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- Principle based in the law of contracts and wills
- Method of integrating material from various documents into a host document
- Saves time and space in the preparation of the host document



- In patent law, the principle is most relied upon when
 - Assertions are made that a prior art document is anticipatory
 - Assertions are made that amendments made to claims are not new matter



- When does a reference in the specification to material from a source act as a proper, compliant incorporation by reference?
- If an attempt at incorporation by reference is improper or noncompliant, can it be cured?



General Electric Co. v. Brenner, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968)

- Provides a brief history of the use of the doctrine with regard to patent law
- Only references available to the public may be incorporated by reference



In re Saunders, 444 F.2d 599, 170 USPQ 213 (CCPA 1971)

 Statement in specification referring to methods of preparing block co-polymers in a patent application was insufficient to incorporate by reference specific compounds prepared in one of the examples



In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973)

- Appellants asserted that lack of disclosure to a Venturi inlet in an application was cured because a grandparent case did disclose the Venturi inlet and was claimed for domestic priority
- The statement of priority was found NOT to act as an incorporation by reference



In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973)

"the incorporation by reference in an application of matter elsewhere written down (not necessarily in a patent application), for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found"



In re Hughes, 550 F.2d 1273, 193 USPQ 141 (CCPA 1977)

- Statement in specification was found to incorporate another application by reference
- "Reference is made to application Ser. No. 131,108 for complete description of methods of preparing aqueous polymeric dispersions applicable in the hereinafter described invention."



In re Voss, 557 F.2d 812, 194 USPQ 267 (CCPA 1977)

- Similar statement in the specification also found to be an effective incorporation by reference
- "Reference is made to United States Patent . . . for a general discussion of glass-ceramic materials and their production."



Advanced Display Systems, Inc. v. Kent State Univ., 212 F.3d 1272, 54 USPQ2d 1673 (Fed. Cir. 2000)

"To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." Advanced Display at **1282.**



Advanced Display Systems, Inc. v. Kent State Univ., 212 F.3d 1272, 54 USPQ2d 1673 (Fed. Cir. 2000)

- "whether and to what extent material has been incorporated by reference into a host document is a question of law"
- "The standard of one reasonably skilled in the art should be used to determine whether the host document describes the matter to be incorporated by reference with sufficient particularity."



Ex parte Raible, 8 USPQ2d 1709 (BPAI 1988)

- Examiner asserted that amendment to include "a heat exchange conduit helically disposed" constituted new matter
- Appellant asserted support via of incorporation by reference to a U.S. patent
- Board held that incorporation by reference statement broadly referred to several patents with no specific indication of the relevance of each to the claimed invention and as a result, amendment was new matter



37 CFR 1.57

- □ Effective October 21, 2004
- Codifies in Sections (b) (g) existing practice with respect to explicit incorporations by reference previously discussed in MPEP 608.01(p)
- Section (a) was added to address inadvertent omissions within a chain of priority
- The practice of permitting incorporation by reference of essential material from unpublished applications in which the issue fee was paid was discontinued



37 CFR 1.57

- 69 FR 56482 (September 21, 2004)
- 1287 OG 87 (October 12, 2004)



37 CFR 1.57

- Minimizes public's burden to search for and obtain copies of documents incorporated by reference
- Ensures that reasonably complete disclosures are found in U.S. patents and published applications



37 CFR 1.57 (b)

- An incorporation by reference 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)

" 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



37 CFR 1.57 (c)

- "Essential material"
 - (1) Provides written description, enablement and/or best mode of the invention
 - (2) Describes the claimed invention as required by 35 USC 112, 2nd paragraph
 - (3) Describes the structure, material or acts corresponding to a means or step + plus function as required by 35 USC, 6th paragraph



37 CFR 1.57 (c)

 Essential material present in the specification as filed may be canceled and replaced by an incorporation by reference to a U.S. patent or published application



37 CFR 1.57 (d)

- "Non -Essential material" can be incorporated from
 - U.S. patents or published applications
 - Foreign patents or published applications
 - Prior and concurrently-owned U.S. applications
 - Non-patent publications
 - However, hyperlink or other browser executable code is NOT permitted



