



IPIC

Draft of the Revised
Chapter 9 (Description) of the
Manual of Patent Office Practice

Submission to the
Canadian Intellectual Property Office
by the
Intellectual Property Institute of Canada

Introduction

Who is IPIC?

The Intellectual Property Institute of Canada (IPIC) is the Canadian professional association of patent agents, trade-mark agents, lawyers and others practicing in all areas of intellectual property law. IPIC members advise individuals, businesses and other entities on the acquisition, commercialization, litigation, and dispute resolution of intellectual property rights, including patents. As part of their role, most IPIC members interact with CIPO on a day-to-day basis.

IPIC's membership totals over 1,700 individuals, including practitioners in law firms and agencies of all sizes, sole practitioners, in-house corporate intellectual property professionals, government personnel, and academics. Our members act on behalf of small and large businesses throughout Canada, Canadian universities, and other institutions with intellectual property rights (e.g. patents, trade-marks, copyright, and industrial designs) in Canada and elsewhere, and foreign companies who do business in Canada exploiting their intellectual property rights.

Why is this Chapter of MOPOP Important?

“A modern intellectual property regime is critical for researchers and creators, whose ability to commercialize the fruit of their labour is directly linked to the protection provided by patent and copyright laws. Canada therefore needs to maintain intellectual property protection that is competitive with its trading partners in order to attract both venture capital and intellectual capital.” *

MOPOP states that it is to be considered solely as a guide, and is not to be quoted as an authority. However, it is also represented to be the official position of CIPO. The persuasive effect of such an official “guide” is undeniable. CIPO examiners, the frontline personnel in examining patent applications, will act in accordance with this Chapter in determining whether the description in a patent application is sufficient to warrant the issuance of a patent. Inaccuracies in MOPOP can lead to lost rights, and additional steps and delay in the examination process. While applicants have the right to appeal the decisions of CIPO, appeals further add to the cost, time, effort, and uncertainty. It is therefore critical that MOPOP be as accurate as possible.

IPIC has reviewed proposed Chapter 9 on “Descriptions” in detail. Many of the changes and points added by the Patent Office to proposed Chapter 9 represent new and unique interpretations of the requirements for the description in a patent application. Moreover, it seems that, as we observed with the revised Chapters 12, 13 and 17, many of the changes continue to demonstrate a policy shift by the Patent Office. This is of considerable concern to IPIC, because many of these changes do not appear to be supported by legislation or case law.

* *Mobilizing Science and Technology to Canada's Advantage (a framework to guide Canada's science and technology policy)*, Government of Canada, 2007

In general, the proposed changes would make Chapter 9 unwieldy and difficult to use. Many of the points raised would be better dealt with, or are already directly addressed, in other chapters of MOPOP.

The court in *Pfizer v. Ranbaxy* (2008 FCA 108) stated:

[59] Only two questions are relevant for the purpose of subsection 27(3) of the Act. What is the invention? How does it work?: see *Consolboard*, supra, at 520.

The simplicity of this message seems to be lost in the complexity of the proposed chapter. There are large sections of proposed Chapter 9 that deal with claims and patentability, with at best peripheral relevance to the written descriptions; for example sections 9.03.01, 9.05.01 and others. The frequent repetition of topics from other chapters is not useful, and may create significant problems in future revisions. A chapter on "descriptions" would be much clearer and more usable by focusing on clearly relevant topics that are not dealt with elsewhere in MOPOP.

Finally, many of the changes present the risk of establishing standards for the written description in a Canadian patent application that differ markedly from international standards. Most patent applications are written in other jurisdictions, often according to international standards without knowledge of specific Canadian practice requirements. Such applications could potentially be rejected in Canada, or their coverage reduced in scope, because of a restrictive interpretation of the straightforward and simple requirements for a written description under the *Patent Act*. This is contrary to the Canadian government's stated objective of maintaining intellectual property protection that is competitive with its trading partners.

