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Chapter 9 The Description

9.01 Scope of this chapter

The description, together with the claims, form the specification of an application.¹ Although the claims play a prominent role in the patent system, in that they define the scope of the exclusive privilege conferred by a patent, a proper description is fundamental to a valid patent. As was noted by the Supreme Court, “[d]isclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*”.²

The present chapter discusses the various requirements for proper disclosure under section 27(3) of the *Patent Act* as well as the various requirements as to the form and content of a description under the *Patent Rules*.

9.02 General requirements of disclosure

The description must provide a clear and complete disclosure of the invention such that the person skilled in the art:

- (1) can unambiguously identify what has been invented; and
- (2) is enabled to practice this invention.³

In *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.*, 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”.⁴ The description must be able to answer the questions “What is your invention?: How does it work?”⁵ 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”.⁶

It is beyond doubt that the “public” referred to in the foregoing quote takes the form of the person skilled in the art.

9.02.01 Proper disclosure

The statutory requirements of proper disclosure are set out in subsection 27(3) of the *Patent Act*, which requires that:

The specification of an invention must

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;

(c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

Thorson P. summarized the foregoing requirements in *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*,⁷ noting that

[t]he 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. The description must also give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the inventor must act *uberrima fide* and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him.⁸

The foregoing touches on both aspects of a sufficient disclosure: that it set out in clear and precise terms what the invention is (i.e. a correct and full description), and that it

provide sufficient instructions to the person skilled in the art so that this person is enabled to reproduce and successfully operate the claimed invention.

9.02.02 Addressee is the person skilled in the art

The specification of an invention is directed to a person skilled in the art or science to which it pertains, or with which it is most closely connected.⁹ Whether or not a description is sufficient depends on the interpretation it would be given by the person skilled in the art, who must interpret it with a mind willing to understand¹⁰ and desirous of success.¹¹

The person skilled in the art is competent, and represents an average, logical but unimaginative worker in the field.¹² This person is neither a dull-witted incompetent nor a creative, intuitive expert,¹³ albeit that in a highly technical field the person skilled in the art may be presumed to have expert-level knowledge and skills.¹⁴ Furthermore, the person skilled in the art is reasonably diligent in keeping up with advances in the field or fields of relevance to the invention,¹⁵ and has the advantage of being multilingual and thereby being able to comprehend prior art in any language.¹⁶

In addition, the person skilled in the art need not be an actual individual; they are a fictitious construct and can represent a team of individuals whose conjoint knowledge is relevant to the invention in suit.¹⁷

In order to properly assess whether a correct and full description of the invention has been provided, it is necessary to identify the person skilled in the art to which the application is directed.

In accordance with paragraph 80(1)(b) and 80(1)(d) of the *Patent Rules*, the description must indicate the technical field of the invention and must allow an understanding of the technical problem being addressed and the solution to that problem through the invention.¹⁸ The person skilled in the art will be competent in the field or fields of relevance to the invention.

A complexity arising from the nature of the person skilled in the art is that, as a general rule, neither the inventors nor the examiner may be directly equated to this person. Examiners and inventors, for example, are not free of creativity and intuition. They may have knowledge that surpasses that expected of the person skilled in the art in a given field, but again may not be as skilled in other fields of the invention as this person. During examination, an examiner must attempt to interpret the application and the prior art using the appropriate knowledge that the person skilled in the art would have possessed at the relevant date [see 9.02.03]. This may be particularly challenging where knowledge in the field at the date of examination has significantly developed since the relevant date, and particularly where certain views held at the relevant date

have subsequently been found to be incorrect.¹⁹

Where the precise nature of the person skilled in the art is relevant for resolving an issue during examination, the examiner will determine who this person is and will take due account of any representations made by the applicant on point.

9.02.03 Description supplemented by common knowledge

A description sufficient to allow the person skilled in the art to practice the invention with the same success as the inventor is said to be enabling. Since the person skilled in the art is the addressee of the description, it is not necessary for common knowledge to be comprehensively disclosed nor to teach to the person skilled in the art things that would be plainly obvious to them.²⁰

The date at which the person skilled in the art brings their knowledge to bear on the application is the date on which the application came into their possession; that is to say, the publication date.²¹

Since the common general knowledge may develop between the filing date and the publication date, this theoretically means that a specification that was not enabling as filed could nevertheless, on the basis of more extensive common general knowledge, be enabling by the publication date. However, the invention must still be fully described as of the filing date, and the utility of the invention must have been established no later than at this date [see 9.04].

9.02.04 Misleading or erroneous statements

The person skilled in the art will read a description with a mind willing to understand and desirous of success. They will use their common general knowledge to supplement the description in order to successfully operate the invention, and will overlook obvious errors or omissions that can be readily corrected.²²

Where, however, a description includes statements that direct the person skilled in the art to attempt to practice the invention in a manner contrary to their common general knowledge, the person skilled in the art will nevertheless follow these explicit instructions. Where the manner of operation so disclosed will in fact not work to achieve the promise of the invention, the description does not comply with subsection 27(3) of the *Patent Act*.²³

[For guidance regarding misleading definitions in the description, see 9.05.03.]

9.02.05 Addressee not to be presented with problems to solve

The person skilled in the art can be called upon to perform routine experiments to ensure proper operation of an invention, but must be able to practice the full scope of the invention without undue burden or the need to exercise their inventive ingenuity.

If the person skilled in the art is called on to solve problems in such a manner that undue burden or an inventive step are required, the description is insufficient (and the attendant claims are unsupported).²⁴ The obligation of the patentee for proper disclosure in this sense was described in *Rice v. Christiani & Nielsen* as:

[h]e must so draft his specification, that a person having a competent knowledge of the industry concerned [...] will be able readily to ascertain from it the relation the invention bears to the existing knowledge in the industry, and so that one should not be called upon to do experimental work in order to discover how the invention may be made operative. There must be an open exposition by the patentee of everything that is necessary for the easy and certain procurement of the commodity for which the patent was granted. The patentee is not to tell a man to make an experiment but to tell him how to do the thing.²⁵

H.G. Fox later described the relationship between the specification and the person skilled in the art as follows:

[t]he person to whom the specification is addressed is presumed to possess all the existing knowledge common to the art to which the invention relates; this knowledge he must bring to bear in interpreting the specification. But he is not required to exercise or to be possessed of more, and, if the specification contains something that necessitates the working out of a problem, the patent cannot be supported.

Where a specification describes an invention sufficiently clearly to enable a reasonably skilled workman to make use of it, even though some experiments are necessary, the patent will be good so long as those experiments do not require any exercise of the inventive faculty.²⁶

In certain arts, it is common to describe an invention as relying on materials having certain required properties (a metal with a certain ductility; an insulator with a certain dielectric value, a molecule with a certain dipole moment), rather than by naming the materials explicitly. This is permissible as long as identifying those materials that have the required property does not require undue burden or inventive effort.

