Chapter 17 - Biotechnology

Draft

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Pending formal approval of this chapter by the Commissioner of Patents, readers should bear in mind that to the extent that the content of this document may differ from content found in the current (i.e. official) version of this chapter, elsewhere in the MOPOP, or in any practice notices published in the C.P.O.R., these latter express the official practice of the Office.

During the review period, the public is invited to submit any comments pertaining to the content of the draft. Comments may be submitted electronically or in writing, using the coordinates available at:

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Chapter 17
Biotechnology

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17.01 Scope of this Chapter

The purpose of this chapter is to highlight Office practice particularly as it pertains to applications concerning those diverse fields of research generically referred to as "biotechnology". In reading this chapter, it should be borne in mind that its purpose is to clarify, through elaboration, the application of the more generic teachings of other chapters to the particular issues encountered in biotechnology inventions.

Nothing in this chapter should be interpreted as providing exceptions to any practice of general applicability set out in any other chapter.

As a matter of administrative economy, certain principles of general applicability are, however, discussed in the present chapter. Inclusion of these sections (e.g. on utility, sufficiency, selection patents, etc.) is intended to clarify practice in these areas of particular importance to biotechnology prior to formal amendment of the relevant chapters to which they more appropriately belong.

Throughout this chapter the term "biomolecule" has been used, as a matter of convenience, to collectively describe nucleic acids, peptides, polypeptides, and proteins.

17.02 Subject Matter

As with every invention, in order to have standing under the *Patent Act* the matter of a biotechnology invention must fall within one of the five categories found within the section 2 definition of "invention", namely art, process, machine, manufacture, and composition of matter. Biotechnology is notable, however, in the number of jurisprudential and administrative decisions whereby certain types of matter have been found not to fall within the scope of section 2.

This section discusses the relationship of several types of biotechnology to section 2 of the *Patent Act*.

17.02.01 Living Matter

17.02.01*a* Higher and Lower Life Forms

For the purposes of section 2 of the *Patent Act*, life forms have in view of jurisprudence been divided into lower life forms (statutory) and higher life forms (non-statutory). With the exception of fertilized eggs and totipotent stem cells, the distinction between lower and higher life forms is whether the life form is unicellular (lower) or multicellular (higher).

In Commissioner's Decision 933 [*Re Application of Abitibi Co.* (1982), 62 C.P.R. (2nd), 81 P.A.B.)] it was determined that lower life forms which are produced *en masse* as chemical compounds are prepared, and which are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics are generally deemed to fall within the scope of section 2 as being either "manufactures" or "compositions of matter".

In contrast, the Supreme Court ruled in *Harvard College v. Canada (Commissioner of Patents)* [(2002), 21 C.P.R. (4th), 417] that higher life forms do not fall within the scope of section 2. This decision has been interpreted by the Patent Office to mean that animals at any stage of development are not statutory matter for letters patent, and consequently that fertilized eggs and totipotent stem cells (which have the inherent ability to develop into animals) are included in the higher life form proscription.

Embryonic, multipotent and pluripotent stem cells, which do not have the inherent ability to develop into an animal, are considered to be lower life forms. Where a claim to a cell could be reasonably understood in view of the description as encompassing within its scope a fertilized egg or totipotent stem cell, this matter should be expressly excluded by proviso to avoid a section 2 "higher life form" rejection.

Note that the fact that a claimed cell could form part of a higher life form does not mean that the claim to the cell should be equated to a claim to the higher life form [*Monsanto Canada Inc. v. Schmeiser* (2004), 31 C.P.R. (4th), 161 (S.C.C.)]. There is no need for a claim to a statutory cell to specify, in order to avoid a "higher life form" rejection, that the cell is "as found in the laboratory" or is "in isolated form".

Lower life forms include: microscopic algae; unicellular fungi, moulds and yeasts; bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic, pluripotent and multipotent stem cells.

Higher life forms include: animals, plants, seeds, mushrooms, fertilized eggs and totipotent stem cells.

Plant varieties that are distinct, uniform and stable may be protected under the *Plant Breeders' Rights Act*, administered by the Canadian Food Inspection Agency.

Examples:

1. A bacterial cell culture deposited as ATCC 1234.
(statutory)

2. A hematopoietic stem cell derived from bone marrow, capable of giving rise to erythrocytes, neutrophils, granulocytes, lymphocytes or platelets, said cell bearing surface markers W, X and Y and obtained by a selective separation method using monoclonal antibody Z.
(statutory)

3. A plant transformed with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(non statutory)

4. A plant cell transformed with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(statutory)

5. A plant propagation material produced by transformation of a plant cell with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.
(non statutory)

6. A fertilized bovine ovum carrying an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1.

(non statutory)

7. A cell transformed with an expression vector comprising the nucleic acid sequence depicted in SEQ ID NO: 1 provided said cell is not a fertilized egg cell or a totipotent stem cell.
(statutory)

Analysis: Examples 1, 2, and 4 are directed to cells that do not fall into the proscribed categories of fertilized eggs and totipotent stem cells. In contrast, examples 3, 5 and 6 are directed to proscribed higher life forms. In the case of example 5, this is because a "plant propagation material" includes seeds, plant cuttings, rhizomes and tubers of tuber-bearing plants. Example 7 is intended to reflect the situation where, in view of the description, it is clear that the cells of the invention include fertilized eggs and totipotent stem cells. To avoid a section 2 rejection, these non-statutory embodiments have been expressly excluded by proviso.

17.02.01*b* Organs and Tissues

Organs and tissues (whether of plant or animal origin) are not considered to be manufactures or compositions of matter for the purposes of section 2 of the *Patent Act*. Organs and tissues are created by complex processes, elements of which require no technical intervention, and do not consist of ingredients or substances that have been combined or mixed together.

Artificial organ-like or tissue-like structures, generated by technical intervention by combining various cellular and/or inert components, may be considered, on a case-by-case basis, to be manufactures or compositions of matter and therefore to be statutory subject matter.

Examples:

1. A heart isolated from a pig and suitable for transplantation into a human, said pig heart being genetically engineered to express human cell surface antigens.
(non statutory)

2. An artificial heart valve comprising polymeric scaffold material configured in

the shape of a human heart valve, said scaffold material seeded with human myocytes derived from a human myogenic stem cell line.
(statutory)

3. Plant tissue genetically altered to express SEQ ID NO: 1.
(non statutory)

17.02.02 Processes to Produce Life Forms

The patentability of a method or process is independent of whether or not the product of the method or process is statutory. Processes to produce higher life forms, organs or tissues are not, therefore, objectionable on the grounds that they produce non-statutory products.

An especially important consideration in biotechnology, however, is the degree of technical intervention embodied in the claimed process. A process which occurs essentially according to nature, with no significant technical intervention by man, is not patentable [*Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, (1989), 25 C.P.R. (3rd), 257 at 263-265 (S.C.C.)]. Thus, for example, a process for producing a plant by traditional cross-breeding techniques is not patentable.

Processes which are considered to include significant technical intervention by man include: processes to produce a lower life form, a higher life form, an organ or a tissue through genetic transformation; processes for the *in vitro* culturing or manipulation of cells; processes to separate cells; and processes to generate mutants using a chemical or physical agent.

Examples:

1. A process to produce an insect resistant plant comprising:
    (i) transforming a plant cell with an expression vector carrying a nucleic acid sequence encoding a protease inhibitor; and
    (ii) regenerating a plant from said transformed cell.
(acceptable)

2. A process for producing a tomato plant with reduced stature comprising:

(i) crossing tomato variety A with tomato variety B;
(ii) selecting progeny of said cross that have reduced stature; and
(iii) backcrossing the selected progeny with tomato variety A.

(not acceptable)

3. A process for producing artificial skin comprising:
(i) providing a perforated biocompatible membrane;
(ii) seeding said membrane with epithelial cells; and
(iii) cultivating said cells thereon *in vitro*.

(acceptable)

17.02.03 Medical Methods

As mentioned in section 12.04.02, a method which provides a therapeutic benefit to a subject, even if this is not its primary or intended purpose, is considered to be a method of medical treatment and is therefore not patentable [*Tennessee Eastman v. Commissioner of Patents* (1972), 8 C.P.R. (2nd), 203 (S.C.C.); *Imperial Chemical Industries Ltd. v. Commissioner of Patents* (1986), 9 C.P.R. (3rd), 289 (F.C.A.)]. By way of examples, surgical, medical, dental and physiotherapeutic methods of treatment are non-statutory matter.

To be considered a method of medical treatment, the method should cure, prevent or ameliorate an ailment or pathological condition. Certain natural conditions such as ageing, pregnancy, baldness and wrinkles are not considered to be pathological, and methods to treat such conditions are therefore not proscribed. Claims which do not reasonably encompass a method of medical treatment are considered to be statutory [*Re application 532,566* (1996) C.D. 1209; *Re application 559,960* (1997) C.D. 1213]. Similarly, claims which are directed to a method of treating an animal solely to derive an economic benefit are statutory [*Re Application 862,758* (1970) C.D. 33; *Re Application 954,851* (1971) C.D. 63].

Methods of diagnosing a disease or medical condition, practiced either *in vitro* or *in vivo*, are also considered to be statutory provided they do not involve a step of surgery or yield a therapeutic benefit [*Re Application No. 003,389 of N.V. Organon* (1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.) - *Organon* hereafter; *Re Application for Patent of Goldenberg* (1988) C.D. 1119, 22 C.P.R. (3rd), 159 (P.A.B.) - *Goldenberg* hereafter].

