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## Incorporation by Reference

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# Incorporation by Reference

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- **New Rule 37 CFR 1.57**
  - 69 FR 56482 (Sept. 21, 2004); 1287 OG 67 (Oct. 12, 2004)
  - OPLA's number is (571) 272-7701
- **Sequence Disclosure and Examples**



## 37 CFR 1.57 (a)

(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).



## 37 CFR 1.57 (part a cont.)

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- (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.



## 37 CFR 1.57 (part a cont.)

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- (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).



## 37 CFR 1.57 (b)

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(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.



## 37 CFR 1.57 (c)

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(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:



## 37 CFR 1.57 (part c cont.)

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- (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;



## 37 CFR 1.57 (part c cont.)

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- (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.



## 37 CFR 1.57 (d)

(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 nonpatent publications. An incorporation by reference by hyperlink or other form of browser executable code is not permitted.



## 37 CFR 1.57 (e)

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(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.



## 37 CFR 1.57 (f)

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(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.



## 37 CFR 1.57 (g)

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(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:



## 37 CFR 1.57 (part g cont.)

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- (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.



# Mechanisms for Disclosing Sequences

- Full disclosure of each sequence in full compliance with rules 37 CFR 1.821-1.825 (recommended).
  - Caution: Full disclosure of each sequence at the time of filing may be necessary when filing abroad.
- Explicit incorporation by reference of copending U.S. patent application, prior art document or database accession number that discloses sequence(s) intended to be part of the specification.
- Citation of, or reference to, a copending U.S. patent application, prior art document or database accession number that discloses sequence(s).
  - Depending on the context, this may or may not evidence a clear intent to incorporate the sequence(s) by reference.



# Sequence Disclosure

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- A rejection under 35 USC 112, 1<sup>st</sup> para (and/or 2<sup>nd</sup> para as appropriate) will be advanced if the examiner determines that a sequence not explicitly disclosed in the specification
  - is essential material and
  - is not incorporated by reference in compliance with 37 CFR 1.57.



# Ineffective Incorporation by Reference

- Incorporation by reference ineffective if it
  - Does not use proper words (“incorporate” and “reference”) or uniquely identify referenced document or
  - Incorporates essential material by reference to other than a U.S. patent or U.S. patent application publication or
  - Incorporates essential material 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 or
  - Incorporates nonessential material by reference to a hyperlink or other form of browser-executable code.
- A correction can be made pursuant to 37 CFR 1.57(g) provided that the correction is timely made, there was clear intent to incorporate, and the publication is uniquely identified.
- Material incorporated by reference may be added to the specification pursuant to 37 CFR 1.57(f), i.e., accompanied by a statement that the material being inserted is the material previously incorporated and that the amendment contains no new matter.



## Possible Options for Overcoming 35 USC 112 Rejection

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- Provide arguments/evidence showing that the material (sequence) is not essential.
- Amend the specification in compliance with 37 CFR 1.57(g) to correct an ineffective incorporation by reference of a U.S. patent or U.S. patent application publication.
- Amend the specification in compliance with 37 CFR 1.57 (f) to insert essential material incorporated by reference.



# Possible Options for Overcoming 35 USC 112 Rejection

- If the application as originally filed incorporates the sequence by reference in compliance with 37 CFR 1.57(b)(i.e., uses proper terms and clearly identifies document), or EVIDENCES A CLEAR INTENT to incorporate the sequence by reference, applicants may overcome the rejection by amending the specification to incorporate the essential material.
  - Such an amendment must comply with 37 CFR 1.57(f), i.e., accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter.
  - An amendment inserting a version of the sequence that was added to a data source after the filing date of the incorporating application (e.g., a corrected sequence) would not comply with 1.57(f) and may trigger a new matter rejection.



# What is Clear Intent?

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- The examiner has the task of determining whether applicants clearly intended to incorporate material by reference. This must be determined upon a case-by-case basis.
- A claim that identifies a sequence by database accession number will usually be accepted as clear intent to incorporate the sequence by reference. This claim must be an original claim that is present as of the filing date.



# What is Clear Intent?

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- In making the determination of clear intent the examiner will consider
  - language used in referencing the sequence
  - the context in which it is disclosed
  - any additional arguments/evidence presented by applicants.
- Language identifying a source only in passing as other prior work of no identified relevance is unlikely to be incorporated by reference.



# What is Clear Intent?

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- If the examiner determines there was no clear intent to incorporate the sequence, the examiner will maintain the 35 USC 112 rejection(s).
  - Final Rule “Discussion” indicates that “[i]f 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.” [69 FR at 56500; 1287 OG at 82]



# Questions?

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