Requiring the absence of inventive effort implies that the solution to the problem being

addressed must be readily apparent to the person skilled in the art (i.e. obvious). Solving a problem with a readily apparent solution is routine, and a description that requires the solving of such a problem could nevertheless be considered to be sufficient. The Courts have noted that it can be considered uninventive to engage in “routine testing to determine characteristics of known compounds, not undertaken for the purpose of ‘searching for something novel’, but rather for the purpose of verifying the actual attributes of already known compounds”.²⁷

While verifying the predicted or predictable properties of known compounds may therefore be considered to be routine,²⁸ “verification” means “confirmation” and determining the unexpected and unpredictable properties of new compounds is consequently not “verification”.²⁹

This reasoning can be extended to disciplines other than the chemical arts by formulating the statement as: a certain amount of routine testing is permitted in order to identify suitable materials for operating an invention, presuming the person skilled in the art knows or has been taught the necessary properties, how to determine them, and broadly what existing materials are likely to possess them.

Examples:

1. An invention describes a particular type of flange for connecting a plumbing fixture to a pipe, wherein it is necessary to construct the flange using a metal whose ductility is within a certain range. Identifying this operative ductility range is the discovery underlying the invention. Several metals having the necessary ductility are identified, and general teachings are given as to what types of metals are likely to have the necessary property. Testing ductility is within the common general knowledge of the person skilled in the art, and is routine.

Claim:

1. A flexible flange for connecting a plumbing fixture to a pipe, said flange comprising a metal having ductility in the range x-y and [...]

Analysis: The claim is given breadth by defining the flange in terms of a metal having ductility in the defined range, rather than in terms of specific operative metals. Whether or not the claim as defined is enabled depends on whether it can be operated without placing undue burden on the person skilled in the art. This depends on whether the person skilled in the art can readily identify suitable metals. Given that the person skilled in the art can test a given metal to determine whether or not it has the necessary ductility, that for many metals this data is already available in published references, and that the description suggests which metals are likely to be suitable, there is no invention in identifying metals that have the necessary property. Verifying the properties of known metals is “routine”, and the person skilled in the art has not improperly been

presented with problems to solve.

2. An applicant asserts as their invention drug compositions having very uniform release profiles for the active ingredient. Certain embodiments are disclosed based on particular salts of protected cyclic amines, but the invention is claimed in terms of drug compositions having the beneficial release profile, and not in terms of drug compositions of the particular family of salts.

Claim:

1. A medicament having a release profile characterised by [description of the profile]

Analysis: Consider that the release profile achieved is an unexpected and very beneficial property of the specific salts disclosed. The description does not disclose what chemical properties of the salt led to the defined release profile, nor does it guide the person skilled in the art as to what other compounds may provide a similar result. In order to operate the full scope of the claim, the person skilled in the art would have to solve the problem of identifying all the other salts that would lead to the same release profile. Since the identity of these other salts (presuming some may exist) is unobvious, an inventive step is associated with their identification. The description is insufficient to support the invention as broadly asserted.

9.02.06 Theory of the invention

As a general proposition, it is not necessary for the description to provide a theory as to why the invention operates as it does. The requirement is, simply, that the description teaches the person skilled in the art what the invention is and how to make it operate to provide the promised benefits.

Thus, as noted in *Apotex v. Wellcome*, “[i]t is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it”.³⁰

This general proposition, however, has to be understood in an appropriate context. The Supreme Court thus added to the comment quoted above by stating, in respect of an invention relying on sound prediction, that “[i]n this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly”.³¹ It can consequently be understood that if the utility of the invention is predicated on a sound prediction [see 12.08.04], and the line of reasoning depends on an understanding of the theory as to why the invention works, it may not be possible to properly express the line of reasoning unless this theory is disclosed.

9.03 Disclosing a solution to a practical problem

As was noted by the Supreme Court in *Apotex v. Wellcome*, the granting of patents is “a method by which inventive solutions to practical problems are coaxed into the public domain”.³² Being a solution to a practical problem is what provides to the invention the practical utility necessary for patentability.

The description must put the person skilled in the art in a position to appreciate the nature of the problem being solved and the solution provided by the invention. For applications filed on or after October 1, 1996, paragraph 80(1)(d) of the *Patent Rules* explicitly provides that the description shall

describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution.

In order to solve a practical problem, the solution must be in a form that can interact directly with the physical world and, hence, that will itself enable a person skilled in the art to obtain the intended result or benefit. That is, a patent is given for “the means by which a result is obtained ... rather than the result itself”.³³ These means must consist of one or several elements, where an element in this sense could be either a physical object (a machine, article of manufacture or composition of matter) or a step leading to a physical effect in an art or process.

The group of elements that are made use of to obtain the benefit of the invention may, in combination, be referred to as the “practical form” of the invention (i.e. the form in which the invention may be practised). The practical form includes all the elements required to provide the utility of the invention.

In order for the description to properly disclose the practical form, it must supplement the common general knowledge of the person skilled in the art so as to put the invention into the hands of this person. Any novel element must therefore be fully described, as it was necessarily not previously known. Also, those elements (new or old) the person skilled in the art would not have known to use in combination to achieve the objects of the invention must be described, not only individually but in the appropriate combination.

For the description to disclose a patentable invention, it must describe (and the claims define) all the elements necessary to provide the useful result in a novel and inventive manner, and without which elements the solution would cease to be inventive.³⁴

It is also necessary that the description provide such instructions as are necessary for the person skilled in the art to understand, where applicable, the interrelationship of the elements necessary to provide the practical form of the invention. The invention must

be described so that, colloquially speaking, “the wheels will go round”,³⁵ and must not require that the person skilled in the art perform modifications to the invention described in order to make it work.³⁶

Although external documents may be referred to in the description, the invention must be described and enabled by the description alone as interpreted by the person skilled in the art in view of their common general knowledge. Specific prior art knowledge (e.g. information only available in one or a few documents, and which has not been shown to be commonly known and accepted) may be considered not to be “common general knowledge”, and in such cases those specific teachings from the prior art necessary to describe or enable the invention must be included in the description in order to provide a full and complete disclosure.

It is not necessary to supplement a description of the foregoing with a description of those elements that would be self-evidently necessary to operate the invention, and whose use in the context of the invention as described would be obvious to the person skilled in the art.³⁷

9.04 Establishing utility

As noted in 12.08.03 of this manual, an applicant must be in a position to establish the utility of their invention, by demonstration or sound prediction, no later than at the filing date of their application.³⁸

As a general proposition, where the utility of an invention is to be established by demonstration, the factual basis that constitutes the demonstration must have existed at the filing date but need not have been included in the description.³⁹

Where it is not evident from the description that the utility of an invention was established by demonstration, an examiner must presume that the applicant is relying on a sound prediction for this purpose. In such cases, an examiner may object to a lack of established utility if no factual basis was disclosed upon which it could be concluded that utility had been properly established. If the utility of the invention had been established by demonstration, the applicant can establish this by submitting the relevant factual basis by way of affidavit.

The utility of an invention, particularly where the essence of the invention is to provide something having new or improved utility, may be interrelated with the inventive step of the invention.

