

608.01(o)

MANUAL OF PATENT EXAMINING PROCEDURE

Form paragraph 7.43 can be used to state the objection.

¶ 7.43 Objection to Claims, Allowable Subject Matter

Claim [1] objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

608.01(o) Basis for Claim Terminology in Description [R-3]

The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import; and in mechanical cases, it should be identified in the descriptive portion of the specification by reference to the drawing, designating the part or parts therein to which the term applies. A term used in the claims may be given a special meaning in the description. ****>See MPEP § 2111.01 and § 2173.05(a).<**

Usually the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted.

New claims and amendments to the claims already in the application should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification, *Ex parte Kotler*, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01. Note that examiners should ensure that the terms and phrases used in claims presented late in prosecution of the application (including claims amended via an examiner's amendment) find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description, see 37 CFR 1.75(d)(1). If the examiner determines that the claims presented late in prosecution do not comply with 37 CFR 1.75(d)(1), applicant will be

required to make appropriate amendment to the description to provide clear support or antecedent basis for the terms appearing in the claims provided no new matter is introduced.

The specification should be objected to if it does not provide proper antecedent basis for the claims by using form paragraph 7.44.

¶ 7.44 Claimed Subject Matter Not in Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: [1]

608.01(p) Completeness [R-3]

Newly filed applications obviously failing to disclose an invention with the clarity required are discussed in MPEP § 702.01.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

A complete disclosure should include a statement of utility. This usually presents no problem in mechanical cases. In chemical cases, varying degrees of specificity are required.

A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications.

PARTS, FORM, AND CONTENT OF APPLICATION

608.01(p)

For “Guidelines For Examination Of Applications For Compliance With The Utility Requirement of 35 U.S.C. 101,” see MPEP § 2107.

For “General Principles Governing Utility Rejections,” see MPEP § 2107.01.

For a discussion of the utility requirement under 35 U.S.C. 112, first paragraph, in drug cases, see MPEP § 2107.03 and § 2164.06(a).

For “Procedural Considerations Related to Rejections for Lack of Utility,” see MPEP § 2107.02.

For “Special Considerations for Asserted Therapeutic or Pharmacological Utilities,” see MPEP § 2107.03.

I. INCORPORATION BY REFERENCE

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37 CFR 1.57. Incorporation by reference.

(a) Subject to the conditions and requirements of this paragraph, if all or a portion of the specification or drawing(s) is inadvertently omitted from an application, but the application contains a claim under § 1.55 for priority of a prior-filed foreign application, or a claim under § 1.78 for the benefit of a prior-filed provisional, nonprovisional, or international application, that was present on the filing date of the application, and the inadvertently omitted portion of the specification or drawing(s) is completely contained in the prior-filed application, the claim under § 1.55 or § 1.78 shall also be considered an incorporation by reference of the prior-filed application as to the inadvertently omitted portion of the specification or drawing(s).

(1) The application must be amended to include the inadvertently omitted portion of the specification or drawing(s) within any time period set by the Office, but in no case later than the close of prosecution as defined by § 1.114 (b), or abandonment of the application, whichever occurs earlier. The applicant is also required to:

(i) Supply a copy of the prior-filed application, except where the prior-filed application is an application filed under 35 U.S.C. 111;

(ii) Supply an English language translation of any prior-filed application that is in a language other than English; and

(iii) Identify where the inadvertently omitted portion of the specification or drawings can be found in the prior-filed application.

(2) Any amendment to an international application pursuant to this paragraph shall be effective only as to the United States, and shall have no effect on the international filing date of the application. In addition, no request to add the inadvertently omitted portion of the specification or drawings in an international application designating the United States will be acted upon by the Office prior to the entry and commencement of the national stage (§ 1.491) or the filing of an application under 35 U.S.C. 111 (a) which claims benefit of the international application.

(3) If an application is not otherwise entitled to a filing date under § 1.53(b), the amendment must be by way of a petition pursuant to this paragraph accompanied by the fee set forth in § 1.17(f).

(b) Except as provided in paragraph (a) of this section, an incorporation by reference must be set forth in the specification and must:

(1) Express a clear intent to incorporate by reference by using the root words “incorporat(e)” and “reference” (e.g., “incorporate by reference”); and

(2) Clearly identify the referenced patent, application, or publication.

