Chapter 17
Biotechnology

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17.01 Scope of this chapter

This chapter outlines practice respecting section 38.1 of the *Patent Act* and sections 103-110, 159-166 and 183-187 of the *Patent Rules* regarding deposits of biological material, as well as practices and procedures as they relate to sections 111 to 131 of the *Patent Rules* regarding sequence listings.

17.02 Biological material

For the purposes of section 38.1 of the *Patent Act*, the term "biological material" includes material which is capable of self-replication, either directly or indirectly. Direct self-replicating biological material is material which replicates by itself. Indirect self-replicating biological material is material which is capable of replication only when it is associated with self-replicating biological material. Bacteria, fungi (including yeast), cells in culture and hybridomas are representative examples of direct self-replicating material; indirect self-replicating material includes nucleotide sequences, plasmids, vectors, viruses, phages and replication-defective cells.

17.03 Deposit of biological material

A specification must contain a full description of an invention, to enable a person skilled in the art or science to which the invention pertains, to make and use the invention. When an invention is a biological material or when a biological material is needed to practice an invention, words alone may not be sufficient to fulfill the statutory requirements of subsection 27(3) of the *Patent Act*. Access to the biological material may also be necessary.

Section 38.1 of the *Patent Act* applies to an application filed in Canada (regardless of its filing date), and to any patent issued on the basis of such an application, and

provides for a deposit of biological material to be taken into consideration when a determination is made as to whether or not subsection 27(3) of the *Patent Act* has been complied with. The deposit must be in accordance with the *Patent Rules* and must have been referred to in the specification at the time of filing.
Reference to a deposit is not intended to replace a written description of an invention but rather to supplement it.

17.04 The Budapest Treaty

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (The Budapest Treaty) was established in 1977. The Treaty is administered by WIPO and obliges contracting states to recognize the fact and date of a deposit of biological material for patent purposes, when it is made in a depositary which has acquired official status under the Treaty. Such a depositary is known as an International Depositary Authority (IDA). An applicant who is making multiple patent filings need only make one IDA deposit to satisfy the deposit practice in all contracting states.

The Budapest Treaty came into force, with respect to Canada, on September 21, 1996.

17.05 When a deposit may be necessary

If an invention relies on biological material, an examiner must determine if the written description alone is sufficient to satisfy the requirements of subsection 27(3) of the *Patent Act* or if access to the material is also necessary. If access is necessary in order to practice the invention, a deposit will be required unless the biological material is publicly known and readily available.

Biological material is considered to be publicly accessible if it can be obtained commercially or if it can be repeatably prepared or isolated from available materials using established procedures and without any further experimentation.

An applicant who relies on public accessibility rather than a deposit takes the risk however, that a patent may some day be held to be invalid if the biological material necessary to practice the invention ceases to be accessible to the public.

17.06 When and where to make a deposit

For an application filed on or after October 1, 1996, an original deposit of biological material must be made by the applicant, in an IDA, on or before the filing date (subsection 104(1) of the *Patent Rules*).

For an application filed before October 1, 1996 (and for a patent which may have issued on the basis of such an application), an original deposit of biological material must have been made by the applicant, on or before the filing date, either in an IDA or in some other depositary from which samples are made available to the public, either after the application is open to public inspection under section 10 of the *Patent Act* (for applications filed on or after October 1, 1989 but before October 1, 1996) or after the issuance of a patent (for applications filed before October 1, 1989). If the deposit was not made in an IDA, a deposit of the same biological material must be made in an IDA on or before October 1, 1997 (subsections 160(1), 160(2), 184(1) and 184(2) of the *Patent Rules*).

17.07 Deposit information

For IDA deposits as well as non-IDA deposits, made for the purposes of section 38.1 of the *Patent Act*, the Commissioner of Patents must be informed of the name of the depositary and the date of the deposit, if this information is not already included in the specification. In the case of an IDA deposit, the accession number given to the deposit is also required. Thus, if a non-IDA deposit was made before October 1, 1996 and then an original IDA deposit of the same biological material was made (on or before October 1, 1997), the names of both depositaries, as well as the dates of deposit in each, and the IDA accession number, must be provided.

