

Chapter 17

Biotechnology

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Chapter 17 Biotechnology

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 interpretations 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

17.02.01a 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).

In Commissioner's Decision *Re Application of Abitibi Co.* it was determined that life forms which are produced *en masse* as chemical compounds are prepared, 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".¹

In contrast, the Supreme Court ruled in *Harvard College v. Canada (Commissioner of Patents)* that higher life forms do not fall within the scope of section 2.²

The Patent Office considers the distinction between lower and higher life forms to be, in general, whether the life form is unicellular (lower) or multicellular (higher). The *Harvard* decision is 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.³

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. 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".⁴

Lower life forms include: microscopic algae; unicellular fungi (including 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.

17.02.01b Organs and tissues

Organs and tissues (whether of plant or animal origin) are generally not considered to be manufactures or compositions of matter for the purposes of section 2 of the *Patent Act*. Organs and tissues are in general 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.⁵ 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 and surgical methods

As mentioned in section 12.04.02, a method which provides a practical 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.⁶ 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, or treat a physical abnormality or deformity such as by physiotherapy or surgery. 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.

Methods that involve performing surgery on the human or animal body are excluded, whether the effect of the surgery is therapeutic or not. Methods that involve the

excision of tissue, organ, or tumour samples from the body are considered to be forms of surgery, and are excluded regardless of their reproducibility. The removal of fluids from the body such as by needle or cannula is not of itself surgery.⁷ A method to remove fluids may nevertheless be proscribed if it otherwise involves surgery, such as in the placement of a cannula or stent in the body,⁸ or if it lacks utility, e.g. for not being reproducible.

Claims which do not involve a step of surgery or provide a practical therapeutic benefit do not form part of the method of surgery or medical treatment exclusion.⁹ Thus, certain methods of diagnosing a disease or medical condition, whether practised *in vitro* or *in vivo*,¹⁰ of treating an animal solely to derive an economic benefit,¹¹ or for achieving a cosmetic result may be patentable.

As mentioned in section 11.10.02, use claims are permitted but are scrutinized closely to ensure they do not equate to a medical or surgical method, for example by the inclusion of a medical or surgical 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.¹² However, dosage forms, pharmaceutical packages or kits, which may physically embody a dosage regime or prescribed dosage amount, are considered patentable subject matter.¹³

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 practical 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.¹⁴

5. A method of analyzing a sample of breast tissue to diagnose breast cancer in a subject, comprising the following steps:
 - (i) homogenizing said sample in extraction buffer to yield soluble and insoluble fractions;
 - (ii) separating the soluble fraction from the insoluble fraction;
 - (iii) reacting the soluble fraction with [novel] antibody X; and
 - (iv) 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 clearly a diagnostic method and has been drafted in such a manner that any acts required to obtain the necessary sample of breast tissue do not form part of the claimed invention.

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. A 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.
(not acceptable)
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*, 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”.¹⁵ 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 objective and “cannot be a mere laboratory curiosity whose only claim to utility is as a starting material for further research”.¹⁶

The Patent Appeal Board has similarly noted 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.¹⁷

Although an invention need only have one use in order to be patentable, where several uses are promised each must be properly established. For example, if a composition is promised to be useful as a drug in treating a specific disease, it must be established that it is useful in the therapy of that 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 in order for the specification to comply with subsection 27(3) of the *Patent Act* [see 17.04].

To clarify the foregoing, a promised use is one which the inventors assert their invention does have. Comments in the description that are clearly speculative in nature (relating, e.g., to what the inventors believe but do not know, to uses the invention might have, etc.) are not promises of utility.

Examples:

An inventor unexpectedly discovers that novel compound X is useful in treating disease Y (a disease of the kidneys), and files an application for this invention. The inventor has not yet discovered the mode of action of their drug, but rather has provided exemplary data to support the use.

1. In the description, the inventor suggests that “compound X may also be useful in treating other diseases of the kidneys”. Nothing in the description supports that the compound has any utility other than in treating disease Y.

Analysis: The compound can be claimed on the basis of its unexpected utility. The statement in the description suggesting other possible utilities is clearly not an assertion by the inventor that the compound *will* treat other diseases of the kidneys, and does not cause any confusion on that point. No objection should be raised to the description on that point.

2. In the description, the inventor states that “compound X is also useful in treating other diseases of the kidneys such as A, B and C”.

