this section is satisfied or the examiner is convinced that a deposit is not need-
ed.

c) If an application for patent is oth-

erwise in condition for allowance ex-

cept for a needed deposit and the Office

has received a written assurance that an

acceptable deposit will be made, appli-
cant will be notified and given a pe-

riod of time within which the deposit

must be made in order to avoid aban-
donment. This time period is not ex-
tendable under §1.136(a) or (b) if set
forth in a “Notice of Allowability” or

in an Office action having a mail date
on or after the mail date of a “Notice
of Allowability” (see §1.136(c)).

d) For each deposit made pursuant
to these regulations, the specification
shall contain:

(1) The accession number for the de-

posit;

(2) The date of the deposit;

(3) A description of the deposited bio-

tological material sufficient to specifi-
cally identify it and to permit exam-
nation; and

(4) The name and address of the de-

pository.

e) Any amendment required by para-
graphs (d)(1), (d)(2) or (d)(4) of this sec-
tion must be filed before or with the
payment of the issue fee (see §1.312).

[54 FR 34880, Aug. 22, 1989, as amended at 66
FR 21092, Apr. 27, 2001]

APPLICATION DISCLOSURES CONTAINING
NUCLEOTIDE AND/OR AMINO ACID SE-
QUENCES

SOURCE: Sections 1.821 through 1.825 appear
at 55 FR 18245, May 1, 1990, unless otherwise
noted.

§1.821 Nucleotide and/or amino acid
sequence disclosures in patent ap-
plications.

(a) Nucleotide and/or amino acid se-
quences as used in §§1.821 through 1.825
are interpreted to mean an unbranched
sequence of four or more amino acids
or an unbranched sequence of ten or
more nucleotides. Branched sequences
are specifically excluded from this defi-
nition. Sequences with fewer than four
specifically defined nucleotides or
amino acids are specifically excluded
from this section. “Specifically de-

fined” means those amino acids other
than “Xaa” and those nucleotide bases
other than “n”defined in accordance
with the World Intellectual Property
Organization (WIPO) Handbook on In-
dustrial Property Information and Doc-
umentation, Standard ST.25: Standard
for the Presentation of Nucleotide and
Amino Acid Sequence Listings in Pat-
ent Applications (1998), including Ta-
bles 1 through 6 in Appendix 2, herein
incorporated by reference. (Hereinafter
“WIPO Standard ST.25 (1998)”.

This incorporation by reference was ap-
proved by the Director of the Federal
Register in accordance with 5 U.S.C.
552(a) and 1 CFR part 51. Copies of
WIPO Standard ST.25 (1998) may be ob-
tained from the World Intellectual
Property Organization; 34 chemin des
Colombettes; 1211 Geneva 20 Switzer-
land. Copies may also be inspected at
the National Archives and Records Ad-
ministration (NARA). For information
on the availability of this material at
NARA, call 202-741–6030, or go to: http://
www.archives.gov/federal_register/
code_of_federal_regulations/ibr_locations.html. Nucleotides and
amino acids are further defined as fol-

lows:

(1) Nucleotides: Nucleotides are in-

tended to embrace only those nucleo-
tides that can be represented using the
symbols set forth in WIPO Standard
ST.25 (1998), Appendix 2, Table 1. Modi-
fications, e.g., methylated bases, may
be described as set forth in WIPO
Standard ST.25 (1998), Appendix 2,
Table 2, but shall not be shown explic-
itly in the nucleotide sequence.

(2) Amino acids: Amino acids are
those L-amino acids commonly found
in naturally occurring proteins and are
listed in WIPO Standard ST.25 (1998),
Appendix 2, Table 3. Those amino acid
sequences containing D-amino acids
are not intended to be embraced by
this definition. Any amino acid se-
quence that contains post-
translationally modified amino acids
may be described as the amino acid se-
quence that is initially translated
using the symbols shown in WIPO
Standard ST.25 (1998), Appendix 2,
Table 2, but shall not be shown expli-
itly in the nucleotide sequence.