(c) “Essential material” may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. “Essential material” is material that is necessary to:

(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

(2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or

(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

(d) Other material (“Nonessential material”) may be incorporated by reference to U.S. patents, U.S. patent application publications, foreign patents, foreign published applications, prior and concurrently filed commonly owned U.S. applications, or non-patent publications. An incorporation by reference by hyperlink or other form of browser executable code is not permitted.

(e) The examiner may require the applicant to supply a copy of the material incorporated by reference. If the Office requires the applicant to supply a copy of material incorporated by reference, the material must be accompanied by a statement that the copy supplied consists of the same material incorporated by reference in the referencing application.

(f) Any insertion of material incorporated by reference into the specification or drawings of an application must be by way of an amendment to the specification or drawings. Such an amendment must be accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter.

(g) An incorporation of material by reference that does not comply with paragraphs (b), (c), or (d) of this section is not effective to incorporate such material unless corrected within any time period set by the Office, but in no case later than the close of prosecution as defined by § 1.114(b), or abandonment of the application, whichever occurs earlier. In addition:

608.01(p)

MANUAL OF PATENT EXAMINING PROCEDURE

(1) A correction to comply with paragraph (b)(1) of this section is permitted only if the application as filed clearly conveys an intent to incorporate the material by reference. A mere reference to material does not convey an intent to incorporate the material by reference.

(2) A correction to comply with paragraph (b)(2) of this section is only permitted for material that was sufficiently described to uniquely identify the document.

The Director has considerable discretion in determining what may or may not be incorporated by reference in a patent application. *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). Effective October 21, 2004, the Office codified in 37 CFR 1.57(b) – (g) existing practice with respect to explicit incorporations by reference with a few changes to reflect the eighteen-month publication of applications. In addition, 37 CFR 1.57(a) was added to provide a safeguard for applicants when a page(s) of the specification, or a portion thereof, or a sheet(s) of the drawing(s), or a portion thereof, is inadvertently omitted from an application, such as through a clerical error. 37 CFR 1.57(a) applies to applications filed on or after September 21, 2004. 37 CFR 1.57(a) permits inadvertently omitted material to be added to the application by way of a later filed amendment if the inadvertently omitted portion of the specification or drawing(s) is completely contained in a prior-filed application (for which priority/benefit is claimed) even though there is no explicit incorporation by reference of the prior-filed application. See MPEP § 201.17 for discussion regarding 37 CFR 1.57(a).

The incorporation by reference practice with respect to applications which issue as U.S. patents provides the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The following is the manner in which the Director has elected to exercise that discretion. Section A provides the guidance for incorporation by reference in applications which are to issue as U.S. patents. Section B provides guidance for incorporation by reference in benefit applications; i.e., those domestic (35 U.S.C. 120) or foreign (35 U.S.C. 119(a)) applications relied on to establish an earlier effective filing date. See MPEP § 2181 for the impact

of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.

A. *Review of Applications Which Are To Issue as Patents.*

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. App. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, or (2) a U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. See 37 CFR 1.57(c). Prior to October 21, 2004, Office policy also permitted incorporation by reference to a pending U.S. application.

"Essential material" is defined in 37 CFR 1.57(c) as that which is necessary to (1) provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112, (2) describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112, or (3) describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112. In any application that is to issue as a U.S. patent, essential material may only be incorporated by reference to a U.S. patent or patent application publication. The practice of permitting incorporation by reference of material from unpublished applications in which the issue fee was paid was discontinued by rule on October 21, 2004.

Other material ("nonessential subject matter") may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior and concurrently filed, commonly owned U.S. applications, or (3) non-patent publications. Nonessential

PARTS, FORM, AND CONTENT OF APPLICATION

608.01(p)

subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

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An incorporation by reference by hyperlink or other form of browser executable code is not permitted. See 37 CFR 1.57(d) and MPEP § 608.01.

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Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). >37 CFR 1.57(b)(1) limits a proper incorporation by reference (except as provided in 37 CFR 1.57(a)) to instances only where the perfecting words “incorporated by reference” or the root of the words “incorporate” (e.g., incorporating, incorporated) and “reference” (e.g., referencing) appear. The requirement for specific root words will bring greater clarity to the record and provide a bright line test as to where something is being referred to is an incorporation by reference. The Office intends to treat references to documents that do not meet this “bright line” test as noncompliant incorporations by reference and may require correction pursuant to 37 CFR 1.57(g). If a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended.< In addition to other requirements for an application, the referencing application *>must< include an identification of the referenced patent, application, or publication. >See 37 CFR 1.57(b)(2)< Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Application No. _____ left blank in the application as filed can be found in *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See >37 CFR 1.14(a)(i)(iv) and (vi) and< MPEP § 103).