Analysis: The statement in the description is a clear assertion that compound X will

treat the other diseases A, B and C. Unless the inventor is in a position to establish that it will in fact do so, the statement must be viewed as not correct and the description should be objected to under subsection 27(3) of the *Patent Act*. This is so whether the use of the compound to treat those diseases is claimed or not. If a claim is made to the use, the claim should also be objected to for being directed to subject-matter lacking in utility.

17.03.01 Establishing utility

The Supreme Court noted in *Apotex Inc. v. Wellcome Foundation Ltd.* 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).¹⁸

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*,¹⁹ 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”.

17.03.02a 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*, however, “[u]tility and sound prediction are questions of fact and must obviously be supported [...]”.²⁰ 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.

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

17.03.02b 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.

17.03.02c 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.²¹

Note that in making a proper disclosure, it is not necessary for the factual basis to be provided by way of examples. It is only necessary that the person skilled in the art would appreciate that the teachings of the description describe the necessary basis sufficiently, and that it is clear that the basis is factual. In certain cases, a reference to external, publicly-available data could suffice. Where the necessary factual basis is not publicly available as of the filing date it must be found within the description.

Determining whether or not the factual basis provided is sufficient must be assessed on a case-by-case basis in view of factors such as how developed the specific field is, how predictable inventions in that field are and the scope of the claims.

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.²² 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 include in the application as filed matter not present in the priority document(s), 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, where 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. Where 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*, 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.²³ 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 where 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 regard 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 ground 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 comprising 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". Thorson P. summarized the requirements for sufficient specification in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, and later described this "onus of disclosure" as "a heavy and exacting one".²⁴

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.²⁵

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*, Dickson J. noted 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”.²⁶ The description must be able to answer the questions “What is your invention?: How does it work?”²⁷ 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”.²⁸

A description sufficient to allow the public (in the form of a person skilled in the art) to practice the invention 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.

17.04.01a 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 17.04.01b, below) electronic sequence listing has been made of record.

17.04.01b 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

17.04.01c Addition of a sequence listing to an 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”.

17.04.01d 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 inferable 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.

17.04.01f 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.

17.04.01g 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 or not it is necessary to enable the invention. Where the invention cannot be enabled [see 17.04] in the absence of access to a biological material, 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 of a biological deposit does not change the requirements of subsection 27(3) of the *Patent Act* except, as provided by subsection 38.1(1) of the *Patent Act*, to the extent subsection 27(3) cannot otherwise reasonably be complied with. The fact

that a biological deposit has been made does not of itself mean that an invention has been adequately described.²⁹ A claim to a desired product does not merit protection simply because reference is made to where the product can be found.

Whenever possible, it is preferable that both methods of disclosure should be used.³⁰

For example, consider an application that claims an uncharacterized gene by reference to a deposit of a micro-organism containing the gene. The deposit is not a substitute for a full and complete description of the gene itself and, in view of subsection 38.1(1) of the *Patent Act* (vide supra), would not of itself meet the requirements of subsection 27(3) of the *Patent Act*.

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

Given the complexity of some biotechnology inventions, it is not always feasible for an applicant to provide a complete description of their invention by words alone. This is acknowledged, e.g., by the presence of section 38.1 of the *Patent Act*.

Although there is no absolute requirement under subsection 27(3) of the *Patent Act* for an application to include examples, the practical effect of the complex nature of some biotechnology inventions is that it may not be possible for an applicant to fulfill the “what is your invention” [see 17.04] aspect of proper disclosure without exemplary support for their invention. Whether or not exemplary support is necessary must be assessed on a case-by-case basis, in view of the completeness of the remainder of the written description.³¹

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...*

The use of the wording “where appropriate” in this rule reflects that an exemplary basis may or may not be necessary depending on the case at hand. The language “where appropriate” does not merely mean “if the applicant deems it appropriate”, and does not provide any exception to the requirements of subsection 27(3) of the *Patent Act*.

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).

For a prior disclosure to be anticipatory, it must describe the invention being claimed and provide an enabling disclosure of that invention. An invention is considered to have been previously described where the subject-matter previously disclosed would, if performed, infringe the later claim. A prior disclosure is considered to be enabling for the purposes of anticipation where the person skilled in the art, if necessary through trial and error experimentation that is neither inventive nor an undue burden, can operate it successfully.³²

The various tests articulated in the cases *Reeves Bros. v. Toronto Quilting*³³ and *Beloit Canada Ltd. v. Valmet Oy*³⁴ deal with the aspect of prior disclosure, and their guidance in terms of a requirement for an “exact description” of the same invention must be understood in this context.³⁵ Note that in *Diversified Products v. Tye-Sil*, the Court discussed the tests provided in both *Reeves Bros.* and *Beloit* with no suggestion that the various tests found in the two cases are mutually inconsistent.³⁶ It can therefore be concluded that a claim lacks novelty if any one embodiment falling within its scope is described according to the standard expressed in *Beloit*.