Some of IPIC's concerns have been raised in previous submissions. Recognizing that proposed Chapter 9 contains many amendments consequent to the approaches adopted in previously amended MOPOP chapters and practice notices, and in the interest of best assisting CIPO and other stakeholders, IPIC has limited its detailed comments to the issues which are considered to be most problematic.

Those specific concerns and recommendations are set out in detail below.

How to Read this Document

A Note by IPIC

The following text, in black Arial font, is the draft of the revised Chapter 9 of the MOPOP as proposed by the Patent Office.

IPIC's comments are inserted in the relevant sections in blue, Times New Roman font with a wavy line on the left.

Chapter 9 - Descriptions

DRAFT
(WP file sent to IPIC)

08-10-2009

This document is a draft of a revised chapter of the MOPOP. The Commissioner of Patents has authorized that this draft be released for public review until December 30, 2009, subsequent to which the chapter, in its present or an amended form, may be adopted by the Office as expressing official practice.

Pending formal approval of this chapter by the Commissioner of Patents, readers should bear in mind that to the extent that the content of this document may differ from content found in the current (i.e. official) version of this chapter, or elsewhere in the MOPOP, this document does not reflect the official practice of the Office

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

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Chapter 9 Descriptions

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

This introductory paragraph (and indeed the entire section) should focus on the leading decisions of the Supreme Court of Canada concerning sufficiency of description, which are *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] S.C.R. 504 and *Pioneer Hi-Bred Ltd. v. Canada (Commr. of Patents)*, [1989] 1 S.C.R. 1623. In *Consolboard* and *Pioneer Hi-Bred* the Supreme Court described the test for sufficiency of description in clear terms and it is unnecessary to refer to other cases for the general requirements.

In *Consolboard*, Dickson J. set out for the Court the test for sufficiency, or enablement, at pages 524-525 as follows:

There is but a single test, and that test is whether the specification adequately describes the invention for a person skilled in the art, though, in the case of patents of a highly technical and scientific nature, that person may be someone possessing a high degree of expert scientific knowledge and skill in the particular branch of science to which the patent relates.

He emphasized at p. 521 that, "In my view it is a well established principle that a patent

specification is addressed, not to the public generally, but to persons skilled in the particular art."

Justice Dickson, in support of this point, quoted Dr. Harold Fox:

The persons to whom the specification is addressed are "ordinary workmen", ordinarily skilled in the art to which the invention relates and possessing the ordinary amount of knowledge incidental to that particular trade. The true interpretation of the patent is to be arrived at by a consideration of what a competent workman reading the specification at its date would have understood it to have disclosed and claimed.

and also quoted Lord Halsbury in *Tubes, Ltd. v. Perfecta Seamless Steel Tube Company, Ltd.*:

The meaning which I think, in my view of the patent law, has always been placed on the object and purpose of a specification, is that it is to enable, not anybody, but a reasonably well informed artisan dealing with a subject-matter with which he is familiar, to make the thing, so as to make it available for the public at the end of the protected period.

A comparable test of sufficiency was enunciated by Lamer J. in *Pioneer Hi-Bred*:

The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built. . . . The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application.

Leithiser [FN3] does not contain the expression "unambiguously identify what has been invented" and is not a leading case on sufficiency of description. The test is as described in *Consolboard* and *Pioneer Hi-Bred*.

The discussion in [FN3] and throughout chapter 9 concerning *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* [2008] SCC 61 is misplaced.

Sanofi is not a case about sufficiency of description and the Supreme Court emphasized at paragraph 26 that it was considering enablement only in the context of novelty, not in the context of the requirement for sufficiency of description:

If the disclosure requirement is satisfied, the second requirement to prove

anticipation is "enablement" which means that the person skilled in the art would have been able to perform the invention (para. 26). Lord Hoffmann held that the test for enablement for purposes of anticipation was the same as the test for sufficiency under the relevant United Kingdom legislation. (Enablement for the purposes of sufficiency of the patent specification under the Canadian *Patent Act*, s. 34(1)(b) of the pre-October 1, 1989 Act, now s. 27(3)(b), is not an issue to be decided in this case and my analysis of enablement is solely related to the test for anticipation. The question of whether enablement for purposes of sufficiency is identical in Canada is better left to another day.)