37 CFR 1.57 (c) & (d)

- "Non-essential" subject matter may become "essential" subject matter and vice versa depending on specific claim amendments
- As a result, previously proper incorporations by reference may become improper or vice versa



37 CFR 1.57 (e)

- Examiner may require a copy of material incorporated by reference
- If required, material must be accompanied by a statement that the copy supplied consists of the same material incorporated by reference



37 CFR 1.57 (f)

- Improper incorporations by reference can only be cured by amendment to insert material previously incorporated by reference
 - No new matter
 - Improper attempt to incorporate essential subject matter is subject to rejection/objection until cured



37 CFR 1.57 (f)

 Amendment must be accompanied by a statement that material added has been previously incorporated by reference and that amendment contains no new matter



37 CFR 1.57 (g)

- Correction of improper incorporation by reference must be timely and no later than
 - Time period set when notified by PTO in office action
 - Close of prosecution defined by Rule 1.114(b) or abandonment when not notified by PTO



37 CFR 1.57 (g)

- Petitions under 37 CFR 1.183 to suspend time period requirement are not effective
- If abandoned, petition to revive under 37 CFR 1.137 must be filed
- After issue, correction must be made by reissue – certificate of correction is not effective



37 CFR 1.57 (g)(1)

- Corrections to comply with paragraph (b)(1) only permitted
 - If application as filed clearly conveys an intent to incorporate the material by reference
 - Mere reference to material does not convey an intent to incorporate the material by reference



37 CFR 1.57 (g)(2)

 Corrections to comply with paragraph (b)(2) only permitted for material that was sufficiently described to uniquely identify the document



- de Seversky (as restated by Advanced Display) sets forth the requirements of a proper incorporation by reference
- 37 CFR 1.57 requires the manner in which such a proper incorporation by reference must be made and how cure of improper/noncompliant incorporations can be made



Questions

- What constitutes "clear intent" per 37 CFR 1.57(g)(1)?
- What constitutes "clearly identify[ing] the subject matter which is incorporated "per de Seversky?
- What constitutes "uniquely identify" per 37 CFR 1.57(g)(2)?



Clear Intent

- Compare In re Hughes and In re Voss with Adang v. Umbeck, 2007 U.S. App. LEXIS 25198 (Fed. Cir. Unpub. 2007)
- Express use of root terms indicated clear intent which resulted in finding that reference cited without use of root terms showed no intent to incorporate



Clear Intent

- See also Southern Clay Products v.
 United Catalysts, 64 USPQ2d 1606 (Fed. Cir. Unpub. 2002).
- "Exemplary of commonly employed physical or comminuting techniques for breaking the bonds between the colloidal particles in a clay particle aggregate are those techniques disclosed in United States Pat. Nos. . . . "



Clear Intent

- Sequences identified by accession number in <u>original claims</u> will usually be accepted as clear intent to incorporate the sequence by reference
- Problems may occur however if the accession number does not "uniquely identify" the sequence desired to be incorporated by reference



Highlights and Guidance

- □ "Bright-Line" test after 37 CFR 1.57
 - Use the root terms "incorporate" and "reference"
- Before 37 CFR 1.57, look to
 - Language used in referring to the document
 - The context in which the document is discussed



Clearly Identify The Subject Matter

- Zenon Environmental, Inc. v. U.S.
 Filter Corp., 506 F.3d 1370 (Fed. Cir. 2007)
- Incorporation by reference of the vertical skein disclosure did not extend to incorporation of the entire document to include the gas distribution disclosure



Clearly Identify The Subject Matter

- Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 44 USPQ2d 1336 (Fed. Cir. 1997)
- The commercial product PROXIGEL, described in U.S. Patent No. 3,657,413 issued on Apr. 18, 1972 to M.W. Rosenthal, which patent is hereby incorporated by reference . . . "



Clearly Identify The Subject Matter

- Hayes Lemmerz International v.
 Kuhl Wheels, 2007 U.S. District
 LEXIS 30298 (E.D. Mich. 2007)
- Incorporation by reference of center hub portion of wheel support assemblies fails to provide detailed particularity to allow incorporation by reference of spoke arrangements