As mentioned in section 11.10.02, use claims are permitted but are scrutinized closely to ensure they do not equate to a method of medical treatment, for example by the inclusion of a medical step.

Similarly, a claim which recites a dosage regime, or a prescribed dosage amount, may be directed to a method of medical treatment since dosage regimes and prescribed dosage amounts fall within the purview of a medical professional [*Axcan Pharma Inc. v. Pharmascience Inc.,* 2006 FC 527; *Axcan* hereafter]. However, dosage forms, pharmaceutical packages or kits, which may physically embody a dosage regime or prescribed dosage amount, are considered patentable subject matter [*Re application 3,772*, (1975) C.D. 254; *Merck & Co. v. Apotex Inc.* (2005), 41 C.P.R. (4th), 35 (F.C.)].

A claim which might otherwise appear to be properly directed to a diagnostic method, a cosmetic method, a method of treating an animal solely to derive an economic benefit or which recites a new use, may nonetheless still be objectionable, for example if it relies essentially on judgement or reasoning or involves a surgical step.

The removal of the medical aspect of a claim may render it acceptable. Inclusion of terms such as “cosmetic”, “diagnostic” or “non-medical” in a claim may be taken as disclaimers to medical methods provided the description contains adequate support for such terminology and provided the claim can reasonably be understood to be directed to a non-medical method the results of which cannot reasonably be said to produce a therapeutic effect.

Examples:

> 1. A method of preventing cervical cancer in a human subject comprising administering a human papilloma virus peptide defined by SEQ ID NO: 1 to said subject.

Analysis: non statutory, since the method is self-evidently a method of medical treatment.

> 2. A method of producing antibodies specific for the human papilloma virus peptide defined by SEQ ID NO: 1 comprising administering said peptide to a rodent.

Analysis: statutory since rodents are not susceptible to human papilloma virus and do not derive any therapeutic benefit from the administration of the peptide.

3. A method of producing tenderized meat comprising:
(i) injecting an animal with a proteolytic composition; and
(ii) slaughtering said animal after a period of time sufficient to allow for tenderization of the meat of said animal.

Analysis: statutory since the animals do not obtain any therapeutic benefit from the method, and the method has clear industrial applicability.

4. A method for detecting and localizing a breast tumour, without medically treating said tumour, which method comprises the following steps:
(i) injecting a subject with an antibody X which has been labelled with a diagnostically effective amount of a radioactive isotope;
(ii) allowing said labelled antibody to localize at the site of the breast tumour; and
(iii) detecting the emission of radioactivity from said radioactive isotope thereby localizing the site of the breast tumour in said subject.

Analysis: statutory because, in this case, there is a distinction between the concentration of the radioisotope-labelled antibody which is used for diagnosis and that which would provide a therapeutic effect. The proviso “without medically treating said tumour” therefore qualifies the amount of antibody used and restricts it to non-therapeutic concentrations [*Goldenberg*].

5. A method of detecting breast cancer in a subject comprising the following steps:
(i) providing a sample of breast tissue from a subject;
(ii) homogenizing said sample in extraction buffer to yield soluble and insoluble fractions;
(iii) separating the soluble fraction from the insoluble fraction;
(iv) reacting the soluble fraction with [novel] antibody X; and
(v) detecting specific binding of antibody X with antigen Y
wherein specific binding of antibody X to antigen Y indicates the presence of breast cancer.

Analysis: statutory since the method is a diagnostic method which does not require a step of surgery or rely on the professional reasoning or judgement of a medical practitioner. The step of "providing" a sample of breast tissue implies that the claimed method is disassociated from any possible surgical act involved in obtaining the sample.

> 6. A method of detecting breast cancer in a subject comprising the following steps:
>
> (i) obtaining a sample of breast tissue from a subject by [novel] needle biopsy conducted under the virtual guidance of a system which generates a three-dimensional image of a putative breast tumour which has been localized *in vivo* by immuno-radiography with an antibody reactive with antigen Y; and
>
> (ii) detecting the presence of antigen Y in said sample,
>
> wherein the presence of antigen Y at an amount exceeding 125 ng/g of tissue indicates the presence of breast cancer.

Analysis: non statutory since step (i) involves a step (a needle biopsy) which equates to surgery.

> 7. A method of screening for a potential drug for [human] disease X comprising:
>
> (i) administering a plurality of test compounds to [novel] mice which have been genetically engineered by insertion of human gene Y to mimic disease X;
>
> (ii) evaluating the severity of disease progression in said mice in the presence and absence of each of the compounds; and
>
> (iii) selecting compounds which slow disease progression as potentials for treating disease X.

Analysis: statutory, since a method wherein a disease is induced in an otherwise healthy subject is not a method of medical treatment, even if the so-induced disease is subsequently treated.

17.02.04 Bioinformatics

Biomolecules are chemical compounds, and claims to nucleic acids, polypeptides,

proteins and peptides are therefore directed to statutory matter. Certain biomolecules, further, express information through their primary structure (i.e. their sequence).

The three-dimensional structure of a biomolecule is often of importance in understanding its biological activity and behaviour. A claim to a biomolecule, defining the molecule in terms of its atomic coordinates, is statutory. In contrast, a claim to the three-dimensional atomic coordinates that represent the shape of the biomolecule in space is not statutory. The coordinates themselves are simply information, which is non-statutory.

Note that the exclusion from patentability of information does not depend on whether or not the information has been recorded on a carrier, nor on the nature of the carrier.

A computer model of a biomolecule which relies on the structural information of the biomolecule is not patentable, since the model itself equates to a graphical presentation of the underlying information. This exclusion extends to include generic computer systems and/or programs that have merely been configured to generate the model.

Computer models of biomolecules can be used in, for example, *in silico* screening methods. The mere presence of a computer model of a biomolecule in a method does not of itself render the method unpatentable.

Examples:

1. A polypeptide comprising the amino acid sequence depicted in SEQ ID NO: 1.
(statutory)

2. An isolated protein comprising the atomic coordinates set out in figure 1.
(statutory)

3. A computer readable medium having recorded thereon the sequence set forth in SEQ ID NO: 1.
(non statutory)

4. Atomic coordinates of protein X, said coordinates depicted in figure 1.
(non statutory)

5. A method of obtaining inhibitors of protein X comprising the steps of:
(i) generating a three-dimensional computer model of protein X using the atomic coordinates depicted in figure 1;
(ii) identifying the binding site of protein X using said model; and
(iii) electronically screening a library of compounds with defined spatial coordinates in order to identify compounds which are structurally complementary to the binding site of protein X; and
(iv) preparing complementary compounds as inhibitors of protein X.
(statutory)

17.03 Utility

Presuming that the claims define statutory subject-matter, section 2 of the *Patent Act* also requires that the matter of an invention be useful. As noted in *Consolboard v. MacMillan Bloedel* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)], a lack of utility exists if "the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do". Note that the Supreme Court indicates that the broader meaning of utility is "what the specification promises" the invention will do.

An invention must serve to carry out some useful known objective and "cannot be a mere laboratory curiosity whose only claim to utility is as a starting material for further research" [*Re Application of Abitibi Co.* (1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.) - *Abitibi* hereafter].

The Patent Appeal Board has similarly noted [*Re Application No. 003,389 of N.V. Organon* (1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)] that in order to be useful in the sense required by the *Patent Act* an invention must be controllable and reproducible such that the objectives of the invention are predictably achieved.

Although an invention need only have one utility in order to be patentable, where several uses are promised each must be properly supported. For example, if a composition is promised to be useful as a drug, it must be established that it is useful in the therapy of at least one disease. If, however, it is promised to be useful as a drug for treating many diseases, its utility in treating all the diseases must be established.

17.03.01 Establishing Utility

The Supreme Court noted in *Apotex Inc. v. Wellcome Foundation Ltd.* [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] (*Apotex* hereafter) that

> Utility is an essential part of the definition of an invention (*Patent Act*, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner "by law" is required to refuse the patent (*Patent Act*, s. 40).

Following 17.03, it is the invention's utility for achieving the objects indicated in the specification that the inventors must be in a position to establish.

Demonstrated utility pertains to embodiments of the invention that have been shown to actually work for the ends promised by the inventors. Utility can be demonstrated, for example, via working examples.

Soundly predicted utility pertains to embodiments of the invention which have not themselves been demonstrated to work for the ends promised by the inventors, but for which an appropriate basis exists upon which this utility can be predicted.

17.03.02 Sound Prediction

In order for a prediction to be deemed to be "sound", it must meet the test set out in *Apotex*, namely that there must be:

> (i) a factual basis for the prediction;
>
> (ii) an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
>
> (iii) proper disclosure.

It is important to keep in mind that a "sound prediction" does not imply certainty. It is clear from the very term "prediction" that this is so. At the same time, the Supreme Court was clear in *Apotex* that a patent monopoly is not to be granted in return for mere speculation. Consequently, in assessing whether or not utility has been established via sound prediction the emphasis is appropriately placed on "sound", and the question is whether a prediction is "sound" or "speculative".

17.03.02*a* Factual Basis

Evaluating what will be a sufficient factual basis for a sound prediction must be conducted on a case-by-case basis, and will depend on such factors as:

(i) the scope of the claims;

(ii) the state of the art;

(iii) the nature of the invention and its predictability; and

(iv) the extent to which the applicant has explored the area claimed, for example by conducting experiments which provide factual support for the utility asserted.

It is clear from *Apotex* that, while the factual basis may be provided by way of examples, there is no requirement that this be so.