Thus, 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. Further, the prior disclosure must be enabling of the embodiment which is allegedly anticipated.³⁷

By way of non-limiting examples, it is noted that a claim to a composition of matter is anticipated if a composition of matter falling within that claim has already been made or, where one such composition of matter has not been made, but nonetheless has been described and enabled and its actual utility soundly predicted.

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.³⁸

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.³⁹

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.

Claim:

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. Effectively, the claim is asserting that every nucleic acid having the defined structure will encode an enzyme having protease activity. The prior disclosure of the cosmid is anticipatory. A claim to a nucleic acid molecule consisting solely of the sequence defined in SEQ ID NO: 1 would, however, not be anticipated.

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 having 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.

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.⁴⁰ 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 comply with the requirements of section 28.3 of the *Patent Act*. The invention as claimed must consequently not be obvious or, equivalently, must be the result of inventive ingenuity.⁴¹ It has been noted by the courts that the addition to the *Patent Act* of section 28.3 merely codified what was already accepted, and has not changed the inherent requirement that an invention be the result of ingenuity.⁴² Thus, the courts have noted that “obviousness is an attack on a patent based on its lack of inventiveness”⁴³ and “[t]he courts have chosen to define ‘lack of inventiveness’ rather than ‘inventiveness’ and have called it ‘obviousness’”.⁴⁴

To meet the requirement of section 28.3 of the *Patent Act* there must, in view of the state of the art and the common general knowledge as of the claim date, be present that “characteristic or quality” (i.e. a “scintilla of inventiveness”) which serves to elevate the matter of the claims from mere workshop improvement to real invention.⁴⁵

When comparing the matter of the claims to teachings found in the prior art, it is usual to approach the question by asking whether or not the prior art renders the claimed invention obvious. It has been noted that no single test for obviousness exists that can be appropriately applied to all inventions.⁴⁶ Rather, several factors should be considered, including the level of common general knowledge of the person skilled in the art, the climate in the relevant field at the time the alleged invention was made, and whether there was motivation in existence at that time to solve a recognized problem.⁴⁷ It can also be relevant to consider whether certain matter would have been “obvious to try” at the date of invention, but this factor must be approached cautiously, and considered in view of whether the person skilled in the art would have both the motivation to perform certain routine experiments and a reasonable expectation of success in making these inquiries.⁴⁸

An invention can be found to be obvious if the question set out in *Beloit*, when asked in the proper context, is answered in the affirmative. This question may be paraphrased as: would a person skilled in the art, in view of the state of the art and their common general knowledge as of the claim date, have come directly and without difficulty to the solution taught by the patent.⁴⁹ The aspect of “directly and without difficulty”, in view of the more recent guidance set out in the previous paragraph, must not be interpreted too narrowly.

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.

Claims:

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,⁵⁰ 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*,⁵¹ and have been repeatedly cited with approbation in Canadian jurisprudence.⁵²

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., “[i]t must be remembered, of course, that the selected compounds have not been made before, or the patent would fail for want of novelty”.⁵³

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.⁵⁴

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, and should be carefully considered. A proviso not disclosed in the

application as filed, for example, has the potential of introducing subject-matter not reasonably to be inferred from the specification as originally filed, and consequently as being contrary to subsection 38.2(2) of the *Patent Act*. No presumption exists that the introduction of a proviso not disclosed at filing is automatically the addition of new subject-matter.

17.07.02a 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.

17.07.02b 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.

17.07.02c 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.

Examples:

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.

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.⁵⁵

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.*, “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”.⁵⁶ 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 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” on 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.*, “[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”.⁵⁷

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 where 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, or be able to reasonably predict or determine, what polyols fall within the scope of the claim.

17.07.05a Recourse to the description

During examination, the language of the claims is interpreted by giving each term its plain and usual meaning in the art to which the invention pertains unless it is clear from the description that a term in the claims is to be given a different meaning.