1. Complete Disclosure Filed

If an application is filed with a complete disclosure, essential material may be canceled by amendment and may be substituted by reference to a U.S. patent or **>a U.S. patent application publication.< The amendment must be accompanied by **>a statement< signed by the applicant, or a practitioner representing the applicant, stating that the material canceled from the application is the same material that has been incorporated by reference >and no new matter has been included (see 37 CFR 1.57(f)). The same procedure is available for nonessential material.<

If an application as filed incorporates * material by reference **>, a copy of the incorporated by reference material may be required to be submitted to the Office even if the material is properly incorporated by reference. The examiner may require a copy of the incorporated material to review and to understand what is being incorporated or to put the description of the material in its proper context. Another instance where a copy of the incorporated material may be required is where the material is being inserted by amendment into the body of the application to replace an improper incorporation by reference statement so that the Office can determine that the material being added by amendment in lieu of the incorporation is the same material as was attempted to be incorporated. If the Office requires the applicant to supply a copy of the material incorporated by reference, the material must be accompanied by a statement that the copy supplied consists of the same material incorporated by reference in the referencing application. See 37 CFR 1.57(e).<

2. Improper Incorporation

**

>37 CFR 1.57(f) addresses corrections of incorporation by reference by inserting the material previously incorporated by reference. A noncompliant incorporation by reference statement may be corrected by an amendment. 37 CFR 1.57(f). However, the amendment must not include new matter. Incorporating by reference material that was not incorporated by reference on filing of an application may introduce new matter. An incorporation by reference of essential material to an unpublished U.S. patent application, a foreign application or patent, or to a publication is improper under 37 CFR 1.57(c). The improper incor-

608.01(p)

MANUAL OF PATENT EXAMINING PROCEDURE

poration by reference is not effective to incorporate the material unless corrected by the applicant (37 CFR 1.57(g)). Any underlying objection or rejection (e.g., under 35 U.S.C. 112) should be made by the examiner until applicant corrects the improper incorporation by reference by submitting an amendment to amend the specification or drawings to include the material incorporated by reference. A statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter is also required. 37 CFR 1.57(f). See also *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Improper incorporation by reference statements and late corrections thereof require expenditure of unnecessary examination resources and slow the prosecution process. Applicants know (or should know) whether they want material incorporated by reference, and must timely correct any incorporation by reference errors. Correction must be done within the time period set forth in 37 CFR 1.57(g).

An incorporation by reference that does not comply with 37 CFR 1.57(b), (c), or (d) is not effective to incorporate such material unless corrected within any time period set by the Office (should the noncompliant incorporation by reference be first noticed by the Office and applicant informed thereof), but in no case later than the close of prosecution as defined by 37 CFR 1.114(b) (should applicant be the first to notice the noncompliant incorporation by reference and the Office informed thereof), or abandonment of the application, whichever occurs earlier. The phrase “or abandonment of the application” is included in 37 CFR 1.57(g) to address the situations where an application is abandoned prior to the close of prosecution, e.g., the situation where an application is abandoned after a non-final Office action.

37 CFR 1.57(g)(1) authorizes the correction of non-compliant incorporation by reference statements that do not use the root of the words “incorporate” and “reference” in the incorporation by reference statement. This correction cannot be made when the material was merely referred to and there was no clear specific intent to incorporate it by reference.

37 CFR 1.57(g)(2) states that a citation of a document can be corrected where the document is sufficiently described to uniquely identify the document. Correction of a citation for a document that cannot be identified as the incorporated document may be new matter and is not authorized by 37 CFR 1.57(g)(2). An example would be where applicant intended to incorporate a particular journal article but supplied the citation information for a completely unrelated book by a different author, and there is no other information to identify the correct journal article. Since it cannot be determined from the citation originally supplied what article was intended to be incorporated, it would be improper (e.g., new matter) to replace the original incorporation by reference with the intended incorporation by reference. A citation of a patent application by attorney docket number, inventor name, filing date and title of invention may sufficiently describe the document, but even then correction should be made to specify the application number.