Hence, the numerous references to *Sanofi* throughout chapter 9 are problematic. Chapter 9 should focus on the leading Supreme Court cases concerning sufficiency of description (i.e. subsection 27(3) of the *Patent Act*), which are *Consolboard* and *Pioneer Hi-Bred*.

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 and later described the “onus of disclosure” as “a heavy and exacting one”.⁸

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. 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.⁹

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 invention.

This last paragraph should state “...so that this person is enabled to reproduce and successfully operate the claimed invention.” Sufficiency of description is determined in the context of the claimed invention. See e.g. *Lundbeck* (2009), 73 CPR (4th) 69 at para. 135-136.

We note that CIPO has referenced *Radio Corporation of America v. Raytheon Manufacturing Co.* [FN 8] to describe the “onus of disclosure” as “heavy and exacting”. It is our understanding that the referenced case had a unique set of facts and is not widely applicable or balanced. The

courts have not maintained the onus as being "heavy and exacting". We suggest therefore that the quote based on *Raytheon* be removed.

Note also that Thorson P.'s judgment in *Minerals Separation* was later addressed by the Supreme Court in *Consolboard* as follows:

27 Section 36(1) seeks an answer to the questions: "What is your invention?" How does it work?" With respect to each question the description must be correct and full in order that, as Thorson P. said in *Minerals Separation North American Corporation v. Noranda Mines, Limited*:

...when the period of 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.

Thus, the Supreme Court has read *Minerals Separation* consistently with the Supreme Court's own statement of the description requirement, which is that it must be sufficient to allow the skilled person to put the invention into practice, and *Minerals Separation* sets no higher standard than that set out later by the Supreme Court in both *Consolboard* and *Minerals Separation*. The MOPOP should quote the higher court decisions here, which are the governing authorities.

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.¹⁰ 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 understand¹¹ and desirous of success.¹²

The person skilled in the art is competent, and represents an average, logical but unimaginative worker in the field.¹³ This person is neither a dull-witted incompetent nor a creative, intuitive expert,¹⁴ albeit that in a highly technical field the person skilled in the art may be presumed to have expert-level knowledge and skills.¹⁵ Furthermore, the person skilled in the art is reasonably diligent in keeping up with advances in the field or fields of technology of relevance to the invention,¹⁶ and has the advantage of being multilingual and thereby being able to comprehend prior art in any language.¹⁷

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.¹⁸

In order to properly assess whether a correct and full description of the invention has been provided, it is necessary to determine the particular nature of 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.¹⁹ The person skilled in the art will be competent in the field or fields of technology 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. 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.²⁰

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.²¹

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.²²

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].

~ The reference to *Free World Trust* [FN22] is inappropriate and potentially confusing. As noted in [FN22], *Free World Trust* concerned the relevant date for claim construction — i.e. the

relevant date for assessing what a skilled person would understand the claims to mean — not the date at which sufficiency of description is to be determined. Compliance with section 27(3) is a different matter than claim construction.

In any event, this issue has in fact been dealt with by the Canadian courts and it has been held that compliance with 27(3) is assessed as of the publication date (i.e. grant date for an Old Act patent or the laid-open date for a New Act patent).

Therefore, the description is sufficient if, as of the publication date, the skilled person would be able to make and use the claimed invention. See e.g. *AlliedSignal Inc. v. Du Pont Canada Inc.* (1995), 61 C.P.R. (4th) 417 (F.C.A.) and *Aventis Pharma Inc. v. Apotex Inc.* (2005), 43 C.P.R. (4th) 161 (F.C.T.D.); aff'd (2006), 46 C.P.R. 401 (F.C.A.).

