sales, executive vice-president, assistant treasurer, vice-chairman of the board of directors. In foreign countries, a person who holds the title "Manager" or "Director" is normally an officer and is presumed to have the authority to sign on behalf of the organization.



PARTY WHO MUST SIGN (continued)

- (B) The submission may be signed by any person, if the submission sets forth that the person signing is authorized (or empowered) to act on behalf of the assignee, i.e. ,to sign the submission on behalf of the assignee. 37 CFR 3.73(b)(2)(i).
- (C) The submission may be signed by a person empowered by an organizational resolution (e.g., corporate resolution, partnership resolution) to sign the submission on behalf of the assignee, if a copy of the resolution is, or was previously, submitted in the record.
- Where a submission does not comply with (A), (B), or (C) above, evidence of the person's authority to sign will be required. Attorney of record in itself is not sufficient to allow the attorney to sign the 3.73(b)or consent.



SEQUENCE COMPLIANCE

SEQUENCE ID DATA DOES NOT CONVEY IN A REISSUE FROM THE ORIGINAL PATENT

A reissue application that contains sequences must comply with the sequence rules (37 CFR 1.821-1.825) like any other application. This may be accomplished by filing a new sequence listing via a new diskette plus paper copy plus statement that the diskette and the paper copy are the same or via three copies of a CD plus statement or via EFS (no paper copy of statement required). Compliance may also be accomplished by the less-preferred process of requesting transfer of the sequence listing from the patented file with a paper copy plus statement accompanying the transfer request.



ACCESSING THE PTO FORMS REISSUE QAS TC1600

Use website <u>www.uspto.gov</u> for PTO forms Click on Patents (left side of screen) Then click on (number 9) forms The PTO forms are numerically listed

REISSUE/REEXAM HELP LINE 571-272-7703 JEAN F. VOLLANO 571-272-0648 General questions BENNETT CELSA 571-272-0807 Recapture ROBERT A.(BOB)WAX 571-272-0236 Sequence Listing