(b) Nucleotide and/or amino acid se-
quences as used in §§1.821 through 1.825
are interpreted to mean an unbranched
sequence of four or more amino acids
or an unbranched sequence of ten or
more nucleotides. Branched sequences
are specifically excluded from this defi-
nition. Sequences with fewer than four
specifically defined nucleotides or
amino acids are specifically excluded
from this section. “Specifically de-

fined” means those amino acids other
than “Xaa” and those nucleotide bases
other than “n”defined in accordance
with the World Intellectual Property
Organization (WIPO) Handbook on In-
dustrial Property Information and Doc-
umentation, Standard ST.25: Standard
for the Presentation of Nucleotide and
Amino Acid Sequence Listings in Pat-
ent Applications (1998), including Ta-
bles 1 through 6 in Appendix 2, herein
incorporated by reference. (Hereinafter
“WIPO Standard ST.25 (1998)”.

This incorporation by reference was ap-
proved by the Director of the Federal
Register in accordance with 5 U.S.C.
552(a) and 1 CFR part 51. Copies of
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tained from the World Intellectual
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Colombettes; 1211 Geneva 20 Switzer-
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ministration (NARA). For information
on the availability of this material at
NARA, call 202-741–6030, or go to: http://
www.archives.gov/federal_register/
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(1) Nucleotides: Nucleotides are in-

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ST.25 (1998), Appendix 2, Table 1. Modi-
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be described as set forth in WIPO
Standard ST.25 (1998), Appendix 2,
Table 2, but shall not be shown explic-
itly in the nucleotide sequence.

(2) Amino acids: Amino acids are
those L-amino acids commonly found
in naturally occurring proteins and are
listed in WIPO Standard ST.25 (1998),
Appendix 2, Table 3. Those amino acid
sequences containing D-amino acids
are not intended to be embraced by
this definition. Any amino acid se-
quence that contains post-
translationally modified amino acids
may be described as the amino acid se-
quence that is initially translated
using the symbols shown in WIPO
Standard ST.25 (1998), Appendix 2,
Table 2, but shall not be shown expli-
itly in the nucleotide sequence.
not be shown explicitly in the amino acid sequence. Any peptide or protein that can be expressed as a sequence using the symbols in WIPO Standard ST.25 (1998), Appendix 2, Table 3 in conjunction with a description in the Feature section to describe, for example, modified linkages, cross links and end caps, non-peptidyl bonds, etc., is embraced by this definition.

(b) Patent applications which contain disclosures of nucleotide and/or amino acid sequences, in accordance with the definition in paragraph (a) of this section, shall, with regard to the manner in which the nucleotide and/or amino acid sequences are presented and described, conform exclusively to the requirements of §§1.821 through 1.825.

(c) Patent applications which contain disclosures of nucleotide and/or amino acid sequences must contain, as a separate part of the disclosure, a paper or compact disc copy (see §1.52(e)) disclosing the nucleotide and/or amino acid sequences and associated information using the symbols and format in accordance with the requirements of §§1.822 and 1.823. This paper or compact disc copy is referred to elsewhere in this subpart as the “Sequence Listing.” Each sequence disclosed must appear separately in the “Sequence Listing” and must be assigned a separate sequence identifier. The sequence identifiers must begin with 1 and increase sequentially by integers. If no sequence is present for a sequence identifier, the code “000” must be used in place of the sequence. The response for the numeric identifier <160> must include the total number of SEQ ID NOS, whether followed by a sequence or by the code “000”.

d) Where the description or claims of a patent application discuss a sequence that is set forth in the “Sequence Listing” in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by “SEQ ID NO:’’ in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

e) A copy of the “Sequence Listing” referred to in paragraph (c) of this section must also be submitted in computer readable form (CRF) in accordance with the requirements of §1.824. The computer readable form must be a copy of the “Sequence Listing” and may not be retained as a part of the patent application file. If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference may be made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application if the computer readable form in the other application was compliant with all of the requirements of this subpart. The new application must be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified. In the new application, applicant must also request the use of the compliant computer readable “Sequence Listing” that is already on file for the other application and must state that the paper or compact disc copy of the “Sequence Listing” in the new application is identical to the computer readable copy filed for the other application.