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.²³

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*.²⁴

[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 could be acknowledged, the description is insufficient (and the attendant claims are unsupported).²⁵ The obligation of the patentee for proper disclosure in this sense was described in *Rice v. Christiani & Nielsen* as:

In the first paragraph, "could be acknowledged" could be amended to "are required".

As above, the reference to *Sanofi* [FN25] again appears misplaced. *Sanofi* addresses the

↳ requirement for enabling disclosure in a prior art reference for the purposes of anticipation.

[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.²⁶

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

The 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.²⁷

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.

It can be useful, when inquiring into whether any work the person skilled in the art was called on to perform was either undue or inventive, to consider whether the solution to any problem faced was unobvious. If the solution to a problem is unobvious, then arriving at that solution is the result of an inventive step. Conversely, if the solution was obvious, arriving at it would not require inventive effort.

In this regard, the Courts have noted in the context of obviousness that a solution to a problem may be obvious even if, to identify that solution, it is necessary 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”.²⁸

While verifying the predicted or predictable properties of known compounds is considered to be routine,²⁹ “verification” means “confirmation” and determining the unexpected and unpredictable properties of new compounds is therefore not “verification”.³⁰

This section correctly acknowledges that the courts have held that a specification is not insufficient merely because some experimentation may be required in order to put the invention into practice. Indeed, as Chapter 9 explains, it appears the courts have indicated that the dividing line between a permissible level of experimentation and an impermissible requirement for experimentation is that the experiments themselves do not require the exercise of inventive faculty. In addition to the cases referenced in Chapter 9, this was explained clearly in e.g. *Ernest Scragg & Sons Ltd. v. Leeson Corp.* (1964), 45 CPR 1 (Ex. Ct.):

It is settled law that a patent specification is not insufficient by reason of the fact that a competent workman of ordinary skill in the art to which the invention relates may have to make trials or experiments in order to accomplish the result of the invention, if such trials or experiments are not themselves inventions and the competent workman can accomplish the desired result by following the teaching of the specification. The specification is sufficient if it enables him to put the invention into practice and sufficient directions are given to him to enable him to know what trials or experiments he may have to make and how to make them. (emphasis added)

While it may then be necessary to consider whether any particular experiment involves inventive effort, IPIC believes that this section goes too far in incorporating an analysis of obviousness (and citation of numerous cases on obviousness) in the analysis of sufficiency of description.

In particular, care must be taken in applying any “problem/solution” analysis and to avoid conflating the issues of sufficiency of description of the claimed invention and unobviousness of the claimed invention. These are separate statutory requirements — subsection 27(3) of the *Act* versus section 28.3 of the *Act*, respectively.

Many inventions are unobvious even though they do not involve solving an enablement-type problem. Indeed, an invention may involve identification of the very problem itself, and once it is appreciated that there is a problem, then the solution is technologically facile. Other inventions may not involve a problem/solution analysis at all.

Proper examination requires examination as to whether the subject-matter defined by the claims is obvious over the prior art of record (the s. 28.3 analysis) and separate and independent analysis as to whether the subject-matter defined by the claims is sufficiently described in the specification for the skilled person to put the invention into practice (s. 27(3)).

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.

The above examples would be more instructive if they were in the same technical field.

The first example, dealing with a “mechanical” invention, appears uncontroversial as, based on the facts given, various available metals having the specified ductility clearly could be used, and thus the description supports the scope of the claims.

The second invention is in a different field (pharmaceutical formulation), but differs also in reciting very narrow supporting facts. It is explained that only “particular salts” of protected cyclic amines are disclosed, and there is no guidance given in the specification, either by way of general or specific examples, or scientific reasoning, as to what other compounds might give a similar result. Thus, a claim defining the pharmaceutical formulation solely by its release profile is considered to be too broad, and insufficiently supported by the “specific salts (salt?)” disclosed.