The courts have acknowledged that an applicant can act as their own lexicographer, by specifying in their description that certain terms will have particular meanings for the purposes of the application. Whenever an applicant is desiring to act as their own lexicographer, however, 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, when found in a 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.

It is worth noting that the courts, in construing the claims of a patent, are dealing with a document whose language is fixed. Any deficiencies in the language of the claim can only be remedied by construing the claim in “an informed and purposive way”. During examination, in contrast, the language of the claims may be amended so as to remove ambiguity and maximize their usefulness in serving their public notice function of defining the extent of the monopoly sought.⁵⁸

Where a defect of clarity has been noted by an examiner in the language of a claim, it will generally be maintained in the face of a response arguing that the courts could, with the assistance of expert testimony, arrive at some construction thereof. The purpose of the claims is to serve a public notice function, and “nothing can excuse the use of ambiguous language when simple language can easily be employed”.⁵⁹

17.07.05b 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.

Where, according to the description, structure is essential to determining what subject-matter is useful, this structure must be included in the claims. [See also 17.03.04]

As a matter of clarity, where a biomolecule is defined in terms of its sequence, the claim must define the biomolecule in terms of the sequence listing, and must 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”.

17.07.05c 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.⁶⁰ 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.

17.07.05d 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 to 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.

17.07.05e 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.⁶¹ 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.

17.07.05f 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 alignment⁶²). 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 Antibodies

Antibodies, as a class of chemical compounds, have been structurally and functionally well-characterized and it is known that, in general, immunization of a mammal with an antigen results in the production of antiserum containing antibodies reactive with the antigen. Antiserum contains a generic family, genus or polyclonal mixture of antibodies

where each individual antibody binds to an antigenic determinant or epitope carried on the immunizing antigen. The antiserum is representative of the entire family of antibodies capable of binding to the antigen.

As is the case with claims to any product or process, a claim to an antibody must be supported by a specification which (a) provides a written description of the antibody, and (b) would enable a person of skill in the art to produce the antibody.

17.08.01a “Generic” and polyclonal antibodies

Methods for preparing polyclonal sera are well known in the art and a specification need not describe in detail any of these methods to be enabling.

With respect to written description, an antibody, like any other chemical compound, can be described in terms of its chemical structure (polypeptide sequence). However, antibodies are rarely described this way. Indeed, it has become accepted practice to describe antibodies in terms of the antigen to which they bind and claims to antibodies often include functional language such as “capable of binding to”. Therefore, a written description of an antibody can be provided by a written description of its antigen binding partner. Since antigens are chemical compounds, the best way to describe an antigen is in terms of its chemical structure. A description in terms of physical or chemical properties may be adequate provided that whatever properties are recited are sufficient to distinguish the antigen from other chemical compounds.

Since an antigen is implicitly understood to carry many epitopes, a written description of the antigen is akin to a written description of the collective of epitopes carried on the antigen and therefore provides a description of the corresponding generic or polyclonal binding partners.

If an application includes a claim to an antigen and a claim to an antibody reactive with the antigen, both claims should be commensurate in scope with respect to the antigen.

If the prior art teaches that antigen X is old, obvious or lacks utility, then antibodies reactive with that antigen would generally be considered obvious or lacking utility. Where 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.

A claim to “an antibody capable of binding to antigen X” or “a polyclonal antibody capable of binding to antigen X” will generally be considered to be supported by a specification provided:

- (i) antigen X itself has been adequately described; and
- (ii) either antiserum has been prepared, or where antiserum has not been prepared, there is neither anything peculiar about the antigen nor any indications that would lead a person of skill in the art to question the likelihood of success if that person desired to produce an antibody to the antigen.

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 antibody capable of binding to the protein defined by SEQ ID NO: 1.

Analysis: The claim is acceptable. Since the protein is new, useful as a diagnostic target, and exhibits little structural similarity to known proteins, antibodies prepared against it are likewise, new, useful and unobvious. The specification is both enabling with respect to preparing antibodies and includes a written description (amino acid sequence) of the antigen. The claim is therefore fully supported by the specification.

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 antibody reactive with a close homologue of the protein.

Claim:

1. An antibody capable of binding to the protein defined by SEQ ID NO: 1.

Analysis: The claim is objectionable. Despite the fact that the protein defined by SEQ ID NO: 1 itself appears to be novel, the claimed antibody is anticipated since the claim reads on the old and known antibody that has the requisite binding capability, i.e., the

antibody used for immunoscreening.