A petition under 37 CFR 1.183 to suspend the time period requirement set forth in 37 CFR 1.57(g) will not be appropriate. After the application has been abandoned, applicant must file a petition to revive under 37 CFR 1.137 for the purpose of correcting the incorporation by reference. After the application has issued as a patent, applicant may correct the patent by filing a reissue application. Correcting an improper incorporation by reference with a certificate of correction is not an appropriate means of correction because it may alter the scope of the claims. The scope of the claims may be altered because 37 CFR 1.57(g) provides that an incorporation by reference that does not comply with paragraph (b), (c), or (d) is not an effective incorporation. For example, an equivalent means omitted from a patent disclosure by an ineffective incorporation by reference would be outside the scope of the patented claims. Hence, a correction of an incorporation by reference pursuant to 37 CFR 1.57 may alter the scope of the claims by adding the omitted equivalent means. Changes involving the scope of the claims should be done via the reissue process. Additionally, the availability of the reissue process for corrections would make a successful showing required under 37 CFR 1.183 unlikely. The following examples show when an improper incorporation by reference is required to be corrected:

PARTS, FORM, AND CONTENT OF APPLICATION

608.01(p)

Example 1:

Upon review of the specification, the examiner noticed that the specification included an incorporation by reference statement incorporating essential material disclosed in a foreign patent. In a non-final Office action, the examiner required the applicant to amend the specification to include the essential material.

In reply to the non-final Office action, applicant must correct the improper incorporation by reference by filing an amendment to add the essential material disclosed in the foreign patent and a statement in compliance with 37 CFR 1.57(f) within the time period for reply set forth in the non-final Office action.

Example 2:

Upon review of the specification, the examiner determined that the subject matter incorporated by reference from a foreign patent was “nonessential material” and therefore, did not object to the incorporation by reference. In reply to a non-final Office action, applicant filed an amendment to the claims to add a new limitation that was supported only by the foreign patent. The amendment filed by the applicant caused the examiner to re-determine that the incorporated subject matter was “essential material” under 37 CFR 1.57(c). The examiner rejected the claims that include the new limitation under 35 U.S.C. 112, first paragraph, in a final Office action.

Since the rejection under 35 U.S.C. 112, first paragraph was necessitated by the applicant’s amendment, the finality of the Office action is proper. If the applicant wishes to overcome the rejection under 35 U.S.C. 112, first paragraph by filing an amendment under 37 CFR 1.57(f) to add the subject material disclosed in the foreign patent into the specification, applicant may file the amendment as an after final amendment in compliance with 37 CFR 1.116. Alternatively, applicant may file an RCE under 37 CFR 1.114 accompanied by the appropriate fee, and an amendment per 37 CFR 1.57(f) within the time period for reply set forth in the final Office action.

The following form paragraphs may be used:

¶ *6.19 Incorporation by Reference, Unpublished U.S. Application, Foreign Patent or Application, Publication*

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Examiner Note:

Since the material that applicant is attempting to incorporate in the specification is considered to be essential material, an appropriate objection to the specification and/or rejection of the claim(s) under 35 U.S.C. 112, should be made. One or more of form paragraphs 7.31.01 to 7.31.04, as for example, should be used following this form paragraph.

¶ *6.19.01 Ineffective Incorporation by Reference, General*

The attempt to incorporate subject matter into this application by reference to [1] is ineffective because [2].

Examiner Note:

1. In bracket 1, identify the document such as an application or patent number or other identification.
2. In bracket 2, give reason(s) why it is ineffective (e.g., the root words “incorporate” and/or “reference” have been omitted, see 37 CFR 1.57(b)(1); the reference document is not clearly identified as required by 37 CFR 1.57(b)(2)).
3. This form paragraph should be followed by form paragraph 6.19.03.