As was noted in the case of *Pfizer v. Apotex* ([2007] FC 26; aff'd [2007] FCA 195), however, "[u]tility and sound prediction are questions of fact and must obviously be supported [...]". Consequently, it seems clear that the term "factual" cannot be diluted to mean simple, unsubstantiated statements in the description promising that the invention will work.

17.03.02*b* Sound Line of Reasoning

In order to take a prediction from the realm of speculation and render it "sound", the applicant must be able to provide to the person skilled in the art an explanation of how it is that, on the basis of whatever facts have been identified, of the state of the art, and of whatever the inventors have brought to light in their researches, the entire matter of the

claimed invention can be expected to provide the promised utility. Since a sound line of reasoning is directed to a person skilled in the art, those elements of the sound line of reasoning that would be self-evident to the person skilled in the art in view of their common general knowledge do not need to be explicitly disclosed in the application.

Although no inventor is required to understand why their invention works, this does not dilute the requirements for a sound prediction. If an inventor cannot articulate a line of reasoning to soundly connect their factual support (e.g. their examples) to the remaining matter of their claims, they are not entitled to the full breadth of their claims.

It is not possible to provide exhaustive guidance on the types of reasoning which may be found to be "sound". This assessment depends on too many variables, and a factual basis which in one case may lead to a sound prediction may, in another case, be insufficient.

Knowledge of mechanisms of action and structure-activity relationships, however, are certainly compelling grounds upon which to base predictions. Similarly, in fields where *in vitro* tests are known to be predictive of *in vivo* activity, the *in vitro* tests could be sufficient for a sound prediction.

Where functional limitations appear in claims or are relied upon as the basis of a sound prediction, reference should be made to section 17.07.05.

17.03.02*c* Proper Disclosure

The requirement for proper disclosure means that the person skilled in the art has to, through the specification interpreted in view of their common general knowledge, be provided with sufficient information to understand the basis of the sound prediction and to practice the entire scope of the claimed invention.

17.03.03 Relevant Date

The date at which the applicant must be in a position to establish the utility of their invention is the filing date. Consequently, the factual basis upon which either the demonstration or sound prediction is based must necessarily exist as of the filing date. Similarly, if a sound prediction is to be relied upon, the articulable and sound line of

reasoning referred to in 17.03.02 must also exist as of the filing date.

Where an applicant is claiming priority, this claim is valid only insofar as the document or documents upon which it is based are sufficient to establish the utility of the invention.

Although an applicant is entitled to add matter not included in the priority document(s) to the application as filed, where this matter is necessary to establish the utility of any embodiments of the invention those embodiments do not benefit from the priority date.

17.03.04 Office Actions Relating to Utility

When an examiner has reason to believe that an applicant is not in a position to establish the utility of their invention, when the manner whereby they have attempted to establish utility is defective or when there is evidence of inutility an objection will be raised. The nature of the objection will depend on the specific defect, and should serve to communicate the severity of the perceived deficiency.

If the perceived defect in a claim is one of scope (i.e. the invention has been claimed more broadly than the description appears to support, such that the entire claimed matter does not appear to have the promised utility), an objection can be presented under section 84 of the *Patent Rules* on the grounds of a lack of full support.

Such an objection could be made, for example, because an element of the invention (an “essential” element) has not been defined in the claim.

Similarly, when it does not appear that a sound prediction exists upon which the utility of the entire scope of the claim can be predicated, such that the scope of the claim consequently does not appear to be “fully supported” by the description, a rule 84 objection is appropriate.

Objections under rule 84 suggest that the examiner views the defect in the claim as one of scope, and that it is remediable through amendment. If an applicant declines to amend, however, they are effectively asserting that the entire scope of the claim is their invention and in a subsequent report an objection to lack of utility (under section 2 of the *Patent Act*) and lack of sufficiency of disclosure (under subsection 27(3) of the

Patent Act) could be raised.

Section 2 of the *Patent Act* requires that an invention be useful. When an examiner has reason to believe that the invention as claimed lacks utility, and the matter is not of the nature described above in relation to rule 84, a section 2 objection is raised.

In *Monsanto Co. v. Commissioner of Patents* [(1979), 42 C.P.R. (2nd), 161 (S.C.C.)] (*Monsanto* hereafter), it was noted that inutility should only be alleged on the basis of evidence of inutility or of a reasoned argument as to why the applicant's sound prediction of utility is defective. An objection contending an applicant's sound prediction is flawed should be supported by setting out sufficient facts and reasoning to rebut the applicant's contention. The applicant must be given a sufficiently clear argument by the examiner that they are able to respond in an informed manner to those concerns raised by the examiner.

If the perceived defect is that the specification is, in view of the criteria set out in *Apotex*, insufficient to support a sound prediction, this should be clearly communicated. Where the defect is of the nature that no factual basis appears to exist or that no line of reasoning appears to exist (whether by explicit disclosure or in view of the common general knowledge of the person skilled in the art), the "reasoned argument" can be simply identifying these apparent omissions. In such cases, the objection to the claims under section 2 of the *Patent Act* should be accompanied by an objection to the description under subsection 27(3) of the *Patent Act*.

Conversely, even when an applicant has demonstrated and/or soundly predicted the utility of their invention, it may be the case that some basis exists (a factual basis such as data in the prior art, contravention of a law of science etc.) to contend inutility in regards to some embodiment of the invention. When such a basis can be identified, even as regards only one embodiment of a broad claim, the whole claim is objected to on the grounds of a lack of utility.

It should be noted that evidence of inutility can be provided at any time. There is no requirement that such evidence existed as of the application's claim date.

Examples:

1. The description as filed includes a statement indicating that proteins having 80%

sequence identity to SEQ ID NO: 1 are useful as anti-cancer compounds in humans. No other utilities are disclosed. The sequence in SEQ ID NO: 1 is that of a novel protein bearing only a slight structural similarity (< 20%) to a known protein, and the protein's functional activity is not disclosed. No test data of any kind is included in the description.

Claims:

1. A protein comprising the amino acid sequence depicted in SEQ ID NO: 1.

2. A protein which has at least 80% sequence identity to SEQ ID NO: 1.

3. A pharmaceutical composition comprising a protein as defined in claim 1 or 2 for use as an anti-cancer drug.

Analysis: The description does not contain any factual basis to support a sound prediction that the protein having the sequence provided in SEQ ID NO: 1 is useful as an anti-cancer compound. Given that the protein has only a slight structural similarity to a known protein, extrinsic data does not seem to exist. Neither has any data supporting the promised utility been provided in the description. Consequently, the description appears to be insufficient and is objected to under subsection 27(3) of the *Patent Act*. Similarly, as it is not clear that the inventor is in a position to establish the utility of their invention for the promised purpose, the claims are objected to under section 2 of the *Patent Act*. It is up to the applicant to attempt to explain how they have met the utility requirement identified in *Apotex*.

2. The description as filed discloses an outer membrane protein [SEQ ID NO: 1] from a bacterium which is involved in a human disease X. The description provides pre-clinical data showing that the protein generates a protective immune response when used in a monkey model of disease X. It is understood from the description that the data from the monkey model is predictive of success in humans in view of the model's demonstrated success in predicting the activity of similar known antigens.

Claims:

1. A protein having the sequence defined by SEQ ID NO: 1.

> 2. A vaccine for use in protecting a human subject from disease X, comprising a protein having the sequence defined by SEQ ID NO: 1 and an adjuvant therefor.

Analysis: The description provides data demonstrating the activity of the protein for the promised purpose in monkeys. Extrinsic data, identified in the description, exists to support the utility of the monkey model for predicting human activity of similar antigens. A person skilled in the art would appreciate that this factual basis, properly disclosed in the description, is sufficient to allow the utility of the protein of claim 1 to be soundly predicted.

17.04 Sufficiency of the Description

Closely related to the question of utility is that of sufficiency. Subsection 27(3) of the *Patent Act* requires (inter alia) that the description "correctly and fully describe the invention and its operation or use as contemplated by the inventor". In *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] (*Minerals Separation* hereafter), Thorson P. described the "onus of disclosure" as "a heavy and exacting one".

> The description must be correct; this means that it must be both clear and accurate. It must be free from avoidable obscurity or ambiguity and must be as simple and distinct as the difficulty of description permits. It must not contain erroneous or misleading statements calculated to deceive or mislead the persons to whom the specification is addressed and render it difficult for them without trial and experiment to comprehend in what manner the invention is to be performed. It must not, for example, direct the use of alternative methods of putting it into effect if only one is practicable, even if persons skilled in the art would be likely to choose the practicable method. The description of the invention must also be full; this means that its ambit must be defined, for nothing that has not been described may be validly claimed.

As was noted in section 17.03, the description must contain sufficient information to support a sound prediction of the utility of the invention. Further, it must set out the invention such that a person skilled in the art can practice it having reference only to the description itself and to common general knowledge.

In *Consolboard v. MacMillan Bloedel* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)], Dickson J. quoted H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.] noting that "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired". This passage is reflected by Thorson P. in *Minerals Separation* who noted that the description must be able to answer the questions "What is your invention?: How does it work?" such that "when the period of the monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application".

A description sufficient to allow the public (in the form of a person skilled in the art) to practice the invention with the same success as the inventor is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed. A known assay technique does not need, for example, to be taught in full. Merely referring to this technique is sufficient for the person skilled in the art to know how to practice it.

When an examiner has reason to believe that a description is deficient for not having correctly and fully described the claimed invention, an objection is raised under subsection 27(3). This might be the case, for example, when a broad claim is supported only by its own verbatim language.