However, it does not follow from this that a pharmaceutical formulation cannot in any instance be claimed by dosage release profile. Indeed, if sufficient alternative workable embodiments were provided — e.g. a reasonable number of different salts of the protected cyclic amines or perhaps other useful compounds and/or guidance as to how to identify them without exercise of inventive faculty — then a claim to the pharmaceutical formulation defined by release profile may be appropriate.

Therefore, it would be more helpful to add further examples. For example, a further example could be added to show an unsuitable claim in the non-chemical arts and a further example could be added to show an acceptable chemical arts example. In particular, to contrast the second scenario above, another example could be added relating to a medicament characterized by a release profile, wherein the example sets out facts indicating the type of description that would support a claim of this scope.

These additions would allow the examples to be fairly and more clearly contrasted.

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.³¹ 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.

This general proposition, however, has to be understood in an appropriate context. 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.³²

9.02.06 correctly indicates that it is merely “a general proposition” that “it is not necessary for the description to provide a theory...”. The second paragraph, however, goes on to suggest that “This general proposition, however, has to be understood in an appropriate context. ...”

However, the courts clearly do not agree with this suggestion. For example, the Supreme Court in *Wellcome Foundation* states at paragraph 70:

It is generally not necessary for an inventor to provide a theory of *why* the invention works.

Also in *Consolboard*, [1981] 1 SCR 504 at 525, per Dickson:

“As Thorson P. stated in *R. v. American Optical Company et al.*[13] at p. 85:

Nor is it any objection to the sufficiency of the disclosures that the advantages of the invention as enumerated by Professor Price were not set out in the specification . . . If an inventor has adequately defined his invention he is entitled to its benefit even if he does not fully appreciate or realize the advantages that flow from it or cannot give the scientific reasons for them. It is sufficient if the specification correctly and fully describes the invention and its operation or use as contemplated by the inventor, so that the public, meaning thereby persons skilled in the art, may be able, with only the specification, to use the invention as successfully as the inventor could himself.”

Clearly if an inventor “cannot give scientific reasons”, then still less can it be a requirement to state the underlying scientific theory in the specification.

IPIC submits that there is not now, nor has there ever been, a requirement in Canadian Patent Law that the applicant’s disclosure include an explanation of the scientific theory underlying the invention. If there are ways that the theory of an invention can be beneficially used by an applicant specifically to show “sound prediction” in specific types of cases, these would be better dealt with in the appropriate chapter of MOPOP. They should not be discussed as a requirement of the description, when in fact no such requirement exists.

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”.³³ 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, this requirement is explicitly provided for by paragraph 80(1)(d) of the *Patent Rules*.

Section 80(1)(d) of the *Patent Rules* states 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. Putting a person skilled in the art in a position to appreciate the nature of a problem is substantially different than allowing the understanding of a technical problem, especially if not expressly stated as such. IPIC is concerned that Examiners could misapply the above paragraph by rejecting an application for not expressly describing a particular problem, even though such a description is not required by the *Act* or *Rules*.

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”.³⁴ 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 physical step in an art or process.

When considering the statement “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”, it is our position that there is no support identified for this assertion in either the statute or the caselaw. *Norac Systems* at [FN34] does not support that proposition. The cited paragraph 16 reads as follows:

[16] A purposive construction must amount to more than a summary of the main elements of a device (in the case of a mechanical patent). Since a patent, by definition, concerns a novel and useful device, a purposive construction of a patent must identify the functional elements which make the device novel and inventive. Since it is the means by which a result is obtained which is protected by the patent, rather than the result itself, a purposive construction of a patent should identify those functional elements which produce a useful result in a novel and inventive way. To that extent, it is not useful to say that all elements of a claim are equally essential in that the invention cannot function in

the absence of any one of them. The inquiry ought to focus on identifying the elements whose absence will result in the device ceasing to be inventive.

As can be seen, the paragraph is written in the context of a physical device, a truck load weighing system, not a method nor a composition of matter. It says nothing about solving a practical problem, interaction with the physical world, or intended results or benefits.

