Patent Laws and Regulations

(c) The length of the regulatory review period for a veterinary biological product will be determined by the Secretary of Agriculture. Under 35 U.S.C. 156(g)(5)(B), it is the sum of —

(1) The number of days in the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act; and

(2) The number of days in the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(d) The term of the patent as extended for a veterinary biological product will be determined by —

(1) Subtracting from the number of days determined by the Secretary of Agriculture to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section that were on and before the date on which the patent issued;

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. 156(d)(2)(B) by the Secretary of Agriculture that applicant did not act with due diligence;

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of the issuance of a license under the Virus-Serum-Toxin Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after November 16, 1988, by --

(i) Adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before November 16, 1988, and

(i) If no request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, by --

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, and the commercial marketing or use of the product was not approved before November 16, 1988, by --

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[Added 54 FR 30375, July 20, 1989, effective Aug. 22, 1989]

37 CFR 1.780 Certificate of extension of patent term.

If a determination is made pursuant to § 1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or certificate of interim extension under 35 U.S.C. 156(d)(5) will be issued to the applicant for the extension of the patent term. Such certificate will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate of extension will be published in the Official Gazette of the Patent and Trademark Office. Notification of the issuance of the certificate of interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the Official Gazette of the Patent and Trademark Office and in the Federal Register. No certificate of extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination made pursuant to § 1.750 will indicate that no certificate will issue.

[Added 52 FR 9399, Mar. 24 1987, effective May 26, 1987; para. (as revised, 60 FR 25615, May 12, 1995, effective July 11, 1995]

37 CFR 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

(a) Only one patent may be extended for a regulatory review period for any product § 1.720 (h)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the patents are otherwise eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for extension pursuant to the requirements of this subpart, the certificate of extension of patent term will be issued on the application only if the patent owner or its agent is the holder of the regulatory approval granted with respect to the regulatory review period.

(d) An application for extension shall be considered complete and formal regardless of whether it contains the identification of the holder of the regulatory approval granted with respect to the regulatory review period. When an application contains such information, or is amended to contain such information, it will be considered in determining whether an application is eligible for an extension under this section. A request may be made of any applicant to supply such information within a non-extendable period of not less than one (1) month whenever multiple applications for extension of more than one patent are received and rely upon the same regulatory review period. Failure to provide such information within the period for response set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to § 1.750 and shall be regarded as part of that determination.

[Added 52 FR 9399, Mar. 24 1987, effective May 26, 1987; para. (b) amended 54 FR 30375, July 20, 1989, effective Aug. 22, 1989; revised, 60 FR 25615, May 12, 1995, effective July 11, 1995}

Patent Laws and Regulations

37 CFR 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5)

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under § 1.740 and a complete application under § 1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6) - (a)(17) of § 1.740 and § 1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of § 1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed along with any materials or information required under § 1.740 and § 1.741 that are not present in the preceding interim extension application.

[Added 60 FR 25615, May 12, 1995, effective July 11, 1995]

37 CFR 1.791 Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under § 1.740 and § 1.741 including any additional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

[Added 60 FR 25615, May 12, 1995, effective July 11, 1995]

SUBPART G–BIOTECHNOLOGY INVENTION DISCLOSURES

DEPOSIT OF BIOLOGICAL MATERIAL

37 CFR 1.801 Biological material.

For the purposes of these regulations pertaining to the deposit of biological material for purposes of patents for inventions under 35 U.S.C. 101, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.

[Added 54 FR 34880, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.802 Need or opportunity to make a deposit.

(a) Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material.

(b) Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or

isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

(c) The reference to a biological material in a specification disclosure or the actual deposit of such material by an applicant or patent owner does not create any presumption that such material is necessary to satisfy 35 U.S.C. 112 or that deposit in accordance with these regulations is or was required.

[Added 54 FR 34880, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.803 Acceptable depository.

(a) A deposit shall be recognized for the purposes of these regulations if made in;

(1) any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Commissioner may seek the advice of impartial consultants on the suitability of a depository. The depository must:

(i) Have a continuous existence;

(ii) Exist independent of the control of the depositor;

(iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;

(iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;

(v) Be impartial and objective;

(vi) Furnish samples of the deposited material in an expeditious and proper manner; and

(vii) Promptly notify depositors of its inability to furnish samples, and the reasons why.