It is important to bear in mind that the specification must be sufficient to allow the full scope of the claimed invention to be practised without the need for the person skilled in the art to exercise their inventive ingenuity. If the person skilled in the art is called on to solve problems in such a manner that an inventive step would be present, the description is insufficient (and the attendant claims are unsupported).

17.04.01 Sequence Listings

The following sections apply to applications filed on or after June 2, 2007. For applications filed prior to that date, the applicant may substitute the requirements of sections 111 to 131 of the *Patent Rules* as they read immediately prior to the coming into force of the current rules for the requirements of section 111 of the *Patent Rules*.

Similarly, the requirements of section 62 as it read immediately prior to the coming into force of the current rules may be substituted for the requirements of section 94 of the *Patent Rules*. Guidance on the application of previous versions of the *Patent Rules* can be had by reference to an earlier version of this manual.

17.04.01*a* Requirement for a Sequence Listing

In accordance with subsection 111(1) of the *Patent Rules*, if an application discloses "a nucleotide or amino acid sequence other than a sequence identified as forming a part of the prior art, the description shall contain, in respect of that sequence, a sequence listing in electronic form, and both the sequence listing and the electronic form shall comply with the PCT sequence listing standard".

When this is the case, the provision of said sequence listing is a requirement for completion of the application (whether or not the application is a PCT national phase application). Section 94 of the *Patent Rules* requires that the sequence listing be provided to the Office within the later of twelve-months from filing or three months of a notice requisitioning its provision. Where a sequence listing is requisitioned by the Office, the fee set out in item 2 of Schedule II is payable. To avoid the requirement to pay this fee, the applicant must provide any required sequence listing within "the applicable time". For an application other than a PCT national phase application, the applicable time is 15 months from the earliest priority date or, where no priority is claimed, 15 months from the filing date. For a PCT national phase application, the applicable time is 3 months from payment of the requisite fees for national entry and provision of a copy of the application and/or a translation of the application if applicable (i.e. the requirements of subsections 58(1) and 58(2) of the *Patent Rules*).

When a sequence listing submitted in accordance with subsection 111(1) of the *Patent Rules* is of record in the Office, it is not permissible for a paper copy of the sequence listing to be of record. Applicants will be requisitioned to withdraw any paper copy of a sequence listing for which a PCT sequence listing standard-compliant (see 17.04.01*b*, below) electronic sequence listing has been made of record.

17.04.01*b* The PCT Sequence Listing Standard

The term "PCT sequence listing standard" refers to the *Standard for the Presentation of*

Nucleotide and Amino Acid Sequence Listings in International Patent Applications Under the PCT. This standard is provided in annex C of the *Administrative Instructions under the PCT* and is available at http://www.wipo.int/pct/en/texts/pdf/ai_5.pdf

17.04.01*c* Addition of a Sequence Listing to the Application

In accordance with subsection 111(2) of the *Patent Rules*, if a sequence listing is added to an application originally filed without a sequence listing, "the applicant shall file a statement to the effect that the listing does not go beyond the disclosure in the application as filed".

17.04.01*d* Amendment of a Sequence Listing

In accordance with subsection 111(3) of the *Patent Rules*, if an application as filed contains a sequence listing either in paper form or in an electronic form that does not comply with the PCT sequence listing standard and the applicant replaces the non-compliant sequence listing "by a sequence listing in electronic form that does comply with that standard, the applicant shall file a statement to the effect that the replacement listing does not go beyond the disclosure in the application as filed".

17.04.01e Correction of a Sequence Listing

If a sequence listing is found to contain errors, any correction of the listing must comply with the requirements of subsection 38.2(2) of the *Patent Act*. That is, no new matter may be added to the specification or drawings as originally filed and any correction made to a sequence listing must be reasonably inferrable from the specification or drawings as filed. Where the correct sequence could only be determined by, for example, re-sequencing a sample, the correction is not reasonably to be inferred.

17.04.01*f* Identification of a Sequence Listing

In accordance with subsection 86(3) of the *Patent Rules*, the claims may refer to sequences represented by sequence listings by the sequence identifier and preceded by "SEQ ID NO:". The sequence identifier can simply be an arabic numeral, such that the first sequence identified in the description could be identified as SEQ ID NO: 1, the second as SEQ ID NO: 2, etc.

17.04.01*g* Usage of Variable Symbols in a Sequence Listing

The use of the symbols “n” (or “N”) and “Xaa” to define “unknown or modified” bases and amino acids, respectively, is discussed in paragraphs 10 and 18 of the PCT sequence listing standard. When these symbols are used in a sequence listing, they can represent only a single residue (nucleotide or amino acid, respectively) at a specific position in the sequence.

The Office considers that the residues represented by the symbols “n” (or “N”) and “Xaa” may be defined in the “Features” section as being either present or absent, and that these symbols may also be used to define that a standard nucleotide or amino acid residue is either present or absent. Similarly, these symbols can be used, through the definitions given in the “Features” section, to represent alternate residues at a given position.

Note that since such symbols represent only a single residue, a sequence of variable length must be presented by using a sufficient number of discrete symbols to represent the maximum length of the sequence. Symbols used in such a presentation may then be qualified in the “Features” section to be either present or absent.

The foregoing discussion relates only to the manner in which the foregoing symbols may be used as a matter of nomenclature. During examination, an examiner must consider whether or not the use of such symbols is objectionable, for example on the grounds of lack of clarity or support.

17.04.02 Deposits of Biological Material

Section 38.1(1) of the *Patent Act* provides that:

> *Where a specification refers to a deposit of biological material and the deposit is in accordance with the regulations, the deposit shall be considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, the deposit shall be taken into consideration in determining whether the specification complies with that subsection.*

Section 38.1(2) of the *Patent Act provides that:*

> *For greater certainty, a reference to a deposit of biological material in a specification does not create a presumption that the deposit is required for the purpose of complying with subsection 27(3).*

Therefore, it can be seen from the language of the *Act* that a deposit may be made whether necessary to enable the invention or not. Where the invention cannot be enabled (see 17.04) in the absence of access to a biological deposit, however, the deposit is a necessary element to make the description sufficient unless the required material is publicly known and reliably available to the person skilled in the art. A biological material is considered to be reliably available if it can be obtained commercially or can be reproducibly prepared or isolated from available materials using established procedures and without undue experimentation.

The presence or not of a biological deposit does not change the requirements of subsection 27(3) of the *Patent Act*. The fact that a biological deposit has been made does not of itself mean that an invention has been adequately described. For example, in the case of a claim to an uncharacterized gene the deposit of a micro-organism containing the gene is not a proper substitute for a full and complete description of the gene itself. A claim to a desired product does not merit protection merely because reference is made to where the product can be found.

Whenever possible, it is preferable that both methods of disclosure should be used [*Re Application of Abitibi* (1982) C.D. 933, 62 C.P.R. (2^{nd}) 81; *Re Application 291,870* (1982) C.D. 962].

Sections 103 to 110 of the *Patent Rules* regulate deposits of biological material. The practical aspects of biological deposits covered by these rules are dealt with in Appendix 1 of this chapter.

17.04.03 Inclusion of Examples

Paragraph 80(1)(f) of the *Patent Rules* notes that the description of an invention must

> *set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any...*

It is clear, therefore, that the presence of examples is not a requirement. The wording "where appropriate", however, does not merely mean "when the applicant desires". Rather, whenever the factual basis needed to support a contention made in an application (e.g. in soundly predicting the presence of an unexpected benefit upon which the utility of the application is predicated) is not publicly available as of the filing date, it must be found within the description. If the nature of the application requires that this basis be exemplary, the inclusion of examples is "appropriate" and the examples are consequently necessary.

Note that when a "factual basis" is required, it is not necessary that it be found in a section of the application entitled "Examples". It is sufficient that the person skilled in the art would appreciate that the teachings of the description describe the basis sufficiently, and that it is clear that the basis is factual. In certain cases, a reference to external, publicly-available data could be sufficient.

As regards "prophetic examples", while these are not per se objectionable, they are of limited value in providing factual support. A prophetic example is necessarily a statement of what might be, rather than what is.

17.05 Novelty

As with any invention, a biotechnology invention must be new (novel). Generally, whether an invention is novel or not is answered by asking whether or not it is known in the art (i.e. anticipated).

The leading jurisprudential tests for anticipation are those in *Reeves Bros. v. Toronto Quilting* [(1978), 43 C.P.R. (2nd), 145 (F.C.T.D.)] and *Beloit Canada Ltd. v. Valmet* Oy [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)] (*Beloit* hereafter). From these cases, which were both discussed in *Diversified Products v. Tye-Sil* [(1991), 35 C.P.R. (3rd), 350 (F.C.A.)] with no suggestion that the various tests found in the two cases are mutually inconsistent, it can be concluded that a claim lacks novelty if any one embodiment falling within its scope is anticipated according to the standard expressed in *Beloit*.

Therefore, the anticipatory disclosure must provide all the information necessary, for the purposes of practical utility, to lead the person skilled in the art directly and without difficulty to at least one embodiment of the invention in suit. To meet this standard, the

anticipatory disclosure must be enabling of the embodiment which is allegedly anticipated.

17.05.01 Biological Materials

Recall from 17.04.02 that a description may be considered not to be sufficient unless it provides access, via a deposit made as of the filing date, to biological material associated with the invention. This requirement extends to an allegedly anticipatory disclosure.

Consequently, if the disclosure found in the prior art requires, in order for the invention described therein to be practised, access to a biological material, the biological material must necessarily have been reliably available to the person skilled in the art in order for the document to be anticipatory. To be reliably available it must be either commercially available, be reproducibly preparable or isolable from available materials using established procedures and without undue experimentation, or be accessible via a deposit of biological material.