For an application filed on or after October 1, 1996, the deposit information must be

provided before the application is open to public inspection under section 10 of the *Patent Act* (subsection 104(2) of the *Patent Rules*) and must be included in the description (subsection 104(3) of the *Patent Rules*).

For an application filed on or after October 1, 1989 but before October 1, 1996 (as well as for a patent which may have issued on the basis of such an application), IDA deposit information, as well as that for any prior non-IDA deposit of the same biological material, must be provided on or before January 1, 1998 or before the application is open to public inspection under section 10 of the *Patent Act*, whichever comes later (subsections 160(2) and 160(3) of the *Patent Rules*).

For an application filed before October 1, 1989 (as well as for a patent which may have issued on the basis of such an application), IDA deposit information, as well as that for any prior non-IDA deposit of the same biological material, must be provided on or before January 1, 1998 (subsections 184(2) and 184(3) of the *Patent Rules*).

The time for providing deposit information cannot be extended. If the information is not provided within the prescribed time, the deposit is not a deposit for the purposes of section 38.1 of the *Patent Act*.

17.08 Term of deposit

When a sample of biological material is deposited in an IDA under the Budapest Treaty for the purposes of patent protection, the depositor undertakes not to withdraw the sample for a period of at least 30 years from the date of deposit and for at least five years from the date of the most recent request made to the depositary for the furnishing of a sample of the deposited material (Rules 6 and 9 of the Regulations under the Budapest Treaty).

17.09 Access to deposited biological material

References to deposited biological material become public once a patent application is

open to inspection under section 10 of the *Patent Act* or once a patent issues (for applications filed before October 1, 1989). A request form for the furnishing of a sample of deposited material will be published from time to time in the Canadian Patent Office Record (CPOR).

17.09.01 Access to a deposit referred to in an issued patent

A request for the furnishing of a sample of a deposit can be made by anyone and is filed with the Commissioner of Patents.

17.09.02 Access to a deposit referred to in a laid-open application

A request for the furnishing of a sample of a deposit can be made by anyone if a) the application has been withdrawn, abandoned and no longer subject to reinstatement, or finally refused, or b) the application is still pending and access has not been restricted to an independent expert (see below). The request is filed with the Commissioner of Patents.

An applicant may file notice with the Commissioner of Patents that samples of deposited biological material be furnished only to an independent expert nominated by the Commissioner (subsections 104(4) and 160(4) of the *Patent Rules*). The restriction applies until either a patent has issued on the basis of the application or until the application is finally refused, abandoned and not subject to reinstatement, or withdrawn. The notice must be filed within the following prescribed time periods which cannot be extended: (a) before an application is open to public inspection under Section 10 of the *Patent Act*, for applications filed on or after October 1, 1996 (subsection 104(4) of the *Patent Rules*); (b) on or before January 1, 1998 or before an application is open to public inspection under Section 10 of the *Patent Act*, whichever comes later, for applications filed on or after October 1, 1989 but before October 1, 1996 (subsection 160(4) of the *Patent Act*).

While the access restriction is in effect, only a nominated expert can file a request with the Commissioner of Patents for the furnishing of a sample of a deposit (subsections 110(1) and 166(1) of the *Patent Rules*).

17.09.03 Nomination of an independent expert

The Commissioner of Patents will nominate an independent expert with the agreement of the applicant (subsections 109(1) and 165(1) of the *Patent Rules*). Both the applicant and the person requesting that an expert be nominated may make suggestions as to who would be a suitable expert. In the event that the Commissioner of Patents and the applicant cannot agree on an acceptable expert, within a reasonable time after a request has been made that such an expert be nominated, the notice, that access to a deposit be restricted to an expert, is deemed never to have been filed (subsections 109(2) and 165(2) of the *Patent Rules*).