(b) A depository seeking status under paragraph (a)(2) of this section must direct a communication to the Commissioner which shall:

(1) Indicate the name and address of the depository to which the communication relates;

(2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (a)(2) of this section, including information on its legal status, scientific standing, staff, and facilities;

(3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;

(5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(c) A depository having status under paragraph (a)(2) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Commissioner in accordance with paragraph (b) of this section. If a previous communication under paragraph (b) of this section is of record, items in common with the previous communication may be incorporated by reference.

(d) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office.

[Added 54 FR 34881, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.804 Time of making an original deposit.

(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject tow 1.809, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant shall promptly submit a verified statement from a person in a position to corroborate the fact, and shall state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified.

[Added 54 FR 34881, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.805 Replacement or supplement of deposit.

(a) A depositor, after receiving notice during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, shall notify the Office in writing, in each application for patent or patent affected. In such a case, or where the Office otherwise learns, during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, the need for making a replacement or supplemental deposit will be governed by the same considerations governing the need for making an original deposit under the provisions set forth in § 1.802(b). A replacement or supplemental deposit made during the pendency of an application for patent shall not be accepted unless it meets the requirements for making an original deposit under these regulations, including the requirement set forth under § 1.804(b). A replacement or supplemental deposit made in connection with a patent, whether or not made during the pendency of an application for reissue patent or a reexamination proceeding or both, shall not be accepted unless a certificate of correction under § 1.323 is requested by the patent owner which meets the terms of paragraphs (b) and (c) of this section.

(b) A request for certificate of correction under this section shall not be granted unless the certificate identifies:

(1) The accession number for the replacement or supplemental deposit;

(2) The date of the deposit; and

(3) The name and address of the depository.

(c) A request for a certificate of correction under this section shall not be granted unless the request is made promptly after the replacement or supplemental deposit has been made and:

(1) Includes a verified statement of the reason for making the replacement or supplemental deposit;

(2) Includes a verified statement from a person in a position to corroborate the fact, and shall state, that the replacement or supplemental deposit is of a biological material which is identical to that originally deposited;

(3) Includes a verified showing that the patent owner acted diligently --

(i) In the case of a replacement deposit, in making the deposit after receiving notice that samples could no longer be furnished from an earlier deposit, or

(ii) In the case of a supplemental deposit, in making the deposit after receiving notice that the earlier deposit had become contaminated or had lost its capability to function as described in the specification;

(4) Includes a verified statement that the term of the replacement or supplemental deposit expires no earlier than the term of the deposit being replaced or supplemented; and

(5) Otherwise establishes compliance with these regulations, except that if the person making one or more of the required statements or showing is an attorney or agent registered to practice before the Office, that statement or showing need not be verified.

(d) A depositor's failure to replace a deposit, or in the case of a patent, to diligently replace a deposit and promptly thereafter request a certificate of correction which meets the terms of paragraphs (b) and (c) of this section, after being notified that the depository possessing the deposit cannot furnish samples thereof, shall cause the application or patent involved to be treated in any Office proceeding as if no deposit were made.

(e) In the event a deposit is replaced according to these regulations, the Office will apply a rebuttable presumption of identity between the original and the replacement deposit where a patent making reference to the deposit is relied upon during any Office proceeding.

(f) A replacement or supplemental deposit made during the pendency of an application for patent may be made for any reason.

(g) In no case is a replacement or supplemental deposit of a biological material necessary where the biological material, in accordance with § 1.802(b), need not be deposited.

(h) No replacement deposit of a biological material is necessary where a depository can furnish samples thereof but the depository for national security, health or environmental safety reasons is unable to provide samples to requesters outside of the jurisdiction where the depository is located.

(i) The Office will not recognize in any Office proceeding a replacement deposit of a biological material made by a patent owner where the depository could furnish samples of the deposit being replaced.

[Added 54 FR 34881, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.806 Term of deposit.