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 promised utility of the invention.

For consistency, the last sentence could be amended to read: “The practical form includes all the elements required to provide a solution to a practical problem.”

9.03.01 Essential elements

CIPO's concept of essential elements has already been addressed in Chapters 12 and 13 and is in fact more clearly related to claim analysis than a discussion on descriptions. As such, we feel that inclusion of a section on essential elements in Chapter 9 is unnecessary and may lead to confusion.

However, since the concept of essential elements is covered again here, we do wish to refer to our submission on MOPOP Chapters 12 and 13, Statutory Subject Matter, and state again that we do not agree with CIPO's use of the term "essential elements" in the context of examination. Since the Supreme Court of Canada in *Free World Trust* has already defined a legal principle under the term "essential elements", CIPO should not use that term in an entirely different manner. To avoid confusion, we suggest that CIPO use a term other than "essential elements" when referring to this concept of examination. Since CIPO acknowledges that these are already referred to as “critical elements” or “critical features” in some jurisprudence, CIPO should move to this language so as not to conflate this concept with the entirely unrelated principle of “essential elements.”

While we do not support the use of the term "essential elements" in this context, we have reviewed the following section in any event.

Those elements required in order for the invention to provide a solution to the practical problem addressed by the inventor may be called its “essential elements” (also referred to as “critical elements” or “critical features” in some jurisprudence³⁵). The present section discusses “essential elements” in a general sense, while section 9.03.02 discusses the associated disclosure requirements more particularly.

Identifying the “essential elements” of an invention during examination is performed by relating the matter of a claim to the teachings of the description, recognizing that the subject-matter of each claim should achieve at least one object of the invention, and that if this is not the case in respect of a claim, that claim is not properly supported by the description.

“Objects of the invention” is a term which is not often used anymore, particularly in applications drafted in foreign jurisdictions. As such, “recognizing that the subject-matter of each claim should achieve at least one object of the invention” would be better stated as “recognizing that the subject-matter of each claim should provide at least one solution to a practical problem”.

To identify the “essential elements”, each claim is interpreted in light of the specification as a whole, through the eyes of a person skilled in the art reading the specification with a mind willing to understand and desirous of success [see 9.02.02]. The context for identifying the essential elements of a claimed invention during examination consequently resembles that used by the Courts in placing a legal construction on a claim. It is important, however, to recognize that important differences exist between the analysis performed by an examiner during prosecution of an application and the analysis of the Courts in placing a legal construction on the claims of a patent. The two should not be directly equated.

It is noted that “it has always been a fundamental rule of claims construction that the claims receive one and the same interpretation for all purposes” (*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067) and “the construction of the patent must be conducted without regard to issues of validity or infringement” (*Wellcome Foundation Limited v. Novopharm Ltd.*, 1998 CanLII [F.C.]). So, while the analysis performed by an examiner during prosecution of an application will not always be identical to the analysis of the Courts in placing a legal construction on the claims of an issued patent, CIPO is encouraged to use a similar approach, as there are substantial and significant similarities between the two analyses.

During legal construction of a claim, the Courts will apply the rules established in *Free World Trust*, and will consider an element to be essential if it is required for the invention to work as contemplated and claimed by the inventor and to be non-essential if it may be substituted or omitted without having a material effect on either the structure or operation of the invention defined in the claims.³⁶ Limitations viewed by the inventor as being essential may be construed as essential by the Courts even where the person skilled in the art would not consider them to be so.³⁷

During examination, the perspective is somewhat different. An element will be considered “essential” during examination if, in view of the specification as a whole, the person skilled in the art would understand it to be necessary for the invention defined in a given claim to solve the problem addressed by the inventor.

An examiner will identify the “essential elements” of a claimed invention when evaluating whether it fulfills the promise of the invention. The essential elements also form the basis for the comparison of the claimed invention to the prior art when evaluating novelty and obviousness.