17.09.04 Undertaking

If a request is filed for the furnishing of a sample of deposited biological material referred to in a pending application, the request must include an undertaking that either until a patent has issued on the basis of the application or until the application has been withdrawn, abandoned and no longer subject to reinstatement, or finally refused, the requester will not make a sample of the furnished material available to any other person and will use the sample only for experiments that relate to the subject matter of the application (sections 108 and 164 of the *Patent Rules*).

17.09.05 Certification

After a request has been filed with the Commissioner of Patents for the furnishing of a sample of deposited biological material, the Commissioner will certify that the deposit is referred to in an application for patent in Canada or in a Canadian patent, that the requester has fulfilled all conditions for the furnishing of a sample, and that the requester has a right to a sample of the deposited material (subsections 107(2), 163(2) and 187(2) of the *Patent Rules* and Rule 11.3(a) of the Regulations under the Budapest Treaty).

A copy of the request along with the certification is then sent to the requester (subsections 107(3), 163(3) and 187(3) of the *Patent Rules*) or in the case where the requester is an independent expert, to the applicant and to the person who requested

the nomination of the expert (subsections 110(2) and 166(2) of the *Patent Rules*).

17.10 New and transferred deposits

After an original sample of biological material has been deposited in an IDA (an original IDA deposit), circumstances may necessitate that either a new sample of the same material be deposited in the same or a different IDA (Article 4 of the Budapest Treaty) or that the sample be transferred to a substitute IDA (Rule 5 of the Regulations under the Budapest Treaty).

If an IDA cannot furnish a sample of deposited material because it is no longer viable, a depositor must make a new deposit in the same IDA.

If an IDA cannot furnish a sample of deposited material because a) the sample must be sent abroad and this is prevented by export or import restrictions, or b) the IDA ceases to have the status of an IDA, either entirely or in respect of the kind of material deposited, a depositor must make a new deposit in another IDA.
To maintain an original IDA deposit date, a new deposit must be made within three months of the depositor receiving notice from an IDA that a sample is no longer viable or cannot be sent abroad, or that the IDA's status has changed. The deposit must be accompanied by a statement that the newly deposited material is the same as that originally deposited. If a new deposit is not made, the original deposit is treated as if had never been made (subsection 106(2) of the *Patent Rules*).

If an IDA temporarily or permanently discontinues any of the tasks required of it as an IDA such that samples of deposited biological material can no longer be provided, the defaulting IDA is required to transfer samples of deposited materials to another IDA. The new IDA is referred to as a substitute IDA and the deposit is known as a substitute deposit.

Where an applicant or patentee makes a new deposit of originally deposited biological material, or where an original deposit is transferred to a substitute IDA, the applicant or patentee must inform the Commissioner of Patents of the name of the new or substitute IDA and the accession number given to the deposit by that IDA.

For applications filed on or after October 1, 1996, the new or substitute deposit information must be provided within three months of receiving a deposit receipt from the IDA (section 105 and subsection 106(1) of the *Patent Rules*).

For applications filed before October 1, 1996, the new or substitute deposit information must be provided on or before the later of January 1, 1998 and three months from the date the IDA issues a deposit receipt (sections 161 and 185 and subsections 162(1) and 186(1) of the *Patent Rules*).

17.11 Summary of deposit requirements

The deposit referred to in section 38.1 of the *Patent Act* is considered as part of the specification of a patent application or of an issued patent if:

1) the deposit was made on or before the filing date of the application;

2) the deposit was made in an IDA or in a non-IDA depositary from which samples of deposited material can be obtained on reasonable terms by the public;

3) an original IDA deposit is made within a prescribed period of time where the deposit referred to in the specification was made in a non-IDA depositary;

4) a required new deposit of an original IDA deposit is made within a prescribed period of time;

5) deposit information in respect of any IDA deposit (original, new or substitute) or of a non-IDA deposit is provided to the Commissioner within a prescribed period of time.

If any one of these conditions is not met, a deposit is not a deposit for the purposes of section 38.1 of the *Patent Act*. A specification is then viewed as if the deposit was never made.