A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

[Added 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.807 Viability of deposit.

(a) A deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. No evidence is necessarily required regarding the ability of the deposited material to perform any function described in the patent application.

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must

contain:

(1) The name and address of the depository;

(3) The date of deposit;

(2) The name and address of the depositor;

(4) The identity of the deposit and the accession number given by the depository;

(5) The date of the viability test;

(6) The procedures used to obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

(c) If a viability test indicates that the deposit is not viable upon receipt, or the examiner cannot, for scientific or other valid reasons, accept the statement of viability received from the applicant, the examiner shall proceed as if no deposit has been made. The examiner will accept the conclusion set forth in a viability statement issued by a depository recognized under § 1.803(a).

[Added 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.808 Furnishing of samples.

(a) A deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under § 1.14 and 35 U.S.C. 122, and

(2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:

(1) Is in writing or other tangible form and dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and

(3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

(c) Upon request made to the Office, the Office will certify whether a deposit has been stated to have been made under conditions which make it available to the public as of the issue date of the patent grant provided the request contains:

(1) The name and address of the depository;

(2) The accession number given to the deposit;

(3) The patent number and issue date of the patent referring to the deposit; and

(4) The name and address of the requesting party.

[Added 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990]

37 CFR 1.809 Examination procedures.

(a) The examiner shall determine pursuant tow 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under the appropriate provision of 35 U.S.C. 112,

explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.

(b) The applicant for patent or patent owner shall respond to a rejection under paragraph (a) of this section by --

(1) In the case of an applicant for patent, making an acceptable original or replacement or supplemental deposit or assuring the Office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee, or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of § 1.805, or

(2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered nonresponsive. The rejection will be repeated until either paragraph (b)(1) of this section is satisfied or the examiner is convinced that a deposit is not needed.

(c) If an application for patent is otherwise in condition for allowance except for a needed deposit and the Office has received a written assurance that an acceptable deposit will be made on or before payment of the issue fee, the Office will mail to the applicant a Notice of Allowance and Issue Fee Due together with a requirement that the needed deposit be made within three months. The period for satisfying this requirement is extendable under § 1.136. Failure to make the needed deposit in accordance with this requirement will result in abandonment of the application for failure to prosecute.

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

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

[Added 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990]

APPLICATION DISCLOSURES CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCES

37 CFR 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.

(a) Nucleotide and/or amino acid sequences as used in §§ 1.821 through 1.825 is 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 definition. Nucleotides and amino acids are further defined as follows:

(1) Nucleotides are intended to embrace only those nucleotides that can be represented using the symbols set forth in § 1.822(b)(1). Modifications, e.g., methylated bases, may be described as set forth in § 1.822(b), but shall not be shown explicitly in the nucleotide sequence.

(2) Amino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in § 1.822(b)(2). Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition. Any amino acid sequence that contains post-translationally modified amino acids may be described as the amino acid sequence that is initially translated using the symbols shown in § 1.822(b)(2) with the modified positions; e.g., hydroxylations or glycosylations, being described as set forth in § 1. 822(b), but these modifications shall not be shown explicitly in the amino acid sequence. Any peptide or protein that can be expressed as a sequence using the symbols in § 1.822(b)(2) in conjunction with a description elsewhere in the "Sequence Listing" 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 on paper copy, hereinafter referred to as the "Sequence Listing," a disclosure of 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. Each sequence disclosed must appear separately in the "Sequence Listing." Each sequence set forth in the "Sequence Listing" shall be assigned a separate identifier written as SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, etc.

(d) Where the description or claims of a patent application discuss a sequence listing 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 assigned identifier, 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 in accordance with the requirements of § 1.824. The computer readable form is a copy of the "Sequence Listing" and will not necessarily be retained as 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. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified.

(f) In addition to the paper copy required by paragraph (c) of this section and the computer readable form required by paragraph (e) of this section, a statement that the content of the paper and computer readable copies are the same must be submitted with the computer readable form. Such a statement must be a verified statement if made by a person not registered to practice before the Office.