During prosecution, amendment to the claims may appear to alter the nature of the invention. Care must be taken to ensure that the inventor was, no later than the filing date, in possession of the invention asserted in the amended claims. Inventive

ingenuity can not post-date filing.⁴⁰ This is particularly relevant where features not identified in the original specification as being related to specific advantages are subsequently asserted as rendering the claims non-obvious over prior art disclosures. It is important to consider whether the description teaches that the elements in question are simply optional, or are essential elements of preferred embodiments. Where the inclusion of an element will lead to additional benefits over the invention as broadly disclosed, it should be viewed as an essential element of the “narrower invention” (the subject-matter in a claim of narrower scope).

9.04.01 Sound prediction

The doctrine of sound prediction was given specific form by the Supreme Court, which noted that a sound prediction consists of three elements [see section 12.08.04 of this manual]:⁴¹

- (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.

The aspect of “proper disclosure” means that the description, when read in view of the relevant common general knowledge, must be sufficient to enable the person skilled in the art to soundly predict that the invention would work once reduced to practice.⁴²

9.04.01a Disclosure of the factual basis

The factual basis needed to render the line of reasoning sound must be disclosed. If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified.⁴³ Any necessary facts that are not otherwise publicly available must be included in the description.⁴⁴

A factual basis does not by necessity mean experimental data.⁴⁵ Established principles and laws are also factual, and to the extent that these form part of the sound line of reasoning the foregoing considerations for proper disclosure apply.

The term “factual basis” implies support and proof. Simple, unsubstantiated statements in the description suggesting that the invention will work are not considered to be factual.⁴⁶ Similarly, while an applicant can include “prophetic examples” in their application, they have little value in providing support. A prophetic example is necessarily a statement of what might be, rather than what is, and is therefore not “factual”.

As noted in section 12.08.04a of this manual, 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.

A broad claim, for example, may well require a greater factual basis than a narrow claim. A claim in an established field might benefit from a more developed common general knowledge than one in an emerging field. The necessity to disclose or explicitly refer to the necessary support will depend both on the amount of support required and on how much of that support is already known to the person skilled in the art.

9.04.01b Disclosure of the sound line of reasoning

The person skilled in the art must also appreciate the sound line of reasoning that connects the factual basis to the conclusion that the invention has the promised utility.⁴⁷

Here again, the description must provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit them, in view of the factual basis provided, to soundly predict that the invention will have the utility proposed.

The sound line of reasoning will usually involve an understanding at some level of the theory of the invention [see 9.02.06], and may depend e.g. on structure-activity relationships or accepted scientific principles or laws. The extent to which the sound line of reasoning must be described can only be evaluated on a case-by-case basis, and will depend on similar factors to those related to the factual basis.

As a disclosure requirement, the sound line of reasoning cannot be provided post-filing. Explanations during prosecution as to the nature of the sound line of reasoning can only be considered to the extent they explain why the person skilled in the art would have appreciated the sound line of reasoning on the basis of the description as filed and their common general knowledge.

Since the disclosure is directed to the person skilled in the art, the disclosure must allow that person to make a sound prediction. It is not enough that the description disclose information that allows for a sound prediction only when interpreted in view of proprietary knowledge possessed by the inventors alone or expert level knowledge beyond that expected of the person skilled in the art.

9.04.02 Selections

Selections are inventions based on the identification, from a prior teaching, of certain previously unrecognized advantages possessed by some sub-set of the prior teaching.

The accepted requirements of a selection are that:⁴⁸

- (i) the selection be based on some substantial advantage;
- (ii) the whole of the selection must possess the advantage; and
- (iii) the advantage must be in respect of a quality of a special character peculiar to the whole selection.

It is important to note that the advantage (which can include avoiding a substantial disadvantage) must be in comparison to the overall group from which the selection has been made, and be made on the basis of sufficient representative testing and not simply a comparison to a few isolated members of that group.⁴⁹

The newly discovered and unexpected advantage is what provides to the selection the utility and inventive step upon which its patentability rests.⁵⁰ Its novelty rests on the fact that the selected aspects of the prior teaching had not previously been made: per Maughan J. in *I.G. Farbenindustrie*, “[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”.⁵¹

Although there is no special or higher disclosure burden for a selection by comparison with any other type of invention, the advantage (and, if unclear, the new utility arising from the advantage) must be properly disclosed for there to be an invention.⁵² If there is no way to assess the purported “advantage”, there is no way for the person skilled in the art to appreciate that an invention has been “correctly and fully” described. Again from *I.G. Farbenindustrie*, an inventor “has in truth disclosed no invention whatever if he merely says that the selected group possesses advantages. Apart altogether from the question of what is called sufficiency, he must disclose an invention; he fails to do this in the case of a selection for special characteristics, if he does not adequately define them”.⁵³

A purported selection whose utility has not been established, by demonstration or sound prediction, is necessarily not an invention. Establishing that there is, in fact, an advantage requires that some point of reference be disclosed. Mere statements that a certain embodiment of an identified group is “preferred” or possesses an otherwise unspecified advantage or benefit or improved property are not sufficient to adequately disclose the substantial advantage necessary to establish inventive selection.⁵⁴

9.04.03 Combinations

A combination, in the sense the term is used herein, is an assemblage of parts (often of known parts) whose conjoint use leads to a result that is “different from the sum of the results of the elements” that make it up and “that is not attributable to any of the elements but flows from the combination itself and would not be possible without it”.⁵⁵ Such a result may conveniently be termed a “unitary” result.⁵⁶

A patentable combination has been explained in the following way:

it is accepted as sound law that a mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together have some working inter-relation producing a new or improved result then there is patentable subject matter in the idea of the working inter-relation brought about by the collocation of the integers.⁵⁷

Where several parts are used together, each providing its expected result and the whole not leading to a unitary result, the assemblage is referred to as a “mere aggregation”,⁵⁸ or simply as an “aggregation”, to distinguish it from a true combination.

The utility of a combination is the unitary result it provides, and it is this result that must be established by demonstration or sound prediction.

Where, having described the structure of the combination, it would not be clear to the person skilled in the art what unitary result it achieves, a correct and full description of the result itself may be necessary to show that the combination is useful and inventive and to distinguish it from a mere aggregation.

9.04.04 Chemical combinations and synergy

In the chemical arts, different compounds or products are often combined in order to realize new results. The concept of combinations applies equally to chemical inventions as to any other.

A chemical combination refers to a physical, as opposed to chemical, combination of compounds or products. Generally, implementing the physical acts of mixing or physically combining different compounds or products does not require inventive activity. The inventive step in a chemical combination, by consequence, is typically closely associated with the utility of the combination, and generally arises from a recognition that the combination (as opposed to its individual components) unexpectedly provides a specific unitary result.

Where the combination leads to a new unitary result or one that is different from what the person skilled in the art would have expected the combination to be suitable for, the utility of the combination to produce that result must necessarily be established.