17.12 Nucleotide and amino acid sequence listings

Applications filed on or after October 1, 1996, which disclose nucleotide or amino acid sequences (see definitions in sections 17.13 and 17.14 of this chapter), that do not form part of the prior art, must contain a sequence listing containing the actual sequence(s) and associated information. An applicant must also file a copy of the sequence listing in computer-readable form and a statement that the content of the paper and electronic forms of the listing are the same (section 111 of the *Patent Rules*).

If a sequence listing is amended, an amended copy of the computer-readable form of the listing must also be filed along with a statement that the content of both forms of the amended listing is the same (section 112 of the *Patent Rules*).

The sequence listing is part of the description and must begin on a separate page entitled "Sequence Listing". Each sequence set forth in the listing is recited using a standard set of symbols and in a defined format, and is assigned a separate identifier such as "SEQ ID NO:1", "SEQ ID NO:2", SEQ ID NO:3", etc. (subsection 113(2) of the *Patent Rules*). The identifier may be used in the abstract, description, claims or drawings to refer to the sequence.

If an application requires a sequence listing, and the paper version or computer-readable version is not submitted at the time of filing, the application is incomplete and an applicant must submit the missing document(s) within the time limits set out in section 62 or section 94 of the *Patent Rules* in order to avoid abandonment. However, if a sequence listing is submitted after the filing date of an application, the actual nucleotide or amino acid sequence(s) recited in the listing must have been disclosed somewhere in the application (description, claims or figures) at the time of filing to avoid a "new matter" rejection under section 38.2 of the *Patent Act*.

17.13 Nucleotide sequences

"Nucleotide sequence" means an unbranched sequence of ten or more contiguous nucleotides (section 2 of the *Patent Rules*). "Nucleotides" means those nucleotides

which can be represented using the symbols in TABLE 1 as well as nucleotides derived from these by way of modification (sections 2 and 115 of the *Patent Rules*).

TABLE 1

Symbol	Meaning	Origin of Designation
A	A	Adenine
G	G	Guanine
C	C	Cytosine
T	T	Thymine
U	U	Uracil
R	G or A	puRine
Y	T/U or C	pYrimidine
M	A or C	aMino
K	G or T/U	Keto
S	G or C	Strong interactions (3 H bonds)
W	A or T/U	Weak interactions (2 H bonds)
B	G or C or T/U	not A
D	A or G or T/U	not C
H	A or C or T/U	not G
V	A or G or C	not T, not U
N	A or G or C or T/U or unknown or other	aNy

Modified nucleotides are identified within a sequence by the symbol "N" with the nature of the modification described elsewhere in the sequence listing (normally in the "Feature" section). The symbols set out in TABLE 2 may be used anywhere in the sequence listing, except in the actual sequence, to describe modified nucleotides (section 116 of the *Patent Rules*).

TABLE 2

Symbol	Meaning
ac4c	4-acetylcytidine
chm5u	5-(carboxyhydroxylmethyl)uridine
cm	2'-O-methylcytidine
cmnm5s2u	5-carboxymethylaminomethyl-2-thiouridine
cmnm5u	5-carboxymethylaminomethyluridine
d	dihydrouridine
fm	2'-O-methylpseudouridine
gal q	â,D-galactosylqueuosine
gm	2'-O-methylguanosine
i	inosine
i6a	N6-isopentenyladenosine
m1a	1-methyladenosine
m1f	1-methylpseudouridine
m1g	1-methylguanosine
m1i	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
man q	â,D-mannosylqueosine
mcm5s2u	5-methoxycarbonylmethyl-2-thiouridine
mcm5u	5-methoxycarbonylmethyluridine
mo5u	5-methoxyuridine
ms2i6a	2-methylthio-N6-isopentenyladenosine
ms2t6a	N-((9-â-D-ribofuranosyl-2-methylthiopurine-6-yl)carbamoyl)threonine
mt6a	N-((9-â-D-ribofuranosylpurine-6-yl)N-methylcarbamoyl)threonine
mv	uridine-5-oxyacetic acid-methylester

TABLE 2 (continued)