(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 or at the time of entering the national stage under 35 U.S.C. 371, applicant has one month from the date of a notice which will be sent requiring compliance with the requirements in order to prevent abandonment of the application. Any submission in response to a requirement under this paragraph must be accompanied by a statement that the submission includes no new matter. Such a statement must be a verified statement if made by a person not registered to practice before the Office.

(h) If any of the requirements of paragraphs (b) through (f) of this section are not satisfied at the time of filing, in the United States Receiving Office, an international application under the Patent Cooperation Treaty (PCT) applicant has one month from the date of a notice which will be sent requiring compliance with the requirements, or such other time as may be set by the Commissioner, in which to comply. Any submission in response to a requirement under this paragraph must be accompanied by a statement that the submission does not include new matter or go beyond the disclosure in the international application as filed. Such a statement must be a verified statement if made by a person not registered to practice before the Office. 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.

(i) Neither the presence nor the absence of information which is not required under §§ 1.821 through 1.825, in an application shall create any presumption that such information is necessary to satisfy one or more of the requirements of 35 U.S.C. 112. Further, the grant of a patent on an application that is subject to the requirements of §§ 1.821 through 1.825 shall constitute a conclusive presumption that said patent complies with the requirements of §§ 1.821 through 1.825.

(j) Envelopes containing only application papers, computer readable forms and fees filed

under this section should be marked "Box SEQUENCE."

[Added 55 FR 18230, May 1, 1990, effective Oct. 1, 1990; para. (h) amended, 58 FR 9335, Jan. 14, 1993, effective May 1, 1993]

37 CFR 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 (p) 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 paragraphs (b)(1) and (b)(2) of this section. No code other than that specified in this section shall be used in nucleotide and amino acid sequences. A modified base or amino acid may be presented in a given sequence as the corresponding unmodified base or amino acid if the modified base or amino acid is one of those listed in paragraphs (p)(1) or (p)(2) of this section and the modification is also set forth elsewhere in the Sequence Listing (for example, FEATURES § 1.823(b)(2)(ix)). Otherwise, all bases or amino acids not appearing in paragraphs (b)(1) or (b)(2) of this section shall be listed in a given sequence as "N" or "Xaa," respectively, with further information, as appropriate, given elsewhere in the Sequence Listing.

(1) Base codes:

Symbol	Meaning
A	A; adenine
C	C; cytosine
G	G; guanine
T	T; thymine
U	U; uracil
M	A or C
R	A or G
W	A or T/U
S	C or G
Y	C or T/U
K	G or T/U
V	A or C or G; not T/U
H	A or C or T/U; not G
D	A or G or T/U; not C
B	C or G or T/U; not A
N	(A or C or G or T/U) or (unknown or other)

(2) Amino acid three-letter abbreviations:

Abbreviation	Amino acid name
Ala	Alanine
Arg	Arginine

Patent Laws and Regulations

Asn	Asparagine
Asp	Aspartic Acid
Asx	Aspartic Acid or Asparagine
Cys	Cysteine
Glu	Glutamic Acid
Gln	Glutamine
Glx	Glutamine or Glutamic Acid
Gly	Glycine
His	Histidine
Ile	Isoleucine
Leu	Leucine
Lys	Lysine
Met	Methionine
Phe	Phenylalanine
Pro	Proline
Ser	Serine
Thr	Threonine
Trp	Tryptophan
Tyr	Tyrosine
Val	Valine
Xaa	Unknown or other

(c) A nucleotide sequence shall be listed using the one-letter code for the nucleotide bases, as in paragraph (b)(1) of this section.

(d) 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.

(e) The amino acids in a protein or peptide sequence shall be listed using the three-letter abbreviation with the first letter as an upper case character, as in paragraph (b)(2) of this section.

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

(g) The bases in the coding parts of a nucleotide se- quence shall be listed as triplets (codons).

(h) A protein or peptide sequence shall be listed with a maximum of 16 amino acids per line, with a space provided between each amino acid.

(i) 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.

(j) A nucleotide sequence shall be presented, only by a single strand, in the 5' to 3' direction, from left to right.