Examples:

1. Prior art journal article D1 published by the applicant discloses the discovery of a specific hybridoma (hybridoma X) that produces a monoclonal antibody (antibody Y) which is specific for antigen Z. There is no indication in the journal article that a deposit of hybridoma X has been made.

Claims:

1. Hybridoma X deposited as ATCC 1234 which produces antibody Y.

2. A hybridoma which produces a monoclonal antibody capable of binding antigen Z.

Analysis: claim 2 broadly defines “a hybridoma”, and the prior art does in fact disclose such a hybridoma. Claim 2 lacks novelty. Claim 1, in contrast, defines specifically hybridoma X. The person skilled in the art could not reliably obtain hybridoma X simply by following the methodology disclosed in the article (i.e. they could get a hybridoma which would produce a monoclonal antibody for antigen Z, but not necessarily

hybridoma X). To reliably produce X they would need access to a deposit of X. Without this deposit, the prior art article is not anticipatory of claim 1. (N.B. There remains, of course, the question of whether or not claim 1 has an inventive step.)

2. Prior art journal article D1 describes a plasmid constructed from various known genetic elements using known methods. The genetic elements were also freely available to the public. The plasmid is termed “plasmid X” but has not been deposited.

Claim:

1. Plasmid Y [which has the very same features and arrangement as plasmid X] deposited as ATCC 1235.

Analysis: the claim is anticipated since the claimed plasmid is indistinguishable from the known plasmid X and since a person of skill in the art would be able to construct plasmid Y using known, freely available, genetic elements and methods.

17.05.02 Inherent or Implicit Disclosure

An enabling disclosure is considered to disclose all the inherent properties of the invention. Old and known subject matter is not rendered novel by including a limitation which is inherently or implicitly found in the prior art.

For example, consider that a prior art document discloses a chemical compound X and how to make it, and establishes that compound X is useful in treating disease Y. Where subsequent research uncovers the mechanism of action of the compound, a claim to the use of compound X to treat disease Y via the newly discovered mechanism is not novel. Compound X implicitly treated disease Y via the mechanism, and the discovery has not led to a new use for the known compound.

Where anticipation is predicated on the presence of an inherent or implicit feature, it is necessary to clearly explain the grounds on which the presence of that feature in the matter of the prior disclosure is concluded. Where such a conclusion is supported by secondary references, the date of publication of these references is not important.

Examples:

1. A prior art document discloses a prepared cosmid whose DNA sequence record contains a sub-sequence identical to SEQ ID NO: 1. The record does not disclose any information on the coding capabilities of the cosmid.

Claims:

1. A nucleic acid molecule comprising SEQ ID NO: 1 which encodes an [novel] enzyme having protease activity.

Analysis: the claim is anticipated. The use of the term “comprising” indicates the claim is open-ended and encompasses any nucleic acid molecule, including a cosmid, which minimally contains the structure depicted in SEQ ID NO: 1. Since coding capability inevitably follows from the structure of the sequence itself, this functional feature does not impart novelty over the prior art.

2. A prior art journal publication discloses the amino acid sequence (SEQ ID NO: 1) of a naturally occurring protein.

Claim:

1. A protein comprising the primary amino acid sequence identified in SEQ ID NO: 1 and a three-dimensional structure defined by the newly discovered atomic coordinates depicted in figure 1.

Analysis: the claim is anticipated since the claimed protein appears to be identical to the old and known protein disclosed in the prior art and since the limitation found in the claim which identifies the three-dimensional structure of the protein is something which has been implicitly disclosed. Although the atomic coordinates of the protein may represent something that is newly disclosed, this information is not regarded as something which distinguishes the claimed protein *per se* over the prior art.

3. A prior art patent application discloses a method of increasing insect resistance in a plant comprising (i) inserting an expression vector encoding a protease inhibitor gene into a plant cell and (ii) regenerating a plant from the cell.

Claim:

1. A method of increasing resistance to nematodes in a plant comprising:
(i) inserting an expression vector encoding a protease inhibitor gene into a plant cell; and
(ii) regenerating a plant from said plant cell.

Analysis: the claim is anticipated since the method steps *per se* recited in the claim are found in the prior art despite the inclusion of an apparently novel feature, *i.e.,* nematode resistance. The distinction *vis-à-vis* insects and nematodes is not a feature which distinguishes the claimed method *per se* since the desired result of increasing resistance to nematodes is something which necessarily flows by following the teachings of the prior art.

17.05.03 Products-by-Process

A product may be defined in terms of the process by which it is prepared. It must always be remembered that product-by-process claims are, simply, directed to products. In relation to novelty, therefore, it must be evident that all the products falling within the scope of a product-by-process claim are new.

A known product cannot be patented merely because it has been prepared by a new process [*Hoffmann-LaRoche & Co. Ltd. v. Commissioner of Patents* (1955), 23 C.P.R. (1st) (S.C.C.)]. This is so regardless of the nature of the process. Where a process inevitably results in a product having distinct technical features, however, novelty exists.

A claim to, e.g., “protein X prepared by recombinant means” lacks novelty where protein X is known and is indistinguishable from the protein defined in the claim. If the recombinant process to prepare a protein similar to protein X, however, consistently results in the presence of novel post-translational structural features, a claim to “protein X' prepared by recombinant means” would be novel.

17.06 Ingenuity

As with any invention, a biotechnology invention must be the result of inventive ingenuity. That is, there must be present that “mere scintilla of ingenuity” which elevates the matter of the claims from mere workshop improvement to real invention.

Inventive ingenuity may usefully be considered both in terms of the presence of an inventive step and of non-obviousness over the prior art. Whichever perspective is adopted, the test for ingenuity is always applied in view of the state of the art and common general knowledge as of the claim date.

When testing an alleged inventive step to determine whether or not it is obvious, the proper test to be applied is that set out in *Beloit v. Valmet* [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)], namely: would the person skilled in the art, in view of the state of the art and their common general knowledge as of the claim date, be led directly and without difficulty to the claimed invention.

17.06.01 Nucleic Acids Encoding Amino Acid Sequences

If given the amino acid sequence of a polypeptide, the entire class of nucleic acids encoding it can be generated through simple deduction; *i.e.,* by using the genetic code to back-translate from the amino acid sequence. Therefore, a generic claim to a nucleic acid encoding a known amino acid sequence is considered obvious.

The opposite is also considered obvious. An amino acid sequence encoded by a known nucleic acid can be directly derived through the translation of the known coding nucleic acid provided the correct reading frame has been identified or is obvious.

Given that the class of nucleic acids encoding any particular polypeptide is astronomically large, the identification of a species of the class which has unexpected or advantageous properties can be inventive. The test for a proper selection (see 17.07) should be applied.

Example:

1. A prior art journal article D1 discloses the amino acid sequence (SEQ ID NO: 1) of a 30 amino acid long mammalian peptide whose sequence was derived through Edman degradation. There are no indications that recombinant techniques were used nor is there an explicit disclosure of a nucleic acid molecule which encodes the peptide. A review article D2 discusses methods and codon usage tables that may be used in order to achieve enhanced expression of heterologous genes in plant tissues.

Claim:

1. A nucleic acid encoding the peptide identified by SEQ ID NO: 1.

2. A nucleic acid which has been optimized for expression in plant tissue and which encodes the peptide identified by SEQ ID NO: 1.

3. A nucleic acid comprising the sequence identified by SEQ ID NO: 2 which has been optimized for expression in plant tissue and which encodes the peptide identified by SEQ ID NO: 1.

Analysis: consider that the application properly discloses that the sequence identified by SEQ ID NO: 2 is particularly advantageous for use in encoding the peptide identified by SEQ ID NO: 1. Consider that it would not be obvious to the person skilled in the art that this would be so.

Claim 1 is obvious in view of D1 alone for two reasons. Firstly, the claim does not refer to any nucleic acid in particular and merely reflects the general idea of having a nucleic acid molecule which is capable of encoding the peptide; an idea that a person of skill in the art would readily appreciate in view of D1. Secondly, the prior art provides the amino acid sequence of the peptide making it a simple matter of deduction for the person of skill in the art to generate a nucleic acid sequence capable of encoding the peptide.

Claim 2 is obvious in view of D1 in combination with D2. The claim does not refer to any nucleic acid in particular and again merely reflects, albeit in a somewhat more restricted sense, the general idea of having a nucleic acid molecule which has been optimized for expression in plant tissue; an idea that a person of skill in the art would readily be able to put into practical effect by deducing an appropriate encoding sequence from D1 in view of the more specific guidance offered by D2.

Claim 3 is not obvious since neither reference discloses nor suggests the particular sequence referred to in the claim and since, based on the description, the sequence appears to have unexpected properties. The claim represents the selection of nucleic acids having a particular sequence from amongst the genus of all possible nucleic acids encoding the peptide and from amongst the subgenus of all possible nucleic acids employing plant optimized codons.

17.06.02 Process Claims

A claim to a generic “process for cloning or obtaining a gene encoding a known polypeptide” (of unknown sequence) which relies on generally known methods is considered obvious unless the gene is novel and patentable and the claim contains an explicit indication of its structure.

17.07 Claims

In claiming biotechnology inventions, many different approaches can be taken. Here again, there are no special rules with respect to biotechnology. A claim to a biotechnology invention must consequently be of definite and unambiguous scope, must serve to distinguish the claimed invention from the prior art, must explicitly define all those features necessary to enable the person skilled in the art to realize the promised utility, and must be fully supported by the description. The claims, individually and collectively, must be clear and concise and leave the reader in no doubt as to the nature of the invention. These, collectively, are the usual requirements demanded by subsection 27(4) of the *Patent Act* and section 84 of the *Patent Rules*.