Symbol	Meaning
o5u	uridine-5-oxyacetic acid (v)
osyw	wybutoxosine
p	pseudouridine
q	queuosine
s2c	2-thiocytidine
s2t	5-methyl-2-thiouridine
s2u	2-thiouridine
s4u	4-thiouridine
t	5-methyluridine
t6a	N-((9-â-D-ribofuranosylpurine-6-yl)carbamoyl) threonine
tm	2'-O-methyl-5-methyluridine
um	2'-O-methyluridine
yw	wybutosine
x	3-(3-amino-3-carboxy-propyl)uridine, (acp3)u

A nucleotide sequence recited in a sequence listing is presented only by a single nucleotide strand, in the 5' to 3' direction from left to right (section 114 of the *Patent Rules*).

Nucleotides in the non-coding portion of the sequence (including introns) are listed in groups of 10 with a space between each group with up to 60 nucleotides per line. When there are fewer than 10 "leftover" nucleotides at the ends of non-coding sequences, they are grouped together and separated from adjacent groups by a space (sections 120 and 122 of the *Patent Rules*).

Nucleotides in the coding regions of a nucleotide sequence are grouped together as codons which are separated from each other by a space with a maximum of 16 codons per line.

A nucleotide sequence is numbered continuously from the first nucleotide in the sequence, identified as number 1, in the 5' to 3' direction. In the right margin of the sequence listing, next to each line of one-letter nucleotide codes, is inserted the

number of the last nucleotide in that line (section 125 of the *Patent Rules*).
For circular nucleotide sequences, an applicant can designate any nucleotide to be nucleotide number 1 (section 128 of the *Patent Rules*).

17.14 Amino acid sequences

"Amino acid sequence" means an unbranched sequence of four or more contiguous amino acids. "Amino acid" means those L-amino acids commonly found in naturally occurring proteins as well as amino acids derived from these by way of modification (section 2 of the *Patent Rules*). A D-amino acid is considered to be a modified L-amino acid.

Only the symbols in TABLE 3 may be used within a sequence to identify an amino acid (section 118 of the *Patent Rules*). The symbol "Xaa" is used to denote D-amino acids, or unknown or modified amino acids. Any amino acids designated as "Xaa" are further described elsewhere in the listing (normally under the heading "Feature") with respect to the nature of the modification. The symbols in TABLE 4 may be used anywhere in the sequence listing, except in the actual sequence, to describe modified amino acids (section 119 of the *Patent Rules*).

TABLE 3

Symbol	Meaning
Ala	Alanine
Arg	Arginine
Asn	Asparagine
Asp	Aspartic acid
Asx	Aspartic acid or asparagine
Cys	Cysteine
Glu	Glutamic acid
Gln	Glutamine
Glx	Glutamic acid or glutamine
Gly	Glycine
His	Histidine

TABLE 3 (continued)

Symbol	Meaning
Ile	Isoleucine
Leu	Leucine
Lys	Lysine
Met	Methionine
Phe	Phenylalanine
Pro	Proline
Ser	Serine
Thr	Threonine
Trp	Tryptophan
Tyr	Tyrosine
Val	Valine
Xaa	D-amino acid, unknown or other

TABLE 4

Symbol	Meaning
Aad	2-Aminoadipic acid
bAad	3-Aminoadipic acid
bAla	â-Alanine, â-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

TABLE 4 (continued)

Symbol	Meaning
EtGly	N-Ethylglycine
EtAsn	N-Ethylasparagine
Hyl	Hydroxylysine
aHyl	allo-Hydroxylysine
3Hyp	3-Hydroxyproline
4Hyp	4-Hydroxyproline
Ide	Isodesmosine
alle	allo-Isoleucine
MeGly	N-Methylglycine, sarcosine
Melle	N-Methylisoleucine
MeLys	6-N-Methyllysine
MeVal	N-Methylvaline
Nva	Norvaline
Nle	Norleucine
Orn	Ornithine

Hydroxylations, glycosylations and other post-translational modifications are not to be shown explicitly within the amino acid sequence itself but noted under the heading "Feature" within the sequence listing.