The first sentence should read “An examiner will identify the “essential elements” of a claimed invention when evaluating whether it provides a solution to a practical problem.” Also, it may be helpful to add a cross-reference to Chapter 14, such as for example: “If an application includes multiple independent claims that recite different essential elements, restriction may be required if the claims do not share a single general inventive concept (See section 14.01).”

Identifying the essential elements of the invention generally requires the description to be considered, since even where a claim is properly supported not every element in a claim must necessarily be considered to be essential.

Where the description requires that the invention comprise a given element, that element must appear in each claim to that invention in order that the claim not be broader than the description. This is so regardless of whether the person skilled in the art would view the element as “essential”. The applicant, furthermore, may choose to frame even their broadest independent claims more narrowly than is strictly required by the broadest teachings of the description, e.g. by adding in optional limitations or features that would not be considered “essential” by the person skilled in the art.

This new test of having essential elements in the description is not warranted under the Act or the jurisprudence. *Free World Trust* held that claims, when construed in view of the specification as a whole, will have essential elements. It is the claims that define an invention, and it can be said that the description must support the claims, be it completely as written, or that it must support the essential elements of the claims. There is no requirement that the description be “construed” as suggested here for essential elements, that must then be imported into the claims. There is a doctrine of claims being broader than the description, but there is no doctrine of essential elements in a description, as understood in the absence of the claims, which must then be imported into the claims.

It is also noted that the above explanation provides for a clear inconsistency. How can it be that a skilled person would find an element not essential, but such element would still be “essential” to the description (or invention, as suggested above), when such description is read through the eyes of the skilled person?

It is noted that the Supreme Court endorses “a purposive construction to enable the terms in the claims to be given the meaning intended by the patentee based on a reading of the claims in the context of the patent as a whole. The claims may be broader in scope than the preferred embodiment, but may not be broader than what is disclosed or taught in the disclosure” (*Johnson*

& Johnson Inc. v. Boston Scientific Ltd., 2008 FC 552 [CanLII]). Claim construction identifies “the particular words or phrases in the claims that describe what the inventor considered to be the essential elements” (*Whirlpool*) “on the basis of the common knowledge of the worker skilled in the art to which the patent relates, as of the date the patent is published, having regard to whether or not it was obvious to the skilled reader at the time the patent was published that a variant of a particular element would not make a difference to the way in which the invention works [...]” (*Free World Trust v. Électro Santé Inc.* [2000] SCC 66). “For an element to be considered non-essential and thus substitutable, it must be shown either that on a purposive construction of the words of the claim it was clearly not intended to be essential, or that at the date of publication of the patent, the skilled addressee would have appreciated that a particular element could be substituted or omitted without affecting the working of the invention [...]” (*Free World Trust*).

Where a dependent claim is being considered, whether or not the additional feature or features of that claim are “essential elements” of a narrower invention depends on whether their presence would be understood by the person skilled in the art, in view of their common general knowledge and the teachings of the description, as leading to a specific technological effect related to the objects of the invention. A description can, for example, set forth preferred embodiments that provide specific advantages over broader embodiments of the invention. The additional feature that provides such a preferred embodiment is an essential element of the narrower invention.

A dependent claim does not define “a narrower invention” from that of the independent claim. Section 36 of the *Act* requires that a patent be granted for only one invention. An additional feature that provides an advantage over broader combinations of essential elements is not necessarily an essential element although, the feature could lead to an effect related to an object of the invention.

Where, e.g., a claim has been limited to one member of a family of equivalents and the person skilled in the art would recognize that any member of the family could be substituted without affecting the operation of the invention, that specific member is not “essential” to the invention in comparison with other members of the class. In contrast, if that one member had been associated in the description with a particular advantage over the family in general, it would be an essential element where the claimed invention is to provide that advantage.