17.07.01 Selections

Many inventions are predicated on the selection from a genus of one or several species. The criteria for a proper selection were clearly stated by Maughan J. in the UK case *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289], and have been repeatedly cited with approbation in Canadian jurisprudence.

To be a proper selection, the matter of the selection must be:

(i) based upon a substantial advantage; and
(ii) the whole of the selection must possess the advantage; and
(iii) the advantage must be in respect of a special quality or character common to the whole of the selection.

An important consideration that must be borne in mind is that while embodiments being selected have been disclosed in some generic manner in the prior art, no embodiment falling within the scope of the claim can actually have been prepared. Per Maughan J., “It must be remembered, of course, that the selected compounds have not been made

before, or the patent would fail for want of novelty."

A selection, therefore, is based entirely on the recognition by a later inventor of an advantage present in some subset of an invention more broadly disclosed in the prior art. To be novel, the selection cannot encompass any embodiments that have been previously practiced. To be inventive, the entire matter of the selection must possess the advantage. To be a single inventive selection, the advantage must be in respect of a special quality or character common to the whole of the selection.

The utility of a selection depends on the presence of the "substantial advantage", and it is this utility that the applicant must be in a position to establish by demonstration or sound prediction. Note that the "substantial advantage" may be a disadvantage that is avoided by the selection.

Example:

1. Prior art patent D1 discloses the utility of a known genus of polypeptides (genus A) for a new medicinal use (treating condition Y).

Claim:

1. The use of polypeptide A1 for use in treating condition Y.

Analysis: consider that polypeptide A1 is a member of genus A which was not exemplified in D1. Consequently, its therapeutic activity had not previously been conclusively demonstrated. Consider that the application in question does not provide any exemplary data that polypeptide A1 has properties superior to those of other members of the genus in general. The application provides prophetic examples suggesting polypeptide A1 may be a suitable (even advantageous) alternative to the specific polypeptides mentioned in D1 as examples of genus A. As the prophetic examples suggest the utility is being predicted, it appears there is no factual basis upon which the selection can be fairly based. The matter of the claim, consequently, does not appear to be the result of an inventive step. Rather, it is an arbitrary selection of one of a group of equivalents known in general for the treatment of condition Y.

17.07.02 Provisos

Applicants will sometimes exclude certain embodiments from their claims, usually to avoid inoperative embodiments, known prior art disclosures, or their own copending applications.

While the use of provisos is acceptable, the effect of the proviso on the application as a whole must be carefully considered. Note that in the present discussion, the term "proviso" has been used as a generic term to refer to the exclusion of matter from a claim by negative limitation. Whether the proviso is indicated using language such as "provided that A is not B", "wherein X is not Y", "any <generic element> except Q", or some other form is not material.

The effect of a proviso on a claim will depend on the specific circumstances of each application.

17.07.02*a* Provisos and Utility

Where a proviso has been presented to avoid inoperative subject-matter, the basis upon which the utility of the remaining matter of the claim has been established must be reconsidered. Since utility will often be based on a sound prediction, a proviso to exclude a known inoperative embodiment requires that the line of reasoning upon which the utility of the remaining matter of the claim is based be reassessed.

17.07.02*b* Provisos and Unity

In certain cases, the presence of a proviso will call into question whether the remaining matter of the claims defines a single invention. For example, if a claim defines the use of NSAIDs in combination with another drug to treat some disease, but it excludes ASA, a question arises as to the common general inventive feature upon which the unity of invention is based. It is no longer the use of NSAIDs, since ASA is excluded. This feature is no longer "common" to the invention. It is not the use of a combination therapy to treat a disease, since unity cannot be predicated on a desired result to be achieved, but must rather be resident in the means of achieving the result.

17.07.02*c* Provisos and Non-Essential Elements

The situations referred to in the previous sections generally relate to the use of provisos to exclude embodiments that are members of broadly disclosed essential features (e.g. ASA from the essential element "NSAIDs"). Where a proviso is used to exclude in an arbitrary fashion some non-essential feature, this approach will generally not be sufficient to establish novelty or inventive step over the prior art.

Example:

1. A prior art journal publication D1 discloses murine and bovine growth factor polypeptides. The polypeptides are 85% and 87% identical over their entire length to a human growth factor (SEQ ID NO: 1) disclosed in the application in question.

Claim:

> 1. A growth polypeptide comprising at least 80% identity to SEQ ID NO: 1, provided that said polypeptide is neither the polypeptide depicted below in (a) nor the polypeptide depicted below in (b):
> (a) [murine growth factor amino acid sequence];
> (b) [bovine growth factor amino acid sequence].

Analysis: consider that the proviso was introduced after D1 was cited against the claim. The addition of the proviso does not serve to render the claim patentable over the prior art. D1 calls into question whether the matter of the post-proviso claim is based on a common inventive step in regards to the state of the art. In view of D1, it would be obvious that many polypeptides having sequences within the claimed range would provide the same utility.

2. Prior art application D1 discloses compound X as a useful drug in the therapy of disease Y.

Claim:

> 1. A compound having <structural element A> for use in treating disease Y, provided said compound is not compound X.

Analysis: consider that at the time D1 was filed, the applicant did not know what structure led to compound X's activity. They have now discovered through further research what structure leads to the drug's activity, and wish to claim other drugs related to X via this structure which are useful for the same purpose. The proviso is acceptable in this instance, because the invention of claim 1 is not rendered obvious by D1 and the disclaimer is not arbitrary in nature.

17.07.03 Reach-through Claims

As noted in section 17.04, "nothing that has not been described may be validly claimed". A claim to subject matter which extends beyond the invention adequately described is sometimes termed a "reach-through claim". Reach-through claims typically define products that will be useful for some purpose, but which have not yet been identified.

For example, if an applicant discloses a method for screening drugs for use in treating a certain disease, a claim to useful drugs identified by the method would be a reach-through claim. The claim "reaches through" the method to define the useful products it might identify. Since such products have not yet been identified, they cannot be properly described per se. Similarly, an invention directed to a method of identifying receptor ligand antagonists may not be legitimately extended to generally claim all antagonists which might eventually be discovered through the use of the inventive method.

Similarly, in an application where an antigen has been identified which might be used to obtain monoclonal antibodies, a claim to "a monoclonal antibody" in general is a reach-through claim unless an actual monoclonal antibody has been prepared. This is so despite the fact that it is generally known that "traditional techniques" may be used to generate monoclonal antibodies [*Re Institut Pasteur Patent Application* (1995) C.D. 1206, 76 C.P.R. (3rd) 206].

In the case of a nucleic acid molecule encoding a protein, the provision of a partial amino acid sequence of the protein is not taken as an adequate description of a nucleic acid molecule which is capable of encoding the entire protein [*Re Application 2,017,025* (2007) C.D. 1273].

17.07.04 Functional Limitations

In certain cases, applicants may wish to define an invention using functional language. The use of functional language is not per se objectionable. Such language is generally used to provide breadth, however, and must be carefully considered from the perspective of proper support.

Functional limitations must always be considered from the perspective of the person skilled in the art, and the question to be asked is: "can the person skilled in the art practice the full breadth of the claim without recourse to inventive ingenuity?". If the means to effect the defined function are common general knowledge, the functional limitation is unlikely to be objectionable. Where few or only one means is known to effect the function, however, the functional term exceeds the appropriate scope of the invention by seeking to monopolize speculative embodiments the inventors could not be considered to have adequately described.

To paraphrase *Free World Trust v. Électro Santé Inc*. [(2000), 9 C.P.R. (4th), 168 (S.C.C.)], "it is not legitimate to invent a particular composition that grows hair on bald men and thereafter claim all compositions that grow hair on bald men". Thus, a claim to "a composition comprising a hair-growth activating compound in a pharmaceutically acceptable carrier", where only compound X is known to provide the function, would be too broad. The limitation "hair-growth activating" is a functional limitation to the scope of the compounds found in the composition, but does not serve to make the scope of the claim a priori clear to the person skilled in the art. Identifying all the compounds that would have this activity would require extensive inventive experimentation.

In contrast, where it has been discovered that the combination of a particular drug with any NSAID leads to unexpected advantages, the functional limitation "non-steroidal anti-inflammatory" to the scope of the second component of the composition would not be problematic. The scope of the term "NSAID" would be immediately apparent to the person skilled in the art.

Example:

1. An application describes a novel polypeptide [SEQ ID NO. 1] which is shown to arrest the growth of breast cancer cells *in vitro*.

Claim:

> 1. A pharmaceutical composition for use in the treatment of breast cancer comprising a polypeptide capable of arresting the growth of breast cancer cells and a pharmaceutically acceptable carrier.

Analysis: the claim is overly-broad since the claim fails to include structural features of the "novel polypeptide" and since the description describes with particularity only one polypeptide with the desired property, being that having the structure depicted in SEQ ID NO. 1. Thus, in a first report an objection under section 84 of the *Patent Rules* is warranted, as the claim defines more than the description supports. Note that no related objection is made in this report under subsection 27(3) of the *Patent Act* as long as the description correctly and fully describes the invention in regards to the "novel polypeptide". Note that in a further report, this objection might need to be raised under section 2 of the *Patent Act* with an accompanying objection under subsection 27(3), for example if the applicant argues that the presence of literal support for claim 1 is sufficient to enable the full scope of the claim (see sections 17.03.04 and 17.04).