An amino acid sequence is listed in the amino to carboxyl direction, from left to right, without the presentation of the terminal 5'-amino or 3'-carboxyl groups (section 117 of the *Patent Rules*). Up to 16 amino acids may be listed per line with a space between each three letter amino acid symbol (section 123 of the *Patent Rules*).

If the amino acid sequence does not include a mature protein, the sequence is numbered beginning at the amino terminus with the number 1 placed under the first amino acid. The sequence is then marked every five amino acids with the numbers 5, 10, 15, etc. placed under the sequence.

If the amino acid sequence comprises a mature protein, the amino acid at the amino terminus of this protein is designated as amino acid number 1. Any pre-sequences,

pro-sequences, pre-pro-sequences or signal sequences which precede the mature protein are negatively numbered counting backwards with the amino acid next to the first amino acid of the mature protein designated as number -1 (section 126 of the *Patent Rules*).

In a circular amino acid sequence, which does not include a mature protein, any amino acid can be designated as amino acid number 1 (section 128 of the *Patent Rules*).

17.15 Sequences presenting nucleotides and amino acids

When a nucleotide sequence containing one or more coding regions is listed with the encoded amino acids, the amino acid sequence is typed immediately below the corresponding nucleotide codons. Where a codon spans an intron, the amino acid symbol is typed below that portion of the codon containing two nucleotides (section 124 of the *Patent Rules*).

17.16 Hybrid and gapped sequences

A sequence which is made up of one or more non-contiguous segments of a larger sequence, or consists of segments from different sequences, must be listed as a separate sequence in a sequence listing and assigned its own identifier number. A sequence which contains "gaps", representing undisclosed regions between disclosed regions in a sequence, must be presented as a plurality of separate sequences, each corresponding to a disclosed region and each with its own identifier number in the sequence listing (section 127 of the *Patent Rules*).

17.17 Related sequences

Multiple sequences may be presented on a single page in a sequence listing if a) the sequences are related in some manner, b) the data element information applies to all of the sequences, and c) each sequence is assigned its own identifier number.

A single, general sequence may be presented, and variants of this sequence referred to, without presenting each variant as a separate sequence in a sequence listing. For example, if a sequence is deleted at the C-terminus by 1, 2, 3, 4 or 5 residues, all of the variations do not need to be included in the sequence listing. Only the undeleted sequence needs to be included and the related sequences may be described as SEQUENCE ID NO: X from which deletions have been made at the C terminus by 1, 2, 3, 4 or 5 residues.

Sequence identifiers can be used to refer to parts or fragments of sequences, for example, "residues 14 to 243 of SEQUENCE ID NO: 23". The fragment need not be separately presented in the sequence listing.

17.18 Sequence listing headings

A sequence listing must include at least one nucleotide or amino acid sequence and immediately preceding the sequence(s), the following data element headings (capitalized items) which are followed by text. When more than one line of text is necessary, additional lines are indented from the heading or subheading at the left margin (section 129 of the *Patent Rules*). The information associated with each heading or subheading must be provided, if applicable and when available to the applicant (section 130 of the *Patent Rules*) and the listing must follow the order in which the data element headings are presented in the *Patent Rules*. Data is entered for headings or subheadings which are followed by a colon (:).

(1) GENERAL INFORMATION
(under the following headings or subheadings, provide information about the applicant, the application, the applicant's agent, the number of sequences in the listing and how the computer-readable form of the listing was prepared)

(i) APPLICANT:
(name and address of each applicant - for a person, the family name first followed by a comma and then the first name and/or initials; for a legal entity, its full official name)

(ii) TITLE OF INVENTION:
(as in the petition)

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

(iv) CORRESPONDENCE ADDRESS:
(address in Canada of applicant, agent or representative (as the case may be) where correspondence can be sent)

(v) COMPUTER-READABLE FORM
(provide information under the following subheadings)

a) COMPUTER:
(type of computer used with diskette submitted)

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

c) SOFTWARE:
(type of software used)

(vi) CURRENT APPLICATION DATA
(provide data about the current Canadian application under the following subheadings)

a) APPLICATION NUMBER:

b) FILING DATE:

c) CLASSIFICATION:

(vii) PRIOR APPLICATION DATA
(provide data about any Canadian or foreign priority applications or an international application under the following subheadings)

a) APPLICATION NUMBER:
(specify two letter country code and application number; if a PCT application, identify by the letters "PCT", followed by a slash, followed by the two digit country code of the receiving office, followed by the two digit year of filing, followed by a slash, followed by the application number)

b) FILING DATE:

c) CLASSIFICATION:

(viii) PATENT AGENT INFORMATION
(provide data under the following subheadings)

a) NAME:

b) REFERENCE NUMBER:
(agent's file number)

(2) INFORMATION FOR SEQ ID NO:
(assign an identifier number to the sequence; under the following headings provide information descriptive of the nucleotide or amino acid sequence; repeat (2) for each sequence in the listing)

(i) SEQUENCE CHARACTERISTICS
(provide data under the following subheadings)

a) LENGTH:
(sequence length, expressed as number of nucleotides or amino acids)

b) TYPE:
(sequence type, i.e. whether nucleotide or amino acid)

c) STRANDEDNESS:
(if nucleic acid, number of strands of source organism molecule, i.e., whether single stranded, double stranded, both, or unknown to

applicant)

d) TOPOLOGY:
(whether source organism molecule is circular, linear, both, or unknown to applicant)

(ii) MOLECULE TYPE:
(type of molecule sequenced, i.e., genomic RNA, genomic DNA, mRNA, tRNA, rRNA, snRNA, scRNA, preRNA, cDNA to genomic RNA, cDNA to mRNA, cDNA to tRNA, cDNA to rRNA, cDNA to snRNA, cDNA to scRNA, other nucleic acid (specify), protein, peptide)

(iii) HYPOTHETICAL (yes/no):
(is SEQ ID NO: X a hypothetical sequence?)

(iv) ANTI-SENSE (yes/no):

(v) FRAGMENT TYPE:
(for proteins and peptides only; select from: N-terminal fragment, C-terminal fragment, internal fragment)

(vi) ORIGINAL SOURCE:
(original source of SEQ ID NO: X)

(vii) IMMEDIATE SOURCE:
(immediate experimental source of SEQ ID NO: X)

(viii) POSITION IN GENOME
(provide data under the following subheadings about the position in the genome of SEQ ID NO: X)

a) CHROMOSOME/SEGMENT:
(chromosome/segment - name/number)

b) MAP POSITION:

c) UNITS:
(units for map position, i.e. whether units are genome percent, nucleotide number or other (specify))

(ix) FEATURE

(provide information under the following subheadings about points of biological significance as well as "N" designated nucleotides and "Xaa" designated amino acids in SEQ ID NO: X; repeat for each feature)

(significant features might include: active-site, allele, attenuator, binding-site, CAAT signal, cellular, cleavage-site, coding sequence, cross-link, D-loop, disulfide bond, domain, enhancer, exon, GC signal, inhibitory-site, insertion sequence, intron, LTR (long terminal repeat), mature peptide, modified nucleotide or amino acid, mRNA, mutation, peptide, polyA signal, polyA site, precursor RNA, primary transcript, primer binding, promoter, provirus, RBS (ribosome binding site), repeating unit, repeat region, replication origin, rRNA, satellite, stem loop, TATA signal, terminator, thiolester-bond, transit peptide, transposon, tRNA, variation, virion, 3' clip, 3'UTR, 5' clip, 5'UTR, -10 signal, or -35 signal)

a) NAME/KEY:
(provide appropriate identifier for feature)

b) LOCATION:
(specify location of feature within SEQ ID NO: X with reference to nucleotide or amino acid position numbers; indicate if feature is on the complementary strand to that listed)

c) IDENTIFICATION METHOD:
(method by which the feature was identified, i.e., by experiment, by similarity with known sequence or to an established consensus sequence, or by similarity to some other pattern)

d) OTHER INFORMATION:
(include information on phenotype conferred, biological activity of

sequence or its product, macromolecules which bind to sequence or its product, or other relevant information)