In some combinations, compounds having known activity are combined and jointly applied to achieve an enhanced result. That is, the activity or effect of the combination as a whole is greater or otherwise better than the result that would have been expected from the joint use of its individual components. In order to establish that such a result has been produced, it is necessary for the person skilled in the art to be aware of the point of reference (the result to be expected from combining the individual components), either by virtue of their common general knowledge or in view of the description. The need for a point of reference in such cases is analogous to the need for a point of reference when making an inventive selection [see 9.04.02].

Where the compounds have been jointly applied to their known purpose, the enhanced result may, as a matter of convenience, be referred to as a synergistic effect.

Where a first compound has been applied to its known purpose and another compound in the combination unexpectedly enhances the result of the first compound, the enhancement effect is, in some fields, referred to as potentiation.

9.05 Special topics

The following sections set out practice in respect of certain specific topics which give rise to particular considerations with respect to proper disclosure.

9.05.01 Functional limitations

In certain cases, applicants may wish to describe or define an invention using functional language. The use of functional language, whether in a claim or in the description, is not *per se* objectionable. Such language, however, is generally used to provide breadth 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, with the question to be asked being: “can the person skilled in the art practice, in view of the description, the full breadth of the claimed invention without recourse to undue experimentation or inventive ingenuity?” [see 9.02.05]. 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, broad functional language would direct the claimed invention to be practised in ways that have not been fully described or enabled and consequently would be objectionable.

Typically, the inquiry into the appropriateness of functional language is driven by the language of the claims. Where an invention is defined in terms of an overly broad functional limitation, the claim seeks to monopolize speculative embodiments that the inventors have not adequately described. The corollary is that the description is not sufficient to support the invention as claimed.

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.⁵⁹

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 amounting to invention [see 9.02.05]. The description, therefore, is not sufficient to describe and enable the invention asserted in the claim, and is objectionable under subsection 27(3) of the *Patent Act*.

In contrast, if it had been discovered that the combination of a particular drug with any non-steroidal anti-inflammatory (NSAID) compound led to unexpected advantages, functionally limiting the scope of the second component of the composition by the limitation “NSAID” would not be problematic. The scope of the term “NSAID” (or “NSAID compound”) would be immediately apparent to the person skilled in the art.

Similarly, in a mechanical invention that relies on a “cutting means”, a number of different cutting means would be known to the person skilled in the art. Where it would be readily apparent which would be suitable for operating the claimed invention, the limitation “cutting means” would not improperly broaden the claim. The identification and selection of appropriate cutting means would not require undue effort or further invention in such a circumstance.

9.05.02 Disclosure of biotechnological inventions

Specific disclosure requirements exist for some inventions in the fields of biotechnology. In brief, it may be necessary for a sequence listing of a nucleotide or amino acid sequence to be included with the description or for a deposit of biological material to be made with an International Depository Authority in order for the description of a biotechnology invention to be considered to be sufficient.

Details on the requirements for providing sequence listings or deposits of biological material are provided in sections 17.04.01 and 17.04.02, respectively, of this manual.

9.05.03 The applicant as their own lexicographer

It has long been understood that the language of the claims is to be construed in view of the specification as a whole, and that the applicant can serve as their own lexicographer.

Their Lordships do not doubt that it is possible for a patentee to make his own dictionary in this way. If he has put something in the earlier part of the specification which plainly tells the reader that for the purpose of the specification he is using a particular word with a meaning which he sets out, then the reader knows that when he comes to the claims he must read that word as having that meaning. But this is an awkward method of drafting and is very undesirable where a simpler method could easily be adopted and it is in all cases incumbent on a patentee who chooses to adopt this method to make his intention plain to those who read the specification.⁶⁰

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.

In the context of proper disclosure, it is to be noted that where an applicant, in attempting to act as their own lexicographer, creates a definition for a term that is contrary to the usual meaning ascribed to that term in the art, that is liable to cause confusion or ambiguity, or that is unnecessary in that other plain language could as easily provide the same information, the definition is objectionable. Recall in this context the requirement discussed in 9.02.01 that “[t]he 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”.

For example, where the description teaches that, for the purposes of the invention, the symbol P (phosphorus) designates nitrogen (elemental symbol N), this definition is only liable to cause confusion and is objectionable under subsection 27(3) of the *Patent Act*. The symbol is recognized in chemistry as designating phosphorus, and could readily be replaced by the appropriate symbol, N, to designate nitrogen.

In contrast, a definition is generally acceptable if, for the purposes of expediency and without sacrificing clarity, it narrows the scope of a term that would otherwise be attributed a broader meaning in the art. In a given case, it might be acceptable to define, for example, that the term “ethylene polymer” means “a non-crosslinked polymer comprising at least 80 mol% ethylene, with up to 20% C₃₋₈ alkene comonomer”. Providing the longer definition at multiple instances would be unnecessarily cumbersome, and the definition provided unambiguously restricts the broader term.

9.05.04 Disclosure of trade-marked products

An invention may be operated by way of trade-marked products. Simply naming a trade-marked product is not, however, equivalent to describing the composition of that product.

Further, simply knowing what components are included in a trade-marked product does not identify which of those components is an essential element of the invention (i.e. which component or components are necessary to fulfill the trade-marked product's role in the invention). Thus, even though a person skilled in the art may, depending on the state of the art, be able to reverse engineer a trade-marked product and identify its components, this will not by necessity put them in possession of the invention.

Therefore, where an invention is described only in terms of a trade-marked product, the question of proper support must be carefully considered. If it is not clear which component of the product is responsible for the product's role in the invention, the invention cannot be operated other than by the trade-marked product itself.

If the composition of the trade-marked product is not known, and the product is not commercially available, the invention is not enabled.

Where an invention is described in terms of specific components (e.g. chemical compounds), but is supported by examples that rely on trade-marked products of undisclosed composition, no presumption exists that the examples embody the invention described. The applicant must establish that they were aware of the composition of the trade-marked product no later than at the filing date.

Where the composition of a trade-marked product did not form part of the prior art as of the filing date, its composition cannot subsequently be added to the application [see 9.08].

[For requirements regarding the identification of trade-marks, see 9.07.03.]

9.05.05 Description by reference to the claims

The invention must be "correctly and fully" described in the description, which according to section 2 of the *Patent Rules* is "that part of the specification other than the claims". Furthermore, in accordance with section 84 of the *Patent Rules*, the claims shall be fully supported by the description.

It is consequently improper for the description to state the nature of the invention by reference to the claims. Such statements suggest that the description does not "correctly and fully" disclose the invention and does not comply with subsection 27(3) of

the *Patent Act*.

Therefore, where the description teaches in some fashion that the invention is “according to the claims”, the statement must be removed or replaced by an explicit description of the invention.

By way of example, statements such as “the problem of premature ignition in the combustion chamber is overcome through the method of claim 1” or “the compositions as instantly claimed exhibit superior insecticidal properties” fail to set forth explicitly what the invention in question is, but suggest instead that the invention is whatever might be claimed at any given moment in time.