¶ *6.19.03 Correction of Ineffective Incorporation by Reference*

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorpo-

608.01(p)

MANUAL OF PATENT EXAMINING PROCEDURE

rated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

The filing date of any application wherein essential material is improperly incorporated by reference will not be affected by applicant's correction where (A) there is a clear intent to incorporate by reference the intended material and the correction is to add the root words of "incorporate" and "reference," (B) the incorporated document can be uniquely identified and the correction is to clarify the document's identification, and (C) where the correction is to insert the material from the reference where incorporation is to an unpublished U.S. patent application, foreign application or patent, or to a publication.<

Reliance on a commonly assigned >, prior filed or concurrently filed< copending application by a different inventor may ordinarily be made for the purpose of completing the disclosure >provided the incorporated material is directed to nonessential material. See 37 CFR 1.57(d)<. See *In re Fried*, 329 F.2d 323, 141 USPQ 27 (CCPA 1964), and *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968).

Since a disclosure must be complete as of the filing date, subsequent publications or subsequently filed applications cannot be relied on to establish a constructive reduction to practice or an enabling disclosure as of the filing date. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983); *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974); *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

B. Review of Applications Which Are Relied on To Establish an Earlier Effective Filing Date.

The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120. Neither 35 U.S.C. 119(a) nor 35 U.S.C. 120 places any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with 35 U.S.C. 112, first paragraph. Accordingly, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document. See *Ex parte Maziere*,

27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).

The reason for incorporation by reference practice with respect to applications which are to issue as U.S. patents is to provide the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The same policy concern does not apply where the sole purpose for which an applicant relies on an earlier U.S. or foreign application is to establish an earlier filing date. Incorporation by reference in the earlier application of (1) patents or applications published by foreign countries or regional patent offices, (2) nonpatent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application, is not critical in the case of a "benefit" application.

When an applicant, or a patent owner in a reexamination or interference, claims the benefit of the filing date of an earlier application which incorporates material by reference, the applicant or patent owner may be required to supply copies of the material incorporated by reference. For example, an applicant may claim the benefit of the filing date of a foreign application which itself incorporates by reference another earlier filed foreign application. If necessary, due to an intervening reference, applicant should be required to supply a copy of the earlier filed foreign application, along with an English language translation. A review can then be made of the foreign application and all material incorporated by reference to determine whether the foreign application discloses the invention sought to be patented in the manner required by the first paragraph of 35 U.S.C. 112 so that benefit may be accorded. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

As a safeguard against the omission of a portion of a prior application for which priority is claimed under 35 U.S.C. 119(a)-(d) or (f), or for which benefit is claimed under 35 U.S.C. 119(e) or 120, applicant may include a statement at the time of filing of the later application incorporating by reference the prior application. See MPEP § 201.06(c) >and § 201.11< where domestic benefit is claimed. See MPEP § 201.13

PARTS, FORM, AND CONTENT OF APPLICATION

608.01(q)

where foreign priority is claimed. >See MPEP § 201.17 regarding 37 CFR 1.57(a) for applications filed on or after September 21, 2004.< The inclusion of such an incorporation by reference statement in the later-filed application will permit applicant to include subject matter from the prior application into the later-filed application without the subject matter being considered as new matter. For the incorporation by reference to be effective as a proper safeguard, the incorporation by reference statement must be filed at the time of filing of the later-filed application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)).

II. SIMULATED OR PREDICTED TEST RESULTS OR PROPHETIC EXAMPLES

Simulated or predicted test results and prophetic examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367, 66 USPQ2d 1385, 1394 (Fed. Cir. 2003).

For problems arising from the designation of materials by trademarks and trade names, see MPEP § 608.01(v).

608.01(q) Substitute or Rewritten Specification [R-3]

37 CFR 1.125. *Substitute specification.*

(a) If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof, be rewritten.

(b) Subject to § 1.312, a substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by a statement that the substitute specification includes no new matter.

(c) A substitute specification submitted under this section must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown pursuant to this paragraph.

(d) A substitute specification under this section is not permitted in a reissue application or in a reexamination proceeding.

The specification is sometimes in such faulty English that a new specification is necessary; in such instances, a new specification should be required.

Form paragraph 6.28 may be used where the specification is in faulty English.

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¶ 6.28 *Idiomatic English*

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

37 CFR 1.125(a) applies to a substitute specification required by the Office. If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof be rewritten.

Form paragraph 6.28.01 may be used where the examiner, for reasons other than faulty English, requires a substitute specification.

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¶ 6.28.01 *Substitute Specification Required by Examiner*

A substitute specification [1] the claims is required pursuant to 37 CFR 1.125(a) because [2].

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strikethrough except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strikethrough cannot be easily perceived. An accompanying clean version (without markings) and a statement