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 antibody capable of binding to the peptide defined by SEQ ID NO: 1.

Analysis: The claim is objectionable. No antibodies were raised against the novel peptide and the specification teaches that, despite several attempts, antibodies have never been raised against peptides of similar type. A person skilled in the art would not regard the specification as enabling the production of the claimed antibody.

17.08.01b Monoclonal antibodies

A monoclonal antibody binds to a specific antigenic determinant or epitope carried on an immunizing antigen. A monoclonal antibody can be viewed as one member of the family of polyclonal antibodies contained in antiserum produced by an immunizing antigen.

As with claims to polyclonal antibodies, a claim to a monoclonal must be supported by a specification that is both enabling and includes an adequate written description of the antibody.

The core steps for preparing monoclonal antibodies are now well-known and established. Thus, for a specification to be enabling, the polypeptide antigen against which the monoclonal is raised must be described but an applicant need not set out a detailed procedure for producing the antibody. A detailed step-by-step protocol would only be necessary if the invention resides, at least in part, in an applicant having adapted known procedures to overcome some difficulty in making a monoclonal to a particular antigen.

An examiner will consider the following when determining whether a specification is enabling with respect to monoclonal antibodies:

- (1) whether the applicant actually prepared a monoclonal antibody;
- (2) where a monoclonal antibody has not been prepared,

- (i) whether the antigen and core steps for preparing the monoclonal are described,
- (ii) the availability and/or ease of production of the antigen,
- (iii) whether there are indications that the applicant was unable to produce a monoclonal antibody or to suggest that one of skill in the art would not be able to reproducibly make a monoclonal to the subject antigen,
- (iv) whether there are indications which suggest that undue experimentation or undue adaption of known core steps would be necessary for preparing a monoclonal.

The foregoing list is non-exhaustive and non-cumulative and is intended as a guide only. Each application will be considered on its own merits.

A specification must not only be enabling with respect to a claimed monoclonal antibody but also must provide a written description of the antibody. The written description requirement is satisfied where a specification describes at least one monoclonal and it is evident that the applicant was in possession of the antibody at the time the patent application was filed. Reference to a biological deposit of either a hybridoma or a monoclonal antibody is the best way to demonstrate possession.

Applicants should note however, that a deposit for patent purposes, i.e., for consideration in determining whether or not subsection 27(3) of the *Patent Act* has been complied, must be in accordance with sections 104 to 106 of the *Patent Rules*.

An adequate written description of a monoclonal antibody can also be provided by an explicit description of the epitope to which it binds in the same way as a written description of a generic antibody or polyclonal can be provided by a general description of an antigen. As discussed in section 17.08.01a, a written description of the antigen amounts to a written description of the collective of epitopes carried on the antigen and therefore provides a description of the family of polyclonal binding partners. Since a monoclonal is one member of the family which binds to a specific epitope, if it is to be described in terms of its binding partner, the specification must include a structural description of the epitope.

An epitope on a protein can be described in terms of a specific amino acid sequence which is a subset of the complete polypeptide sequence of the protein, or as a binding pocket defined by specific non-contiguous amino acids.

Where existence of an epitope has not been demonstrated but rather is predicted, for example by computer modelling, a specification must disclose not only a structural description of the epitope, but also a factual basis and sound line of reasoning to support the prediction of a putative antibody binding site.

An examiner will consider the following when determining whether a specification provides a written description with respect to monoclonal antibodies:

- (1) whether the applicant was in physical possession of a monoclonal antibody at the time of filing;
- (2) whether the applicant had made a deposit of a hybridoma or monoclonal antibody for patent purposes or was in a position to do so at the time of filing;
- (3) whether there is specific structural description of an epitope or epitopes carried on the antigen to which the monoclonal will bind.

The foregoing list is non-exhaustive and non-cumulative and is intended as a guide only. Each application will be considered on its own merits.

Where the prior art discloses a monoclonal antibody specific for antigen X, a broad claim would not be acceptable as it would read on the prior art.

A prior art document which merely describes how a monoclonal antibody to an antigen might be prepared yet does not specifically describe such a monoclonal antibody, is not considered an anticipatory document against an application that claims and specifically describes a monoclonal antibody.

Example:

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 describes neither an actual monoclonal antibody, nor a paratope thereof, nor a specific epitope of the protein.