Patent Laws and Regulations

(k) An amino acid sequence shall be presented in the amino to carboxy direction, from left to right, and the amino and carboxy groups shall not be presented in the sequence.

(l) The enumeration of nucleotide bases shall start at the first base of the sequence with number 1. The enumeration shall be continuous through the whole sequence in the direction 5' to 3'. The enumeration shall

be marked in the right margin, next to the line containing

the one-letter codes for the bases, and giving the number of the last base of that line.

(m) The enumeration of amino acids may start at the first amino acid of the first mature protein, with number 1. The amino acids preceding the mature protein, e.g., pre-sequences, pro-sequences, pre-pro-sequences and signal sequences, when presented, shall have negative numbers, counting backwards starting with the amino acid next to number 1. Otherwise, the enumeration of amino acids shall start at the first amino acid at the amino terminal as number 1. It shall be marked below the sequence every 5 amino acids.

(n) For those nucleotide sequences that are circular in configuration, the enumeration method set forth in paragraph (l) of this section remains applicable with the exception that the designation of the first base of the nucleotide sequence may be made at the option of the applicant. The enumeration method for amino acid sequences that is set forth in paragraph (m) of this section remains applicable for amino acid sequences that are circular in configuration.

(o) A sequence with a gap or gaps shall be presented as a plurality of separate sequences, with separate sequence identifiers, with the number of separate sequences being equal in number to the number of continuous strings of sequence data. A sequence that is made up of one or more non-contiguous segments of a larger sequence or segments from different sequences shall be presented as a separate sequence.

(p) The code for representing modified nucleotide bases and modified and unusual amino acids shall conform to the code set forth in the tables in paragraphs (p)(1) and (p)(2) of this section. The modified base controlled vocabulary in paragraph (p)(1) of this section and the modified and unusual amino acids in paragraph (p)(2) of this section shall not be used in the nucleotide and/or amino acid sequences; but may be used in the description and/or the "Sequence Listing" corresponding to, but not including, the nucleotide and/or amino acid sequence.

(1) Modified base controlled vocabulary:

Abbreviation	Modified base description
ac4c	4-acetylcytidine
chm5u	5-(carboxyhydroxylmethyl)uridine
cm	2'-O-methylcytidine
cmnm5s2u	5-carboxymethylaminome thyl-2-thiouridine
cmnm5u	5 carboxymethylaminomethyluridine
d	dihydrouridine
fm	2'-O-methylpseudouridine
gal	q beta,D-galactosylqueosine
gm	2'-O-methylguanosine
i	inosine
i6a	N6-isopentenyladenosine

Patent Laws and Regulations

m1a	1-methyladenosine
m1f	1-methylpseudouridine
m1g	1-methylguanosine
m11	1-methylinosine
m22g	2,2-dimethylguanosine
m2a	2-methyladenosine
m2g	2-methylguanosine
m3c	3-methylcytidine
m5c	5-methylcytidine
m6a	N6-methyladenosine
m7g	7-methylguanosine
mam5u	5-methylaminomethyluridine
mam5s2u	5-methoxyaminomethyl-2-thiouridine
manq	beta,D-mannosylqueosine
mcm5s2u	5-methoxycarbonylmethyluridine
mcm5u	5-methoxycarbonylmethyluridine
mo5u	5-methoxyuridine
ms2i6a	2-methylthio-N6-isopentenyladenosine
ms2t6a	N-((9-beta-D-ribofuranosyl-2-methylthiopurine-6-yl)carbamoyl)threonine
mt6a	N-((9-beta-D-ribofurano-sylpurine-6-yl)N-methyl-carbamoyl)threonine
mv	uridine-5-oxyaceticacid-methylester
o5u	uridine-5-oxyacetic acid (v)
osyw	wybutoxosine
p	pseudouridine
q	queosine
s2c	2-thiocytidine
s2t	5-methyl-2-thiouridine
s2u	2-thiouridine
s4u	4-thiouridine
t	5-methyluridine
t6a	N-((9-beta-D-ribofuranosylpurine-6-yl)carbamoyl) threonine

Patent Laws and Regulations

tm	2'-O-methyl-5-methyluridine
um	2'-O-methyluridine
yw	wybutosine
x	3-(3-amino-3-carboxypropyl)uridine, (acp3)u