Note that amending the description to include the language of the claims originally filed is necessarily compliant with subsection 38.2(2) of the *Patent Act*.

9.05.06 Statements expanding the scope of the claims

Since the claims of a patent must be supported by the description, any statement that the claims are to be viewed as broader than the teachings of the description is incorrect and must be removed. Such statements suggest that the description does not “correctly and fully” disclose the invention and does not comply with subsection 27(3) of the *Patent Act*.

A statement such as “the description should be understood as illustrative of the invention, but should not be considered as limiting on the claims appended hereto”, which suggests that the description merely sets out certain preferred aspects of the invention and is therefore not limiting of the claims, causes a lack of clarity as to the intended scope of the claims and must be removed.

An indication that the claims encompass or must be interpreted having regard to the “spirit of the invention” is also an attempt to expand the scope of the claims in a vague and undefined way, and must be removed.⁶¹

In contrast, a statement such as “the scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be given the broadest interpretation consistent with the description as a whole”, which simply notes that the claims are not to be limited to the preferred or exemplified embodiments of the invention, is permissible.

9.05.07 References to foreign practice or law

Where an application includes a statement whose correctness is dependent on foreign patent prosecution practices or laws, such a statement may be inaccurate or liable to

cause confusion in the context of Canadian law. Where this is the case, the statement must be removed. The statements may be viewed as being “incorrect”, and therefore a defect under subsection 27(3) of the *Patent Act* [see 9.09].

An indication that the application is a continuation-in-part or a divisional of a foreign patent document, for example, is not correct in the context of the Canadian *Patent Act* and must be removed.

A statement regarding the rights of foreign governments to the invention may also be misleading, and should be removed if it is inaccurate.

9.06 Form of the description

The form a description should take is set out in section 80 of the *Patent Rules*.⁶² Thus,

- (1) The description shall
 - (a) state the title of the invention, which shall be short and precise and shall not include any trade-mark, coined word or personal name;
 - (b) specify the technical field to which the invention relates;
 - (c) describe the background art that, as far as is known to the applicant, can be regarded as important for the understanding, searching and examination of the invention;
 - (d) describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution;
 - (e) briefly describe the figures in the drawings, if any;
 - (f) 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; and
 - (g) contain a sequence listing where required by subsection 111(1).
- (2) The description shall be presented in the manner and order specified in subsection (1) unless, because of the nature of the invention, a different manner or a different order would afford a better understanding or a more economical presentation.

The provisions of subsection 80(2) of the *Patent Rules* would allow, for example, that

drawings associated with the prior art be described with the background art, prior to the brief description of the figures in any remaining drawings.

The title of the invention should be descriptive of the invention in suit, and not merely of the field to which the invention pertains. A title such as “flame-retardant rigid polyurethane foam” is acceptable, whereas “foam” is not.⁶³

In accordance with paragraph 80(1)(a) of the *Patent Rules*, the Office considers the title provided in the description to be the correct title of the invention. Where, for any reason, the title ascribed to the invention in the Office’s electronic database differs from the title provided in the description, the electronic database will be updated at the time of grant to reflect the title set out in the description.⁶⁴

Disagreement between the title in the description and the title in the Office’s electronic database is not a defect in the application. An examiner may note the existence of such a disagreement, in order to apprise the applicant of the situation and provide them with an opportunity to address the matter. Such a disagreement may also be brought to the applicant’s attention subsequent to allowance, by way of an Office letter.

Paragraph 80(1)(c) of the *Patent Rules* requires that the applicant describe the background art that, as far as is known to them, is important for the understanding, searching and examination of the invention. Where relevant background art is identified during prosecution, an applicant may, within the limitations imposed by section 38.2 of the *Patent Act* [see 9.08], introduce to the description references to and descriptions of the contents of prior art documents where these are clearly admitted to be prior art with respect to the application. Examiners should, in general, not raise an objection simply because the description has not been amended to identify background art brought to the applicant’s attention subsequent to filing.

Paragraph 80(1)(f) of the *Patent Rules* provides that, “where appropriate”, the applicant must set forth in terms of examples, at least one mode contemplated by the inventor for carrying out the invention. 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 disclosure requirements of subsection 27(3) of the *Patent Act*.

It is not necessary for the description to present the information required by section 80 of the *Patent Rules* in sections bearing headings corresponding to the paragraphs of subsection 80(1), although an applicant may choose to do so for the sake of clarity.

Headings such as “Summary of the Invention”, “Detailed Description of the Invention” and “Detailed Description of the Preferred Embodiments” are permitted in Canadian

practice. It is worth noting, however, that where a heading such as “Detailed Description of the Preferred Embodiments” is used, support for claims broader than these embodiments must be found in other parts of the description which must satisfy the requirements of subsection 27(3) of the *Patent Act*, including enablement and support for any sound prediction, in respect of the invention as broadly claimed.

9.07 Formalities requirements of the description

The description is subject to many formalities requirements dealing with various aspects of its contents and presentation. These are summarized in the following sections.

9.07.01 Pages of the description

In accordance with subsection 73(1) of the *Patent Rules* the description must be on consecutively numbered pages,⁶⁵ and in accordance with section 72 of the *Patent Rules* no page of the description may contain anything belonging to another part of the application.⁶⁶

9.07.02 Drawings, graphics and tables

In accordance with section 74 of the *Patent Rules*, the description shall not contain drawings⁶⁷ but may contain chemical or mathematical formulae or the like.⁶⁸ For greater clarity, a chemical formula may be presented in the description in graphical form (i.e. as a structure).⁶⁹ The description may also contain information presented in tables. In accordance with subsection 75(2) of the *Patent Rules*, any formula or table may, where it aids presentation, be presented sideways (i.e. in landscape format) with the top of the formula or table at the left side of the sheet.⁷⁰ Otherwise, subsection 75(1) of the *Patent Rules* provides that pages of the description must be used upright (i.e. in portrait format).⁷¹

It can be inferred from section 37 of the *Patent Act* that a drawing is an illustration of the invention. Schematics that illustrate a process, such as flow-charts, are generally considered to be drawings.

Graphical representations of data, such as graphs, histograms, pie charts, and spectra, are not necessarily to be viewed as “illustrations of the invention”, and therefore may be included in the description. Where a graphical representation of data is provided as a drawing, it must comply with all the requirements of section 82 of the *Patent Rules*.

Tabulated data generally cannot be considered a “drawing”, and typically should be presented in the description.

Where the application contains drawings, subsection 82(9) of the *Patent Rules* requires

that any reference characters appearing on any figures in the drawings, and only these reference characters, be mentioned in the description.⁷² Further, where features are identified by reference characters, subsection 82(10) of the *Patent Rules* requires that the same reference characters must be used throughout the description to refer to those features, and may not be used to refer to any other features.⁷³

9.07.03 Identification of trade-marks

In accordance with section 76 of the *Patent Rules*, any trade-mark mentioned in the application shall be identified as such.⁷⁴ The Office requires that each trade-mark be identified in an appropriate manner at least once, preferably at its first appearance.