17.07.05 Scope of Claims

In order to fulfill their public notice function, a claim must define the invention in such a manner that the person skilled in the art will understand where they may and may not go without infringing.

As Lord Loreburn noted in *Natural Kinematograph Co. v. Bioschemes Ltd.* [(1915), 32 R.P.C. 256, at pp. 266], "[t]he patent system is designed to advance research and development and to encourage broader economic activity. Achievement of these objectives is undermined however if competitors fear to tread in the vicinity of the patent because its scope lacks a reasonable measure of precision and certainty. A patent of uncertain scope becomes a public nuisance".

An objection to a claim for ambiguity or lack of clarity as to its limits (indefiniteness) is made under subsection 27(4) of the *Patent Act*. A claim is not indefinite simply because it is broad, but rather when the precise limits of the claim are uncertain. A claim that relies, for example, on the use of "a polyol" is not indefinite since the person skilled in the art can immediately appreciate the scope of that term. A claim relying on

"a polyol capable of <performing some function>", however, is indefinite if the person skilled in the art would not know a priori what polyols fall within the scope of the claim.

17.07.05*a* Recourse to the Description

In certain circumstances, terms found in the claims should be interpreted (construed) having regard to the description. Generally, where the language of the claims is plain and unambiguous, this is unnecessary. However, limitations of language will sometimes demand that such a reference be made.

Whenever an applicant is desiring to act as their own lexicographer it is incumbent on them to make this clear from the language of the description. Further, in so acting it is not proper to give a term having a well-known meaning a definition which is contrary to this meaning. In such cases, uncertainty exists as to whether the term found in the claim is intended to have its usual or distorted meaning.

For example, teaching that the term "up" means "down" for the purposes of the invention is only liable to cause confusion and serves no purpose. Such a definition, when made in the description, would be objected to under subsection 27(3) of the *Patent Act*. Further, the claim containing the term "up" is objected to under subsection 27(4) of the *Patent Act* for the lack of clarity as to whether the term is intended to actually mean "up", or rather to mean "down" following the teachings of the description. Similarly, teaching that the symbol "P" indicates nitrogen atoms is misleading; the symbol is recognized in chemistry as designating phosphorus, and could readily be replaced by the appropriate symbol "N" to designate nitrogen. In contrast, teaching that the term "protein", for the purposes of the invention, has some specific but sensible meaning could be acceptable, especially where this avoids having to repeatedly include a lengthy definition in the claims.

Whenever inclusion of the definition found in the description into the claims would not be detrimental to the clarity and conciseness of the claim, however, this should be done.

17.07.05*b* Defining Biomolecules by Structure

According to section 11.08, a product may be defined in three ways: by structure, in terms of the process by which it is made, and in terms of physical or chemical

properties. The most explicit and definite manner in which to define chemical compounds is by structure. Therefore, in the case of claims directed to novel and inventive biomolecules *per se*, the claims should refer to the sequence whenever possible. As a matter of clarity, the claim should define the biomolecule in terms of the sequence listing, but should not simply define "a sequence listing". This latter form could be interpreted as being directed to mere information - i.e. to the string of letters of the sequence listing, rather than to the biomolecule.

The fact that a claim explicitly refers to a sequence does not preclude an objection for lack of clarity; for example, in situations where the reference sequence contains a number of variable symbols; *i.e.*, the symbols "Xaa" or "n".

A claim which merely refers to a sequence contained in a biological deposit is objectionable for failing to define the sequence *per se* in distinct and explicit terms.

17.07.05*c* Defining Families of Biomolecules

Uncertainty as to the scope of a claim is often created when families of biomolecules are defined on the basis of vague terminology and variable methods of analysis [Dufresne, Guillaume and Duval, Manuel, "Genetic sequences: how are they patented?" (2004), 22 Nature Biotechnology 231; Yoo, Heahyun *et al.* , "Intellectual Property Management of Biosequence Information from a Patent Searching Perspective" (2005), 27 World Patent Information 203]. As such, it is critical for claims to include, as far as is possible, accurate terminology and the particulars of any analytical methods which may be needed in order to determine the precise limits of the claim.

17.07.05*d* Families of Hybridizing Nucleic Acids

Families of nucleic acids are often defined as sequences which are capable of hybridizing to a particular target sequence under various reaction, or stringency, conditions. Because there is no clear consensus as to what conditions are be used in a given hybridization reaction, and since the use of different reaction conditions will capture different families of nucleic acids, a claim may be held to be indefinite for failing to define the particular parameters to be used during the hybridization reaction and ensuing washings.

A claim which refers to a family of hybridizing nucleic acids may be held to be indefinite

if the target nucleic acid itself can be any member of a vast family of nucleic acids; for example, a family of degenerate nucleic acids encoding the same amino acid sequence. In such a case, the number of possible combinations of hybridizing and target nucleic acids becomes astronomically large thus obscuring the scope of the claim.

A claim which suggests that a nucleic acid molecule which hybridizes to a target encoding sequence is itself also capable of encoding a functional polypeptide may be held to be ambiguous since hybridizing nucleic acids, even if they do encode polypeptides, may very well simply encode nonsense polypeptides. For greater clarity, such claims should indicate that the nucleic acid molecule hybridizes to the complement of the target sequence.

17.07.05*e* Nucleic and Amino Acid Terminology

Families of nucleic or amino acid sequences defined by a threshold percentage limit as compared to a target sequence may not be adequately defined if the term “homology” is used since the term implies an evolutionary relationship which either exists or does not exist [Reek, Gerald *et al.* , “ ‘Homology’ in proteins and nucleic acids: A terminology muddle and a way out of it” (1987), 50 Science 667]. Applicants are generally permitted to replace the term “homology” with the term “identity” for greater clarity. The term “similarity” may also be objectionable if there is no clear definition of what the applicant considers to be similar residues.

Families of nucleic or amino acid sequences referred to as being “substantially identical” to a target sequence may not be adequately defined since there is no art accepted convention as to what is encompassed by the term “substantially” and since the scope of a claim may vary depending on what one considers to be a “substantially” identical sequence.

17.07.05*f* Sequence Alignment Methods

Whenever a sequence is identified as having a certain percent identity (equivalency) to a reference sequence, it is necessary to define in the claim whether the percent identity is relative to the full length of the reference sequence or is a partial alignment (such as a BLAST alignment). If a partial alignment percent identity is intended, it is necessary that the nature of the alignment method be sufficiently described in order to enable the

basis of the comparison to be fully appreciated.

Sequence alignment over the full length of the reference sequence is greatly preferred.

17.08 Special Topics

This section concerns areas of biotechnology for which particular practices exist and which practices merit particular attention, elaboration or clarification.

17.08.01 Polyclonal Antibodies

The state of the art with respect to the preparation of antibodies is considered to have matured to the point that it is a matter of routine for a person skilled in the art to prepare an antibody to a given antigen, especially to a protein. Antibodies, as a class of chemical compounds, have been structurally and functionally well-characterized and it is known that upon immunization mammals typically produce antibodies reactive with antigens. Where an application describes and claims “antibodies” in a general manner, and there is no indication that monoclonal antibodies have been prepared or are intended to form part of the invention, the term “antibodies” will generally be interpreted by the Office to mean “polyclonal antibodies”. Accordingly, a broad claim to an “isolated antibody specific for antigen X” will generally be considered acceptable provided:

(i) antigen X is novel;

(ii) antigen X is available in isolated/pure form; and

(iii) there is nothing peculiar about antigen X that a person of skill in the art would regard as problematic if it was desired to produce an antibody to it.

If the prior art teaches that antigen X is old, however, then antibodies specific for that antigen would generally be considered obvious. When the prior art discloses antibodies reactive with a close structural relative of antigen X, then a claim to “an antibody capable of binding to antigen X” may read on the old and known antibody by virtue of cross-reactivity and the claim may therefore be considered to be anticipated.

Examples:

1. The specification discloses a novel protein isolated from a bacterial pathogen, that has utility as a diagnostic target for detecting disease caused by the bacterium. Further, the specification provides the amino acid sequence (SEQ ID NO: 1) of the protein, methods of purifying it using recombinant techniques, and methods of preparing antibodies to the protein by immunizing a suitable mammalian host. No working examples of an antibody are provided. The protein appears to be a member of a new class of bacterial proteins and a sequence search reveals that the closest structural relative is 20% identical with no common domains of any significance.

Claim:

1. An isolated antibody specific for the protein defined by SEQ ID NO: 1.

Analysis: the claim is acceptable.

2. The specification discloses a novel protein isolated from a bacterial pathogen, that has utility as a diagnostic target for detecting disease caused by the bacterium. Further, the specification provides the amino acid sequence (SEQ ID NO: 1) of the protein, methods of purifying it using recombinant techniques, and methods of preparing antibodies to the protein by immunizing a suitable mammalian host. No working examples of a novel antibody are provided. The gene encoding the protein was cloned by immunoscreening a phage library with an old and known polyclonal antibody reactive with a close homologue of the protein.

Claim:

1. An isolated antibody specific for the protein defined by SEQ ID NO: 1.

Analysis: despite the fact that the protein defined by SEQ ID NO: 1 itself appears to be novel, the claim is anticipated since the claim reads on the old and known antibody that has the requisite specificity.

3. The specification discloses a correlation, identified by chromatographic analysis, between a novel hydrophobic peptide and a disease. The amino acid sequence of the peptide is provided and reveals that it is a low-molecular-weight member

of a class of peptides to which no known antibodies have ever been prepared despite several attempts. The specification asserts that antibodies to the peptide may be prepared for eventual use in an immunoassay for the disease. The specification does not provide any working examples of an antibody reactive with the peptide.