(f) In addition to the paper or compact disc copy required by paragraph (c) of this section and the computer readable form required by paragraph (e) of this section, a statement that the “Sequence Listing” content of the paper or compact disc copy and the computer readable copy are the same must be submitted with the computer readable form, e.g., a statement that “the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing.”

(g) If any of the requirements of paragraphs (b) through (f) of this section are not satisfied at the time of filing under 35 U.S.C. 111(a) or at the time of entering the national stage under 35 U.S.C. 371, applicant will be notified and given a period of time within which to comply with such requirements in order to prevent abandonment of the application. Any submission in reply to a requirement under this paragraph must be accompanied by a statement that the submission includes no new matter.
(h) If any of the requirements of paragraphs (b) through (f) of this section are not satisfied at the time of filing an international application under the Patent Cooperation Treaty (PCT), which application is to be searched by the United States International Searching Authority or examined by the United States International Preliminary Examining Authority, applicant will be sent a notice necessitating compliance with the requirements within a prescribed time period. Any submission in reply to a requirement under this paragraph must be accompanied by a statement that the submission does not include matter which goes beyond the disclosure in the international application as filed. If applicant fails to timely provide the required computer readable form, the United States International Searching Authority shall search only to the extent that a meaningful search can be performed without the computer readable form and the United States International Preliminary Examining Authority shall examine only to the extent that a meaningful examination can be performed without the computer readable form.

§ 1.822 Symbols and format to be used for nucleotide and/or amino acid sequence data.

(a) The symbols and format to be used for nucleotide and/or amino acid sequence data shall conform to the requirements of paragraphs (b) through (e) of this section.

(b) The code for representing the nucleotide and/or amino acid sequence characters shall conform to the code set forth in the tables in WIPO Standard ST.25 (1998), Appendix 2, Tables 1 and 3. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ST.25 may be obtained from the World Intellectual Property Organization; 34 chemin des Colombettes; 1211 Geneva 20 Switzerland. Copies may also be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/ federal_register/code_of_federal_regulations/ibr_locations.html. No code other than that specified in these sections shall be used in nucleotide and amino acid sequences. A modified base or modified or unusual amino acid may be presented in a given sequence as the corresponding unmodified base or amino acid if the modified base or modified or unusual amino acid is one of those listed in WIPO Standard ST.25 (1998), Appendix 2, Tables 2 and 4, and the modification is also set forth in the Feature section. Otherwise, each occurrence of a base or amino acid not appearing in WIPO Standard ST.25 (1998), Appendix 2, Tables 1 and 3, shall be listed in a given sequence as “n” or “Xaa,” respectively, with further information, as appropriate, given in the Feature section, preferably by including one or more feature keys listed in WIPO Standard ST.25 (1998), Appendix 2, Tables 5 and 6.

(c) Format representation of nucleotides. (1) A nucleotide sequence shall be listed using the lower-case letter for representing the one-letter code for the nucleotide bases set forth in WIPO Standard ST.25 (1998), Appendix 2, Tables 1 and 3.

(2) The bases in a nucleotide sequence (including introns) shall be listed in groups of 10 bases except in the coding parts of the sequence. Leftover bases, fewer than 10 in number, at the end of noncoding parts of a sequence shall be grouped together and separated from adjacent groups of 10 or 3 bases by a space.

(3) The bases in the coding parts of a nucleotide sequence shall be listed as triplets (codons). The amino acids corresponding to the codons in the coding parts of a nucleotide sequence shall be typed immediately below the corresponding codons. Where a codon spans an intron, the amino acid symbol shall be typed below the portion of the codon containing two nucleotides.

(4) A nucleotide sequence shall be listed with a maximum of 16 codons or 60 bases per line, with a space provided between each codon or group of 10 bases.