Claim:

1. A monoclonal antibody capable of binding to the peptide defined by SEQ ID NO: 1.

Analysis: The claim is objectionable. Although the specification is enabling with respect to preparing a monoclonal antibody capable of binding to the antigen, there is no written description of such a monoclonal. The specification does not disclose that the applicant was in possession of a monoclonal antibody nor does it disclose a structural description of a specific epitope where a putative monoclonal antibody would bind.

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 parts I through IV of the request form;
- (ii) the requesting party prepares a letter of undertaking, agreeing 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 letter of undertaking and the request form to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;
- (iv) the Commissioner, or a designate, completes part V of the request form, certifies it with the seal of the Patent Office and returns it to the requesting party under a covering letter;
- (v) the requesting party sends the request form, a purchase order and any fee required to the IDA;
- (vi) the IDA sends a sample 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 parts I through IV of the request form;
- (iv) the independent expert prepares a letter of undertaking, agreeing 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 letter of undertaking and the request form to the Commissioner of Patents, Place du Portage I, 50 Victoria St., Gatineau, Canada, K1A 0C9;
- (vi) the Commissioner, or a designate, completes part V of the request form, and certifies it with the seal of the Patent Office;
- (vii) the Commissioner sends, under covering letters, the completed request form to the requesting party, and a copy of thereof to the applicant;
- (viii) the requesting party sends the request form, a purchase order and any fee required to the IDA;
- (ix) the IDA sends a sample 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.

Endnotes for Chapter 17

1. *Re Application of Abitibi Co.* [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)]
2. *Harvard College v. Canada (Commissioner of Patents)* [2002] SCC 76; [(2002), 21 C.P.R. (4th), 417 (S.C.C.)]
3. *Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues* C.P.O.R. Vol. 134, No. 25, June 20, 2006
4. *Monsanto Canada Inc. v. Schmeiser* [2004] SCC 34; [(2004), 31 C.P.R. (4th), 161 (S.C.C.)] at paragraph 17
5. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] S.C.R. 1623 [(1989), 25 C.P.R. (3rd), 257(S.C.C.)] at pages 263-265 (cited to C.P.R.)
6. *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.)]
7. This conclusion is inferred from the decision in *Re Application 319,105 of Boehringer Mannheim G.m.b.H.* (1987) C.D. 1108, allowing a diagnostic method involving the removal of blood from the body
8. *Re Application 394,006 of Catheter Technology Corporation* (1986) C.D. 1082
9. *Re Application No. 532,566 of General Hospital Corporation* (1996) C.D. 1209; *Re Application No. 559,960 of Senentek* (1997) C.D. 1213
10. *Re Application No. 003,389 of N.V. Organon* [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)]; *Re Application for Patent of Goldenberg* [(1988) C.D. 1119, 22 C.P.R. (3rd), 159 (P.A.B.)]
11. *Re Application No. 862,758* (1970) C.D. 33; *Re Application No. 954,851 of Biehl* (1971) C.D. 63
12. *Axcan Pharma Inc. v. Pharmascience Inc.*, [2006] FC 527 [(2006), 50 C.P.R. (4th), 321 (F.C.)]
13. *Re Application No. 003,772 of Ijzerman* (1975) C.D. 254; *Merck & Co. v. Apotex Inc.* [2005] FC 755 [(2005), 41 C.P.R. (4th), 35 (F.C.)]
14. *Goldenberg* (supra at 10)