Use of the words “trade-mark” in parentheses, of the designation “™”, or of an indicator such as an asterisk (*) linked to a footnote denoting that the asterisk designates a trade-mark are all examples of appropriate manners for identifying a trade-mark in an application.

9.07.04 Identification of documents

In accordance with section 81 of the *Patent Rules*, a document referred to in the description must be available to the public and be fully identified, and shall not be incorporated by reference.⁷⁵

The Office considers a patent document to be properly identified when the country or office code is provided along with a number under which the published version of the document can be found. Thus, the number provided can be that given to a granted patent, or be either the application number or publication number of a published application.

WO 96/937212, US 5,410,288, and EP 1 004 793 are examples of patent documents properly identified by a publication or patent number.

PCT CA2006/001,285 and U.S.S.N. 11/421,399 are examples of application numbers which are acceptable if the identified application has been published.

PCT applications, and US applications filed after November 28, 2000, will generally be published unless the application has been withdrawn (or, in the case of US applications, abandoned) prior to the publication date. Under 35 U.S.C. 122, a US application may also be kept confidential (i.e. will not be published) if the applicant certifies that they will not file an application for the disclosed invention in any other country. Where a US application is relied on as a priority document, this provision does not apply. US provisional applications, applications for design patents, and applications in series 09 or earlier are not necessarily published and may not be referred to by their

application numbers unless the document is available to the public.⁷⁶

For non-patent documents, the requirement is that the document be sufficiently well identified to permit it to be obtained by an interested party.

For a journal article, textbook, or the like, the document should be identified by the names of the author and the publication, the year of publication, the volume and/or issue number(s) if applicable, and the page numbers of the article, number of the chapter or the like. Preferably, the title of an article or title of a chapter should be provided. Additional information, such as the name of the publisher, may be included. Where a unique document identifier such as an ISBN code is provided, this does not replace any of the foregoing requirements.

References to internet pages present a particular difficulty in that neither the URL nor the content of such pages is necessarily fixed. Examiners will object to the identification of a document by way of a URL where it is not clear that the URL refers to a reliable, publically available source that can reasonably be expected to ensure the information in question is of fixed content and will be more or less permanently retrievable.

9.08 Amendments to the description

In accordance with subsection 38.2(1) of the *Patent Act*, the description is subject to amendment before grant. Under subsection 38.2(2) of the *Patent Act*, any such amendment may not introduce “matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application” (for convenience, such matter may be referred to simply as “new matter”).

Note that one amendment that is always permissible from the standpoint of “new matter” is the inclusion of the language of the originally filed claims in the description.

General guidance regarding the amendment of applications is provided in chapter 19 of the manual.

As regards the description, particular attention must be given to amendments that replace restrictive language with permissive language. Where an application teaches that the invention (as opposed to an embodiment of the invention) “must be” or “is” (or the like) operated in a certain way, amendment of this language to indicate that the invention “preferably” or “optionally” (or the like) is operated in that way enlarges the scope of the invention and may be seen as the addition of new matter.

Similarly, it is possible for the deletion of text to amount to the addition of new matter. If

a passage in the description teaches that an invention is inoperative under certain conditions, an amendment to remove this guidance could be viewed as introducing new matter by expanding the scope of the operable invention.

Where a description included both permissive and restrictive language regarding a certain limitation, amending the description to make it self-consistent throughout will generally not be seen as the addition of new matter.

An invention requires an inventive step, and the presence of this inventive step must be evaluated in view of the specification as filed. Amendments that appear to introduce new aspects of “inventiveness” to the application introduce new matter.

Remembering that an invention is a solution to a practical problem, it can be understood that amendments that tend to transform the invention as originally disclosed into a new invention - that is to say, into a new solution to the same or a different problem - constitute the addition of new matter.

Such amendments shift the point of invention and have the effect of causing a different invention to be disclosed than that in the specification as originally filed.

The description may be amended to make reference to prior art documents. Where the amendment is merely to clarify the state of the art, this will generally not be considered to introduce new matter. Where, however, an amendment introduces information from a prior art document, these amendments may, depending on the circumstances, introduce new matter.

Where specific teachings in a prior art document are required in order to enable the invention to be operated, or in order to support a sound prediction of utility, and it would not have been clear to the person skilled in the art, as of the claim date, which teachings in the prior art document were necessary for this purpose, identifying or including the specific teachings constitutes the addition of new matter.

9.09 Office actions on the description

Objections dealing with substantive issues of sufficiency are presented under subsection 27(3) of the *Patent Act*, or a specific paragraph of that subsection where this precision may be helpful in underlining the basis of the objection.

As is the case with objections under subsection 27(4) of the *Patent Act*, however, the defects being objected to under subsection 27(3) can range from significant issues of sufficiency to fairly minor defects of clarity. The presence of a subsection 27(3) objection is not by necessity an indication of any un-remediable defect relating to sufficiency.

Nevertheless, wherever a more specific authority exists on which to base the objection being made, this authority should be used in place of subsection 27(3) of the *Patent Act*. For example, if a reference character has been included in the drawings but is not mentioned in the description, this defect should be presented under subsection 82(9) of the *Patent Rules* rather than under subsection 27(3) of the *Patent Act*.

Objections to formatting or other minor problems are presented under authority of whichever section relates to the defect under consideration [see 9.07 and the related endnotes].

Non-compliance with the formatting requirements set out in sections 68, 69 and 70 of the *Patent Rules* [see section 5.03 of this manual] can be identified by an examiner in order to inform applicants of any defects and expedite advancing the application to allowance. It is not, however, required for an examiner to do so, since correction of these defects can also be requisitioned by examination support staff. It is noted that the Canadian requirements as to formatting are based on those required under the Patent Cooperation Treaty, and requisitioning compliance with the Canadian requirements is therefore permissible under Article 27, PCT.