Clearly Identify The Subject Matter

- Telcordia Technologies v. Lucent Technologies, 514 F.Supp.2d 598 (D. Del. 2007)
- "For broadband services previous contributions have indicated that packet-mode techniques are a way to achieve flexibility at rates lower than the broadband channel rate (T1D1.1/85-113, T1D1.1/85 149). The modular approach described here is necessary to construct channels at rates higher than the STS-1 rate for basic transport of broadband services and to facilitate the introduction of other undefined services."



Clearly Identify The Subject Matter

- Callaway Golf Co. v. Acushnet Co., 523 F.Supp.2d 388 (D. Del. 2007)
- Reference to "a number of foamable compositions" for golf ball construction did not permit the incorporation by reference of polyurethane



Highlights and Guidance

- Be specific with regard to subject matter to be incorporated
- Statements incorporating a document "in its entirety" may not be sufficient to permit incorporation of material not specifically identified in the incorporation statement



- Corrections to improper incorporations by reference can only be made when the source document is sufficiently described to uniquely identify the document
- References to sequences by database accession or identification numbers may or may not uniquely identify a sequence



- Accession number identifies the nature of the sequence and does not vary with different versions of the actual sequence that may change over time
- "g" number identifies the specific sequence and is unique to any specific sequence
- Look to the "Reports" link to determine the presence of multiple versions and to compare changes made



1: N87092. Reports L2193F Human feta...[gi:1440294]

IDENTIFIERS

dbEST Id: 493303 EST name: L2193F GenBank Acc: N87092 GenBank gi: 1440294

CLONE INFO

Clone Id: L2193 (5')

DNA type: cDNA

PRIMERS

Sequencing: GAAATTAACCCTCACTAAAGGG

PolyA Tail: Unknown

SEQUENCE

GAAATCTCAGCCCCCACCTCCACAGCCAGCAAGGTCAGCTTCTAGTTCAACCATCAATCT
AATGGTGAGCACAGAACCATTGGCTCTCACTGAAACAGATATATGCAAGTTGCCGAAAGA
CGAAGGAACTTGCAGGGATTTCATATTAAAATGGTACTATGATCCAAACACCCAAAAGCTG
TGCAAGATTCTGGTATGGAGGTTGTGGTGGAACCGAAAACAAATTTGGATCACAGAAAGA
TTGTTAAAGGTTTGCGCTCCTGTGCTCGACACCCGGAGTCATCAGTGTGATGGCACCTA

GCG

Entry Created: Apr 1 1996 Last Updated: Apr 1 1996



Revision history for N87092

Gl	Version	Update Date
1440294	1	<u>Apr 1 1996 5:23 PM</u>

Accession N87092 was first seen at NCBI on Apr 1 1996 5:23 PM



```
1: L21934. Reports Homo sapiens acyl...[gi:4878021]
 Comment Features Sequence
LOCUS
            HUMACYLCOA
                                     4011 bp
                                                mRNA
                                                        linear
                                                                  PRI 20-MAY-1999
DEFINITION Homo sapiens acyl-coenzyme A: cholesterol acyltransferase mRNA,
            complete cds.
ACCESSION
            L21934
VERSTON
            T.21934.2 GT:4878021
KEYWORDS
SOURCE
            Homo sapiens (human)
  ORGANISM Homo sapiens
            Eukarvota: Metazoa: Chordata: Craniata: Vertebrata: Euteleostomi:
            Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
            Catarrhini: Hominidae: Homo.
REFERENCE
               (bases 1 to 4011)
  AUTHORS
            Chang, C.C., Huh, H.Y., Cadigan, K.M. and Chang, T.Y.
  TITLE
            Molecular cloning and functional expression of human acyl-coenzyme
            A:cholesterol acyltransferase cDNA in mutant Chinese hamster ovary
            cells
            J. Biol. Chem. 268 (28), 20747-20755 (1993)
  JOURNAL
   PUBMED
            8407899
REFERENCE
               (bases 1 to 4011)
  AUTHORS
            Chang, C.C. and Chang, T.Y.
  TITLE
            Direct Submission
  JOURNAL.
            Submitted (02-NOV-1993) Biochemistry Dept, Dartmouth Medical
            School, Hanover, NH 03755, USA
REFERENCE
               (bases 1 to 4011)
            Chang, C.C. and Chang, T.Y.
  AUTHORS
  TITLE
            Direct Submission
  JOURNAL
            Submitted (20-MAY-1999) Biochemistry Dept, Dartmouth Medical
            School, Hanover, NH 03755, USA
  REMARK
            Sequence update by submitter
COMMENT
            On May 20, 1999 this sequence version replaced gi:409203.
```