15. *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at page 160 citing *Halsbury's Laws of England* (3rd ed.), vol. 29 at page 59
16. *Re Application of Abitibi Co.* [(1982) C.D. 933, 62 C.P.R. (2nd), 81 (P.A.B.)]
17. *Re Application No. 003,389 of N.V. Organon* [(1973) C.D. 144, 15 C.P.R. (2nd), 253 (P.A.B.)]; the criteria “controllable and reproducible by the means disclosed” were commented on by the Federal Court of Appeal in *Harvard College v. Canada (Commissioner of Patents)* [(2000), 7 C.P.R. (4th), 1 (F.C.A.)] at paragraph 70 (page 26); it was clarified at paragraph 75 that these requirements pertain only to those features necessary to achieve the objects of the invention.
18. *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] SCC 77 [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] at paragraph 46
19. *Apotex* (supra at 18) at paragraph 70
20. *Pfizer Canada Inc. v. Apotex Inc.* [2007] FC 26 [(2007), 59 C.P.R. (4th), 183 (F.C.)] at paragraph 70; aff'd [2007] FCA 195 [(2007), 60 C.P.R. (4th), 177 (F.C.A.)]
21. The Office's interpretation of *Apotex* (supra at 18) as regards proper disclosure has recently been confirmed in *Eli Lilly Canada Inc. v. Apotex Inc.* [2008] FC 142 at paragraph 164.
22. *Aventis Pharma Inc. v. Apotex Inc.* [2005] FC 1283 [(2005), 43 C.P.R. (4th), 161 (F.C.)] at paragraphs 93 and 164; aff'd [[2006] FCA 64 [(2006), 46 C.P.R. (4th), 401 (F.C.A.)] at paragraph 30
23. *Monsanto Co. v. Commissioner of Patents* [(1979), 42 C.P.R. (2nd), 161 (S.C.C.)]
24. *Radio Corporation of America v. Raytheon Manufacturing Co.* [(1957), 27 C.P.R. (1st), 1 (Ex.Ct.)] at page 14
25. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111; the cited passage has been referred to more recently in, e.g., *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.* [2001] FCT 889 [(2001), 13 C.P.R. (4th), 193 (F.C.T.D.)] (rev'd on other grounds) and *671905 Alberta Inc. v. Q'Max Solutions Inc.* [2001] FCT 888 [(2001), 14 C.P.R. (4th), 129 (F.C.T.D.)] (varied [(2003), 27 C.P.R. (4th), 385 (F.C.A.)]). *Minerals Separation* was referred to in both *Consolboard* (supra at 15) at page 157 and *Pioneer Hi-bred* (supra at 5) at page 268 as in a general sense setting out the requirements of a sufficient disclosure.

26. *Consolboard* (supra at 15) at pages 154 to 155, Dickson J. quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.]
27. *Consolboard* (supra at 15) at page 157
28. *Minerals Separation* (supra at 25) at page 111; this passage endorsed in *Consolboard* (supra at 15) at page 157
29. *Pioneer Hi-Bred* (supra at 5) at page 271
30. *Abitibi* (supra at 16); *Re Application No. 291,870 of Connaught Laboratories* (1982) C.D. 962
31. Little jurisprudence of direct relevance to biotechnology exists on point. Consider, however, the conclusions reached in *Re Institut Pasteur Patent Application* [(1995) C.D. 1206, 76 C.P.R. (3rd) 206], *Re Application No. 610,944 of Alonso* (2006) C.D. 1269, and *Re Application No. 471,056 of Research Corporation* (1992) C.D. 1171. In *Pasteur*, claims to a hybridoma and to a monoclonal antibody were refused because these species were deemed not to be adequately described - no example of a successfully prepared hybridoma or monoclonal antibody having been provided. In comparison, in *Alonso* and *Research Corporation* a number of examples of prepared hybridomas or mutant oyster setting bacteria were considered to provide a proper description of the claimed subject-matter.
32. *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* [2008] SCC 61 at paragraphs 24-27 and 33-37
33. *Reeves Bros. v. Toronto Quilting* [(1978), 43 C.P.R. (2nd), 145 (F.C.T.D.)]
34. *Beloit Canada Ltd. v. Valmet Oy* [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)]
35. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraph 28. Although the Supreme Court was here only referring to the decision in *Beloit*, the same conclusion would seemingly apply to the earlier guidance in *Reeves Bros.*
36. *Diversified Products v. Tye-Sil* [(1991), 35 C.P.R. (3rd), 350 (F.C.A.)]
37. *Apotex v. Sanofi-Synthelabo* (supra at 32); *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.* [2002] FCA 158 [(2002), 17 C.P.R. (4th), 478 (F.C.A.)]
38. *Abbott Laboratories v. Canada (Minister of Health)* [2006] FCA 187 at paragraphs 23 to 25; *Calgon Carbon Corporation v. North Bay (City)* [2006] FC