Endnotes for chapter 9

1. See the definitions of “description” and “claims” in section 2 of the *Patent Rules*.
2. *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 at paragraph 37
3. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* [(1989), 25 C.P.R. (3rd), 257 (S.C.C.)] at page 268; *Apotex v. Wellcome* (supra at 2) at paragraph 70; *Electrolytic Zinc Process Co. v. French’s Complex Ore Reduction Co.* [1930] S.C.R. 462 at paragraph 22; *Leithiser v. Pengo Hydra-Pull of Canada Ltd.* [(1974), 17 C.P.R. (2nd), 110 (F.C.A.)] at pages 113-115; *Lundbeck Canada Inc. v. Minister of Health* 2009 FC 146 at paragraph 135; *Pfizer Canada Inc. v. Novopharm Limited* 2009 FC 638 at paragraph 105. See also *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61, e.g. at paragraph 26, applying these requirements to prior disclosures being considered for the purposes of anticipation.
4. *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1981), 56 C.P.R. (2nd), 145 (S.C.C.)] at pages 154-155, Dickson J. quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.]
5. *Consolboard* (supra at 4) at page 157
6. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1947), 12 C.P.R. (1st), 102 (Ex.Ct.)] at page 111
7. *Minerals Separation* (supra at 6)
8. *Minerals Separation* (supra at 6) at pages 111-112, with these points being reasserted by Thurlow J. in *Société des Usines Chimiques Rhone-Poulenc et al. v. Jules R. Gilbert Ltd. et al.* [(1968), 55 C.P.R. (1st), 207 (S.C.C.)] at pages 225-226; *Wandscheer et al. v. Sicard Limitée* [(1947), 8 C.P.R. (1st), 35 (S.C.C.)] at pages 39-40.
9. This position has been adopted by the courts so often that it has become axiomatic. See, e.g., *Whirlpool Corp. v. Camco Inc.* 2000 SCC 67 at paragraph 53; *Consolboard* (supra at 4) at page 160
10. *Free World Trust v. Électro Santé Inc.* 2000 SCC 66 at paragraph 44, quoting H.G. Fox from his *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.] at page 184; *Whirlpool* (supra at 9) at paragraph 49, citing *Lister v. Norton Brothers and Co.* [(1986), 3 R.P.C. 199 (Ch.D.)] at page 203

11. *Free World Trust* (supra at 10) at paragraph 44
12. From *Beloit Canada Ltd. v. Valmet Oy* [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)] at page 294 we know them to be a “paragon of deduction” and from *Whirlpool* (supra at 9 at paragraph 74) we know them to be “reasonably diligent in keeping up with advances in the field to which the patent relates”. See also the comments on point in *Janssen-Ortho Inc. v. Novopharm Limited* 2006 FC 1234 at paragraph 113.
13. *Bayer Aktiengesellschaft v. Apotex Inc.* [(1995), 60 C.P.R. (3rd), 58 (On.Ct.G.D.)] at page 79
14. *Servier Canada Inc. v. Apotex Inc.* 2008 FC 825 at paragraph 99
15. *Servier* (supra at 14) at paragraph 254
16. *Axcan Pharma Inc. v. Pharmascience Inc.* 2006 FC 527 at paragraph 38
17. *Bayer AG* (supra at 13) at page 79; *Johnson & Johnson Inc. v. Boston Scientific Ltd.* 2008 FC 552 at paragraph 97; *Lundbeck Canada Inc v. Minister of Health* 2009 FC 146 at paragraph 36
18. In respect of applications filed on or after October 1, 1996.
19. The comments in *GlaxoSmithKline Inc. v. Pharmascience Inc.* 2008 FC 593 at paragraph 35, while they relate to expert witnesses at trial and not to examiners and inventors/applicants during examination, are illustrative.
20. see, e.g., *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 37; *Burton Parsons Chemical Inc. v. Hewlett-Packard (Canada) Ltd.* [(1976), 17 C.P.R. (2nd), 97 (S.C.C.)] at page 105
21. *Pfizer v. Novopharm* (supra at 3) at paragraph 108; *Sanofi-Aventis Canada Inc. v. Apotex* 2009 FC 676 at paragraph 233; *Free World Trust* (supra at 10) at paragraph 54. Note, however, that the Supreme Court in *Free World Trust* was addressing the date for claim construction rather than enablement.
22. *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 37. During examination, such obvious errors should be corrected whenever identified.
23. *TRW Inc. v. Walbar of Canada Inc.* [(1991), 39 C.P.R. (3rd), 176 (F.C.A.)] at page 197
24. *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.* [(1978), 39 C.P.R. (2nd), 145 (F.C.T.D.)] at pages 159-160, aff'd [(1979), 42 C.P.R. (2nd), 33 (F.C.A.)]; see also

- Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraphs 33-37
25. *Rice v. Christiani & Nielsen* [1929] Ex.C.R. 111 at paragraph 9, rev'd on other grounds
 26. H.G. Fox, *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed., Carswell (Toronto)] at page 171; the last sentence in the first paragraph was quoted with approval in *Pioneer Hi-Bred* (supra at 3) at page 270
 27. *Janssen-Ortho Inc. v. Novopharm Ltd.* 2004 FC 1631 at paragraph 54; quoted in *Bristol-Myers Squibb Canada Co. v. Novopharm Ltd.* 2005 FC 1458 at paragraph 71, *Aventis Pharma Inc. v. Apotex Inc.* 2005 FC 1504 at paragraph 126. Note that in the foregoing cases the Courts were addressing the question of obviousness, and whether engaging in routine testing made the result of that testing unobvious. However, the link between the obviousness analysis and the evaluation of sufficiency is addressed in *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.* 2010 FC 230 at paragraphs 57-80. See also the comments in *Pfizer Limited v. Ratiopharm* 2010 FCA 204 at paragraphs 16 to 27.
 28. *Pfizer Canada Inc. v. Canada (Minister of Health)* 2006 FCA 214 at paragraph 24
 29. *Janssen-Ortho Inc. v. Apotex Inc.* 2008 FC 744 at paragraph 111; *Pfizer v. Canada* (supra at 28) at paragraphs 26 and 27
 30. *Apotex* (supra at 2) at paragraph 70
 31. *Apotex* (supra at 2) at paragraph 70
 32. *Apotex* (supra at 2) at paragraph 37
 33. *Norac Systems International Inc. v. Prairie Systems & Equipment Ltd.* 2002 FCT 337 at paragraph 16, rev'd in part on other grounds 2003 FCA 187
 34. *Dimplex North America Ltd. v. CFM Corp.* 2006 FC 586 at paragraph 80, aff'd 2007 FCA 278; citing *Norac Systems* (supra at 33)
 35. Fox (supra at 26) citing at pages 150-151 *Mullard Radio Valve Company Ltd. v. Philco Radio and Television Corporation of Great Britain Ltd.* [(1935), 52 R.P.C. 261] at page 287; quoted in *Eli Lilly Canada Inc. v. Novopharm Ltd.* 2007 FC 596 at paragraph 188 and in *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1978), 39 C.P.R. (2nd), 191 F.C.T.D.] at page 216
 36. *Norac Systems* (supra at 33) at paragraph 41; *Almecon Industries Ltd. v. Anchortek Ltd.* 2001 FCT 1404 at paragraph 45, aff'd 2003 FCA 168, citing

- Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.* [(1978), 39 C.P.R. (2nd), 191 F.C.T.D.] at page 216
37. *Metalliflex Ltd. v. Rodi & Wienenberger Aktiengesellschaft* [(1960), 35 C.P.R. (1st), 49 (S.C.C.)] at pages 53-54
38. *Apotex* (supra at 2) at paragraph 46
39. *Pfizer v. Novopharm* (supra at 3) at paragraphs 76 and 82, aff'd 2010 FCA 242 at paragraph 82
40. see, e.g., *Novopharm Limited v. Janssen-Ortho Inc.* 2007 FCA 217 at paragraph 26; *Johnson & Johnson Inc. v. Boston Scientific Ltd.* 2008 FC 552 at paragraphs 376-377; *Pfizer Canada Inc. v. The Minister of Health* 2008 FC 13 at paragraphs 99 and 118
41. *Apotex* (supra at 2) at paragraph 70
42. *Eli Lilly Canada Inc. v. Apotex Inc.* 2009 FCA 97 at paragraphs 10-18; *Eli Lilly Canada Inc. v. Novopharm Limited* 2009 FC 235 at paragraph 101; *Servier* (supra at 14) at paragraph 379
43. *Eli Lilly Canada Inc. v. Apotex Inc.* 2008 FC 142 at paragraphs 163-164; *Eli Lilly v. Apotex* (supra at 42) at paragraph 12
44. *Eli Lilly v. Apotex* (supra at 42) at paragraph 18; this requirement extends equally to any factual basis needed to support a sound prediction of an advantage possessed by a selection from a broader group, see *Pfizer Canada Inc. v. Canada (Minister of Health)* 2008 FC 500 at paragraph 97 and *GlaxoSmithKline* (supra at 19) at paragraph 71
45. *Apotex* (supra at 2) at paragraph 70; *Pfizer Canada Inc. v. Canada (Minister of Health)* 2007 FCA 209 at paragraph 152
46. *Pfizer Canada Inc. v. Apotex Inc.* 2007 FC 26 at paragraphs 66-70; aff'd 2007 FCA 195 - the Court concluded its observations on the patent in suit by noting that "[u]tility and sound prediction are questions of fact and must obviously be supported by evidence."
47. *Servier Canada Inc. v. Apotex* 2008 FC 825 at paragraph 379; *Eli Lilly v. Apotex* (supra at 42) at paragraph 18; *Eli Lilly v. Novopharm* (supra at 42) at paragraphs 101 and 107; *Merck & Co. v. Apotex Inc.* 2005 FC 755 at paragraphs 125-126

48. *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289] at pages 322-323; these criteria appear to have been endorsed in Canada at least as early as 1947 in *Minerals Separation* (supra at 6 at pages 163-164). They were endorsed by the Supreme Court in *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 10.
49. *GlaxoSmithKline* (supra at 19) at paragraph 70 and at paragraph 51 with reference to *Dreyfus and Others Application* [(1945), 62 R.P.C. 125 (H.L.)] at page 133; *I.G. Farbenindustrie* (supra at 48) at page 327
50. *Pfizer Canada Inc. v. Canada* 2006 FCA 214 at paragraph 4
51. *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 9; *I.G. Farbenindustrie* (supra at 48) at page 321
52. *Pfizer Canada Inc. v. Ranbaxy Laboratories Limited* 2008 FCA 108 at paragraph 59; *Eli Lilly Canada Inc. v. Apotex Inc.* 2007 FC 455 at paragraph 89
53. *I.G. Farbenindustrie* (supra at 48) at page 323
54. see, e.g., *Eli Lilly Canada Inc. v. Novopharm Limited* 2009 FC 235 at paragraph 100; *Eli Lilly Canada Inc. v. Novopharm Ltd.* (supra at 35) at paragraph 162; *Ratiopharm Inc. v. Pfizer Limited* 2009 FC 711 at paragraph 179; *Pfizer Canada Inc. v. The Minister of Health* (supra at 40) at paragraphs 115-116; note the similarity to the comments rendered in *Pfizer v. Apotex* (supra at 46) at paragraphs 66 and 69
55. *The King v. American Optical Co.* [(1950), 13 C.P.R. (1st), 87 (Ex.Ct.)] at page 98
56. *The King v. American Optical* (supra at 55)
57. *Lester v. Commissioner of Patents* [(1946), 6 C.P.R. (1st), 2 (Ex.Ct.)] citing at page 3 *British Celanese Ltd. v. Courtaulds Ltd.* [1935] 52 R.P.C. 171 at page 193
58. *Domtar Ltd. v. MacMillan Bloedel Packaging Ltd.* [(1977), 33 C.P.R. (2nd), 182 (F.C.T.D.)] at pages 189-190; *Bergeon v. De Kermor Electric Heating Co.* [1927] Ex. C.R. 181 at paragraphs 29 and 81; *Schmuel HersHKovitz v. Tyco Safety Products Canada Ltd.* 2009 FC 256 at paragraph 148; *Free World Trust* (supra at 10) at paragraph 27
59. *Free World Trust* (supra at 10) at paragraph 32
60. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1952), 15 C.P.R. (1st), 133 (P.C.)] at pages 144-145

61. *Free World Trust* (supra at 10) at paragraph 31
62. Section 80 of the *Patent Rules* applies to applications filed after October 1, 1996. There is no equivalent to this rule for earlier-filed applications.
63. Note that, for applications filed prior to October 1, 1996 and October 1, 1989, respectively, the requirement that an invention have a title are governed by sections 134 and 170 of the *Patent Rules*.
64. This practice was first communicated in the practice notice *Title of Invention* [C.P.O.R. Vol. 137, No. 4, January 27, 2009].
65. This requirement is governed by subsection 135(4) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(4) of the *Patent Rules* for applications filed before October 1, 1989.
66. There is no such requirement in the *Patent Rules* governing applications filed prior to October 1, 1996.
67. This requirement is explicitly governed by subsection 74(1) of the *Patent Rules* for applications filed on or after October 1, 1996, by subsection 135(3) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(3) of the *Patent Rules* for applications filed before October 1, 1989.
68. The permissibility of chemical and mathematical formulae, and the like, is provided by subsection 74(2) of the *Patent Rules* for applications filed on or after October 1, 1996; for applications filed prior to October 1, 1996 this may only be implied by the lack of any proscription to formulae *per se*.
69. The permissibility of such presentation in applications filed on or after October 1, 1996 is implied from subsection 74(2) of the *Patent Rules*. Explicit permission for such presentation is provided by subsection 135(3) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(3) of the *Patent Rules* for applications filed before October 1, 1989.
70. This requirement is governed by subsection 135(2) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(2) of the *Patent Rules* for applications filed before October 1, 1989.
71. This requirement is governed by subsection 135(2) of the *Patent Rules* for applications filed before October 1, 1996 and by subsection 171(2) of the *Patent Rules* for applications filed before October 1, 1989.
72. No such explicit provision exists for applications filed prior to October 1, 1996.

73. This requirement is governed by paragraphs 141(1)(g) of the *Patent Rules* for applications filed before October 1, 1996 and by paragraph 177(1)(g) of the *Patent Rules* for applications filed before October 1, 1989.
74. This requirement is governed by section 140 of the *Patent Rules* for applications filed before October 1, 1996 and by section 176 of the *Patent Rules* for applications filed before October 1, 1989.
75. These requirements are governed by section 137 of the *Patent Rules* for applications filed before October 1, 1996 and by section 173 of the *Patent Rules* for applications filed before October 1, 1989.
76. Information regarding the publication of US patent documents is provided based on an interpretation of US practice as expressed in the USPTO's *Manual of Patent Examining Procedure*, 8th Ed. (August 2001) as revised July 2008. See, e.g., sections 101 and 103.