(2) Modified and unusual amino acids:

Abbreviation	Modified and unusual amino acid
Aad	2-Aminoadipic acid
bAad	3-aminoadipic acid
bAla	beta-Alanine,beta-Aminopropionic acid
Abu	2-Aminobutyric acid
4Abu	4-Aminobutyric acid, piperidinic acid
Acp	6-Aminocaproic acid
Ahe	2-Aminoheptanoic acid
Aib	2-Aminoisobutyric acid
bAib	3-Aminoisobutyric acid
Apm	2-Aminopimelic acid
Dbu	2,4-Diaminobutyric acid
Des	Desmosine
Dpm	2,2'-Diaminopimelic acid
Dpr	2,3-Diaminopropionic acid
EtGly	N-Ethylglycine
EtAsn	N-Ethylasparagine
Hyl	Hydroxylysine
aHyl	allo-Hydroxylysine
3Hyp	3-Hydroxyproline
4Hyp	4-Hydroxyproline
Ide	Isodesmosine
aIle	allo-Isoleucine
MeGly	N-Methylglycine, sarcosine
MeIle	N-Methylisoleucine
MeLys	N-Methylvaline
Nva	Norvaline
Nle	Norleucine

Patent Laws and Regulations

Orn	Ornithine

[Added 55 FR 18230, May 1, 1990, effective Oct. 1, 1990]

37 CFR 1.823 Requirements for nucleotide and/or amino acid sequences as part of the application papers.

(a) The "Sequence Listing," required by § 1.821(c), setting forth the nucleotide and/or amino acid sequences, and associated information in accordance with paragraph (b) of this section, must begin on a new page and be titled "Sequence Listing" and appear immediately prior to the claims. Each page of the "Sequence Listing" shall contain no more than 66 lines and each line shall contain no more than 72 characters. A fixed-width font shall be used exclusively throughout the "Sequence Listing."

(b) The "Sequence Listing" shall, except as otherwise indicated, include, in addition to and immediately preceding the actual nucleotide and/or amino acid sequence, the following items of information. The order and presentation of the items of information in the "Sequence Listing" shall conform to the arrangement given below, except that parenthetical explanatory information following the headings (identifiers) is to be omitted. Each item of information shall begin on a new line, enumerated with the number/numeral/letter in parentheses as shown below, with the heading (identifier) in upper case characters, followed by a colon, and then followed by the information provided. Except as allowed below, no item of information shall occupy more than one line. Those items of information that are applicable for all sequences shall only be set forth once in the "Sequence Listing." The submission of those items of information designated with an "M" is mandatory. The submission of those items of information designated with an "R" is recommended, but not required. The submission of those items of information designated with an "O" is optional. Those items designated with "rep" may have multiple responses and, as such, the item may be repeated in the "Sequence Listing."

(1) GENERAL INFORMATION (Application, diskette/tape and publication information):

(i) APPLICANT (maximum of first ten named applicants; specify one name per line: SURNAME comma OTHER NAMES and/or INITIALS - M/rep):

(ii) TITLE OF INVENTION (title of the invention, as elsewhere in application, four lines maximum - M)

(iii) NUMBER OF SEQUENCES (number of sequences in the "Sequence Listing" - M):

(iv) CORRESPONDENCE ADDRESS (M):

(A) ADDRESSEE (name of applicant, firm, company or institution, as may be appropriate):

(B) STREET (correspondence street address, as elsewhere in application, four lines maximum):

(C) CITY (correspondence city address, as elsewhere in application):

(D) STATE (correspondence state, as elsewhere in application):

(E) COUNTRY (correspondence country, as elsewhere in application):

(F) ZIP (correspondence zip or postal code, as elsewhere in application):

(v) COMPUTER READABLE FORM (M):

(A) MEDIUM TYPE (type of diskette/tape submitted):

(B) COMPUTER (type of computer used with diskette/tape submitted):

(C) OPERATING SYSTEM (type of operating system used):

(D) SOFTWARE (type of software used to create computer readable form):