- 1373 [(2006), 41 C.P.R. (4th), 78 (F.C.)] at paragraphs 114 to 136
39. *Astrazeneca AB v. Apotex Inc.* [2007] FC 688 [(2007), 60 C.P.R. (4th), 199 (F.C.)] at paragraphs 50-53
40. *Hoffmann-LaRoche & Co. Ltd. v. Commissioner of Patents* [(1955), 23 C.P.R. (1st), 1 (S.C.C.)]
41. *Janssen-Ortho Inc. v. Novopharm Limited* [2006] FC 1234 [(2006), 57 C.P.R. (4th), 6 (F.C.)] at paragraphs 99, aff'd [2007] FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)]. The requirement of s.28.3 has been variously described by the courts as one of “ingenuity”, “inventive ingenuity”, “invention”, “inventiveness”, and “non-obviousness”. These terms can be used more or less interchangeably to describe the requirement codified in s.28.3.
42. *Janssen-Ortho* (supra at 41) at paragraphs 109-110; *Canamould Extrusions Ltd. v. Driangle Inc.* [2003] FCT 244 [(2003), 25 C.P.R. (4th), 343 (F.C.T.D.)] at paragraph 61 (rev'd on other grounds); *Baker Petrolite* [2001] FCT 889 [(2001), 13 C.P.R. (4th), 193 (F.C.T.D.)] at paragraphs 94-96 (rev'd on other grounds, see supra at 33); *Harvard College v. Canada (Commissioner of Patents)* [2000] 4 F.C. 528 [(2000), 7 C.P.R. (4th), 1 (F.C.A.)] at paragraph 28 (rev'd on other grounds, see supra at 2)
43. *Beloit* (supra at 34) at page 293
44. *Diversified Products* (supra at 36) at page 366
45. *The King v. Uhlemann Optical Co.* [1952] 1 S.C.R. 143 at paragraph 19 [(1951), 15 C.P.R. (1st), 99 (S.C.C.)] at pages 104-105; *Wandscheer v. Sicard Ltd* [1948] S.C.R. 1 [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at page 48; both case citing *Samuel Parkes & Co. v. Cocker Bros. Ltd.* 46 R.P.C. 241 at page 248.
46. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraphs 61-64; *Janssen-Ortho Inc. v. Novopharm Limited* [2007] FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)] at paragraph 25. In *Sanofi-Synthelabo*, the Supreme Court refers at paragraph 67 to a general 4-step approach that may be used in framing the inquiry.
47. *Janssen-Ortho Inc. v. Novopharm Limited* [2006] FC 1234 [(2006), 57 C.P.R. (4th), 6 (F.C.)] at paragraph 113, aff'd [2007] FCA 217 [(2007), 59 C.P.R. (4th), 116 (F.C.A.)] at paragraph 25
48. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraphs 59-69, especially at 59, 64, 68 and 69

49. *Beloit* (supra at 34) at page 294; for the purposes of examination, the term “patent” must be understood to mean “application”.
50. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1949), 12 C.P.R. (1st), 102 (S.C.C.)] at pages 199, 203 to 204, and 218 citing *Natural Colour Kinematograph Co. v. Bioschemes Ltd.* 32 R.P.C. 256 at pages 266 and 269; *Free World Trust v. Électro Santé Inc.* [2000] SCC 66 [(2000), 9 C.P.R. (4th), 168 (S.C.C.)] at paragraphs 41 to 43
51. *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289] at pages 322 to 323
52. The *Farbenindustrie* criteria appear to have been endorsed at least as early as 1947 in *Minerals Separation* (supra at 25 at pages 163 to 164) and were affirmed by the Supreme Court in *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraph 9.
53. *Apotex v. Sanofi-Synthelabo* (supra at 32) at paragraph 9; *I.G. Farbenindustrie* (supra at 51) at page 321
54. *Pfizer Canada Inc. v. Canada (Minister of Health)* [2006] FCA 214 [(2006), 52 C.P.R. (4th), 241 (F.C.A.)] at paragraph 31; *I.G. Farbenindustrie* (supra at 51) at page 323
55. *Re Application 2,017,025 of Yeda Research and Development Corporation* (2007) C.D. 1273
56. *Free World Trust* (supra at 50) at paragraph 32
57. *Natural Colour Kinematograph* (supra at 50) at page 266; this passage also cited in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1952), 15 C.P.R. (1st), 133 (P.C.)]
58. Any such amendment, of course, must not introduce new subject-matter such as to contravene subsection 38.2(2) of the *Patent Act*.
59. *Natural Kinematograph* (supra at 50) at page 266. The use of “ambiguous” in this context should be understood in the context of the entire passage, wherein it was earlier stated that a patent is invalid if it relies on “language which, when fairly read, is avoidably obscure or ambiguous”.
60. 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

61. Reeck, Gerald *et al.*, " 'Homology' in proteins and nucleic acids: A terminology muddle and a way out of it" (1987), 50 *Science* 667
62. Altschul, S. *et al.*, "Basic Local Alignment Search Tool" (1990), 215 *Journal of Molecular Biology* 403