Claim:

1. An isolated antibody specific for the peptide defined by SEQ ID NO: 1.

Analysis: the claim is objectionable since the specification fails to provide adequate description of the claimed antibody and since a person skilled in the art, based on their knowledge of the difficulty in producing antibodies to such peptides, would not appreciate that the applicant was in possession of such an antibody at the time of filing.

17.08.02 Monoclonal Antibodies

The state of the art with respect to the preparation of monoclonal antibodies is considered to be unpredictable. Consequently, adequate support for claims to hybridomas and monolconal antibodies they produce requires more than identifying an (novel) antigen. Merely describing an antigen does not provide adequate support for claims to hybridomas or monoclonal antibodies nor does it provide sufficient instruction to a person of skill in the art on how to make the monoclonal antibodies. Further, mere descriptive literal statements to the effect that hybridomas and monoclonals may be prepared using “traditional techniques”, no matter how well described, are also not considered sufficient support. The specification must provide sufficient information, by way of at least one example, such that a person reading the specification would appreciate that the applicant was actually in possession of a hybridoma and/or a monoclonal antibody produced by it.

Consequently, a broad claim to a “monoclonal antibody specific for antigen X” will be considered acceptable provided:

(i) it is apparent upon reading the specification that the applicant was actually in possession of a monoclonal antibody against the antigen at the time of filing; and

(ii) the prior art does not disclose any monoclonal antibody that is specific for

antigen X.

In such a case, the examiner will not deem a biological deposit of the monoclonal and/or the hybridoma to be an essential requirement for support for the broad claim. When a claim specifically refers to a biological deposit of a monoclonal antibody or hybridoma, however, the deposit requirements set out in sections 103-110 of the *Patent Rules* must be fulfilled. When the prior art discloses a monoclonal antibody specific for antigen X, a broad claim would not be acceptable.

By extending the foregoing reasoning, a prior art document which merely describes how a monoclonal antibody to an antigen might be prepared yet does not disclose an actual example of one, is not considered an anticipatory document against an application that claims and describes a working example of a monoclonal antibody.

Examples:

1. The specification discloses a novel isolated protein from a bacterial pathogen that has utility as a diagnostic target for detecting disease caused by the bacterium. Further, the specification provides the amino acid sequence (SEQ ID NO: 1) of the protein, methods of purifying it using recombinant techniques as well as methods of preparing monoclonal antibodies to the protein by using traditional techniques. The specification does not disclose, by way of a working example, the successful production of a monoclonal antibody which specifically binds to the protein defined by SEQ ID NO: 1.

Claim:

1. An isolated monoclonal antibody specific for the peptide defined by SEQ ID NO: 1.

Analysis: the claim is not acceptable, since not such antibody has been properly disclosed.

Appendix 1 - Deposits of Biological Material

For the purposes of section 38.1 of the *Patent Act*, the term "biological material" includes material which is capable of direct or indirect self-replication. Directly self-replicating biological materials are those that replicate by themselves. Indirectly self-replicating biological materials are those that are capable of replication only in association with a directly self-replicating biological material. Bacteria, fungi (including yeast), cells in culture and hybridomas are representative examples of directly self-replicating materials; indirectly self-replicating materials include nucleotide sequences, plasmids, vectors, viruses, phages and replication-defective cells.

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 term “microorganism” is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

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

Where to Make a Deposit

A list of International Depositary Authorities and their specific requirements is available at the following site:

http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/pdf/idalist.pdf

When to Make a Deposit

In accordance with subsection 104(1) of the *Patent Rules*, a deposit of biological material with an international depositary authority must be made on or before the filing date of the application.

Identifying a Deposit

In accordance with subsections 104(2) and 104(3) of the *Patent Rules*, the applicant must inform the Commissioner, prior to publication of the application, of the name of the IDA and the accession number given by the IDA to the deposit, and must include that information in the description. Further, in accordance with section 104.1 of the *Patent Rules*, the applicant must include in the description the date of the original deposit with the IDA.

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*).

New and Substitute Deposits

After an original sample of biological material has been deposited in an IDA (an original IDA deposit), circumstances may necessitate that a new sample of the same material be deposited in either 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 the sample must be sent abroad and this is prevented by export or import restrictions, a depositor may 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. Under subsection 106(2) of the *Patent Rules*, if a new deposit is not made in accordance with Article 4 of the *Budapest Treaty*, the application is treated as if no deposit had ever been made.

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.

In accordance with section 105 and subsection 106(1) of the *Patent Rules*, whenever a deposit of a biological material is made (or transferred) to an IDA different from the original IDA, the applicant must inform the Commissioner of the name of the new IDA and of the accession number given by the new IDA to the deposit before the expiry of the three-month period after the date of issuance of a receipt by that IDA.

Access to Deposited Biological Material

Deposited biological material becomes available to the public once a patent application is open to inspection under section 10 of the *Patent Act,* or for applications filed before October 1, 1989 once a patent issues.

In accordance with subsection 104(4) of the *Patent Rules*, an applicant is entitled to restrict access to a deposit of biological material until such time as a patent has issued, or the application is refused, abandoned and no longer subject to reinstatement, or withdrawn. In such cases, any person may request that an independent expert be nominated by the Commissioner in accordance with subsection 109(1) of the *Patent Rules*. Once so nominated, that expert will have access to the deposit in accordance

with subsection 104(4) of the *Patent Rules*.

In order to access a deposited biological material, a request must be made. Where a restriction has been made by the applicant and is in effect, only the independent expert may make such a request. When such a restriction is not in place, or no longer applicable, any person may request access to the deposited material.

A request for a sample of the biological material must be submitted to the Commissioner of Patents and requires, inter alia, that the requester undertake in accordance with section 108 of the *Patent Rules* not to make the sample, or any culture derived from the sample, available to any other person nor to use the sample, or any culture derived from the sample, for any purpose other than experiments that relate to the subject-matter of the application until such time as a patent issues, or the application is refused, abandoned and no longer subject to reinstatement, or withdrawn.

In the case of a granted patent, the request for a sample of the deposited material may be made directly to the IDA, without the need to provide a request form certified by the Commissioner of Patents unless the IDA specifically requires that a certified request form indicating that the patent has been issued be submitted.

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) and is also provided on-line at:

http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/app3_budapest_forms.pdf.

Detailed procedures for obtaining samples of biological materials are provided in appendix 2.

Nomination of an Independent Expert

In accordance with subsection 109(1) of the *Patent Rules*, the Commissioner of Patents will nominate an independent expert with the agreement of the applicant. 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 applicant's notice under subsection 104(4) of the *Patent Rules* that access to a deposit be restricted to an expert is deemed, in accordance with subsection 109(2) of the *Patent Rules*, never to have been filed.

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, in accordance with subsection 107(2) of the *Patent Rules*, make the certification referred to in Rule 11.3(a) of the *Regulations Under the Budapest Treaty* that the deposit is referred to in an application for patent in Canada, 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.

A copy of the request along with the certification is then sent to the requester in accordance with subsection 107(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 in accordance with subsection 110(2) of the *Patent Rules*.

Appendix 2 - Steps for Obtaining Samples of Biological Materials

To obtain a sample of a biological material referred to in a pending application on which no restriction has been placed under section 104(4) or 160(4) of the *Patent Rules*:

(i) the requesting party completes duplicates of the request form (parts I through IV);
(ii) the requesting party prepares two copies of a letter of undertaking stating that he undertakes to abide by the conditions set out in section 108 or 164 of the *Patent Rules*;
(iii) the requesting party, under a covering letter, sends the letters of undertaking and the request forms to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;
(iv) the Commissioner, or his designate, completes part V of the request forms, certifies them with the seal of the Patent Office and returns them, along with the letters of undertaking, to the requesting party under a covering letter;
(v) the requesting party sends the request forms, the letters of undertaking, a purchase order and any fee required to the IDA;
(vi) the IDA sends the samples of the biological material to the requesting party.

To release a sample of a biological material referred to in a pending application, on which a restriction has been placed under section 104(4) or 160(4) of the *Patent Rules,* to an independent expert:

(i) the requesting party requests that the Commissioner of Patents nominate an independent expert for the purposes of the application;
(ii) the Commissioner of Patents, with the agreement of the applicant, nominates an independent expert within a reasonable time;
(iii) the independent expert completes duplicates of the request form (parts I through IV);
(iv) the independent expert prepares two copies of a letter of undertaking stating that he undertakes to abide by the conditions set out in section 108 or 164 of the *Patent Rules*;
(v) the independent expert, under a covering letter, sends the letters of undertaking and the request forms to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;

(vi) the Commissioner, or his designate, completes part V of the request forms, and certifies them with the seal of the Patent Office;
(vii) the Commissioner sends, under covering letters, a copy of the request form and a letter of undertaking to the applicant and sends the other copy of the request form and a letter of undertaking to the requesting party;
(viii) the requesting party sends the request form, a purchase order and any fee required to the IDA;
(ix) the IDA sends the samples of the biological material to the independent expert.

To obtain a sample of a biological material referred to in an issued patent:

(i) the requesting party writes to the IDA with a purchase order giving the name and address of the requesting party;
(ii) the order should include evidence, *e.g.* a copy of the cover page of the Canadian patent, indicating that the patent has issued and the accession number of the biological material desired;
(iii) where required, the fee charged by the IDA for furnishing the sample is submitted along with the order.