(x) PUBLICATION INFORMATION

(publications in which SEQ ID NO: X is disclosed; provide data under the following subheadings; repeat for each relevant publication)

a) AUTHOR(S):

b) TITLE:
(title of publication)

c) JOURNAL:
(journal name)

d) VOLUME:
(journal volume)

e) ISSUE:
(journal issue number)

f) PAGE(S):
(journal page number(s))

g) DATE:
(date of journal publication)

h) DOCUMENT NUMBER:
(patent document number; specify two letter country code and publication number; if a PCT publication, identify by the letters "WO", followed by a slash, followed by the publication number)

i) FILING DATE:
(patent document filing date)

j) PUBLICATION DATE:
(patent document publication date)

k) RELEVANT RESIDUES IN SEQUENCE ID NO:
(insert the identifier number and indicate relevant residues with reference to nucleotide or amino acid position numbers)

(xi) SEQUENCE DESCRIPTION: SEQUENCE ID NO:
(insert the identifier number)

17.19 Computer-readable form of the sequence listing

The electronic version of the listing must be submitted on diskette which is write-protected and permanently affixed with a label containing the following information: the format of the diskette, the type of computer and operating system that generated the file on the diskette, the date on which the data file was generated, the name of the applicant, the title of the invention and a reference number related to the application. If the diskette is submitted after the filing date of an application, the label must also include the filing date of the application, the application number and any other information necessary to identify the application. If all of the foregoing information cannot be included on a permanently affixed label, the label must include at least the name of the applicant, the title of the invention and a reference number. The remainder of the information must be provided on the container that the diskette was provided in (section 131 of the *Patent Rules*).

The computer-readable version of the sequence listing is encoded in a subset of the American Standard Code for Information Interchange (ASCII). This subset consists of all the printable ASCII characters including the space, line-termination, pagination and end-of-file characters associated with the computer/operating system configurations specified below. The diskette must be readable on one of these configurations and formatted such that a printed copy of the sequence listing can be recreated. Any changes in acceptable computer/operating systems for sequence submissions will be published in the Canadian Patent Office Record (subsection 131(1) of the *Patent Rules*).

(1) Computer: IBM [1] PC/XT/AT, IBM PS/2 or compatibles

Operating system: PC-DOS or MS-DOS [2] (Versions 2.1 or above)

Line Terminator:
ASCII Carriage Return plus ASCII Line Feed

Pagination: ASCII Form Feed or Series of Line Terminators

End-of-File: ASCII SUB (Ctrl-Z)

Print Command:
PRINT filename.extension

(2) Computer: Apple Macintosh [3]

Operating System:
Macintosh

Macintosh File Type: Text with line termination

Line Terminator:
Pre-defined by text type file

Pagination: Pre-defined by text type file

End-of-file: Pre-defined by text type file

Print Command: Use PRINT command from any Macintosh application that processes text files, such as MacWrite [4] or TeachText

17.20 Utility program

To facilitate compliance with the *Patent Rules*, an input program is available for

preparing sequence listings. This program is called PatentIn and is available from the United States Patent and Trademark Office or from the European Patent Office.

PatentIn is designed for IBM PC XT, AT, PS/2 and compatible computers and runs only on a system with a hard disk drive. MS-DOS or PC-DOS Version 3.0 or higher is recommended. A Macintosh version of PatentIn is not available.

PatentIn is not required for creating a sequence listing. However, its use is highly recommended.

17.21 CPOR publications

From time to time, the Commissioner of Patents will publish the following in the Canadian Patent Office Record (CPOR): a) a request form for the furnishing of a sample of a deposit, b) a list of IDAs, and c) acceptable computer/operating systems for preparing diskettes containing computer-readable copies of sequence listings.

Endnotes for Chapter 17

[1] IBM is a registered trade-mark of International Business Machine Corporation

[2] MS-DOS is a registered trade-mark of Microsoft Corporation

[3] Apple and Macintosh are registered trade-marks of Apple Computer, Inc.

[4] MacWrite is a registered trade-mark of Claris Corporation