Revision history for <u>L21934</u>

GI	Version	Update Date
4878021	2	May 20 1999 9:18 AM
409203	1	Sep 23 1998 12:59 PM
409203	1	Nov 24 1993 1:20 PM
409203	1	Oct 22 1993 12:08 AM

Accession L21934 was first seen at NCBI on Oct 22 1993 12:08 AM



- Not all records are so clear, e.g.
 NCBI SNP records
- Presence of differing entry and update dates indicate changes but it is unclear as to the nature of the changes



Reference SNP(refSNP) Cluster Report: rs343

refSNP ID: rs343	Allele		
Organism: human (<u>Homo sapiens</u>)	Variation Class: SNP: single nucleotide polymorphism		
Molecule Type: Genomic	single nucleotide polymorphism		
Created/Updated in build: 36/129	RefSNP Alleles: A/C		
Map to Genome Build: 36.3	Ancestral Allele: C		
	Clinical Association: unknown		



NCBI Assay ID	Handle Submitter ID	Validation Status	ss to rs Orientation /Strand	Alleles
<u>ss344</u>	DEBNICK lp00106	B	fwd/T	A/C
ss6804713	WI_SSAHASNP NT_030737.5_3637251	$m{\kappa}$	fwd/T	A/C
ss16343018	IMCJ-GDT IMCJ-LPL_3-ac		fwd/T	A/C
ss24421365	PERLEGEN afd4591955	$m{\kappa}$	fwd/T	A/C
ss75139237	ILLUMINA ILMN_Human_1M_rs343		fwd/T	A/C
ss76661873	AFFY AFFY_6_1M_SNP_A-8523169		fwd/T	A/C
ss80743679	KRIBB_YJKIM KHS1000005		fwd/T	A/C
ss83741132	HGSV Cor18555_SNV_20070510.chr8_19855067		fwd/T	A/C



5' Near Seq 30 bp	3' Near Seq 30 bp	Entry Date	Update Date		Molecule Type
ttgtttcttttagttttatttttggcagaa	tgtaagcaccttcattttctttttcta	11/24/98	12/23/03	36	Genomic
ttgtttcttttagttttatttttggcagaa	tgtaagcaccttcattttctttttcta	02/12/03	10/25/06	111	Genomic
ttgtttcttttagttttatttttggcagaa	tgtaagcaccttcattttctttttcttnca	01/16/04	01/23/04	120	Genomic
ttgtttcttttagttttatttttggcagaa	tgtaagcaccttcattttctttttcta	08/10/04	09/13/04	123	Genomic
ttgtttcttttagttttatttttggcagaa	tgtaagcaccttcattttctttttcta	08/28/07	08/29/07	129	Genomic
tttatttttggcagaa	tgtaagcaccttcatt	08/28/07	08/30/07	129	Genomic
ttgtttcttttagttttatttttggcagaa	tgtmagcaccttcattttctttttcttyca	11/26/07	11/26/07	130	Genomic
ttgtttcttttagttttatttttggcagaa	tgtaagcaccttcattttctttttcta	11/27/07	12/05/07	130	Genomic



Highlights and Guidance

- Submit the sequence at time of filing
- Be specific as to version or use identifier unique to specific sequence
- Retain documentation of database source indicating exact sequence and date accessed



Thank You!

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- **571-272-0927**