The last sentence of the above paragraph could be misapplied by an Examiner to require that any advantageous feature(s) of a particular preferred embodiment be included in all of the claims of an application. However, note that “the claims may be broader in scope than the preferred embodiment” (*Johnson & Johnson, supra*) and “the substitutability of non-essential elements derives from an informed interpretation of the language of the claims at the time they are revealed to the target audience of persons skilled in the relevant art [...] and asked whether the variant would obviously [...] perform substantially the same function in substantially the same way to obtain substantially the same result.” (*Free World Trust*)

Where a claim includes an element that could be omitted without materially affecting the operation of the invention, that element is non-essential and is treated as such when assessing novelty and ingenuity.

Regardless of whether some elements are considered essential or not, the specification must support all of the elements of the claim, and the Examiner has a duty to search and examine all elements, whether the Examiner considers the elements essential or not.

9.03.02 Describing the practical form

A practical form necessarily includes all the “essential elements” 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 such 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.³⁸

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 essential elements necessary to provide the practical form of the invention. The invention must be described so that, colloquially speaking, “the wheels will go round”,³⁹ and must not require that the person skilled in the art perform modifications to the invention described in order to make it work.⁴⁰

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 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 would be helpful to include examples of prior art which qualify as “common general knowledge”, as well as some examples of “specific prior art knowledge” which do not so qualify.

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.⁴¹

9.04 Establishing utility

Many of the concepts dealt with in Section 9.04 and its subsections have already been addressed in Chapter 17. Again, we feel that the inclusion of these sections leads to lack of clarity in the Chapter 17 and is likely to complicate later revisions. That being said, we have entered specific comments where we deem them appropriate.

As noted in 17.03.03 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.⁴²

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.

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.⁴³ This is particularly relevant where features clearly identified in the original specification as being optional in nature are subsequently included in the claims and asserted as rendering the amended claims non-obvious in view of prior art disclosures.

Pfizer Canada Inc. v. Minister of Health 2008 FC 13 [FN 43] indeed states at paragraph 118 that “...a finding which post-dates the priority date of a patent cannot be the basis of an assertion of earlier inventiveness.” But this was in the context of data concerning surprising and unexpected

results to support a claimed selection. At issue was obviousness, not utility.

Certainly, this case does not stand for the stated proposition that features described in the specification as being “optional” cannot be relied upon to distinguish over the prior art. Would this apply also to ostensibly “optional” features recited in a dependent claim if the claim features are incorporated into an independent claim to address a rejection for obviousness? If optional features are described in the application as filed, then the inventive ingenuity occurred before filing when it was determined that those features, however optional they may have been thought to be, provide or contribute to a new and useful invention. IPIC submits that the stated proposition is simply untrue and is contrary to the way patent applications are drafted.

IPIC notes that neither this section nor Chapter 17.03 provides any discussion of the degree of utility that is required for patentability.

While section 17.03 cites *Consolboard v. MacMillan Bloedel* for the proposition that 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”, this provides little guidance as to what is required in a patent specification to establish utility. Rather, the passage highlights when an invention is not useful.

IPIC submits that a discussion concerning the topic of “Establishing Utility” should provide at least some commentary relating to the degree of utility that an invention must have to be patentable.

As was enunciated by the Federal Court in *Pfizer Canada Inc. v. Novopharm Ltd.*, 2009 FC 638 at paragraph 77, “usefulness, while essential for patentability, need only satisfy a low threshold” (emphasis added). In support of this proposition the Court provided a more complete recitation of the cited passage from *Consolboard*.

There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. It means "that 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...The discussion in Halsbury's Laws of England, *ibid.*, continues:

...the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested.

The Court in *Pfizer* went on at paragraph 78 to cite with approval the comments of Justice Mactavish in *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, where at paragraph 271 she stated that:

In order to be patentable, an invention must be novel, inventive and useful. Where the specification does not promise a specific result, no particular level of utility is required - a "mere scintilla" of utility will suffice: Fox, Canadian Law and Practice Relating to Letters Patent for Invention, 4th Ed., at p. 153.

Indeed, recent Federal Court decisions where the issue of utility has arisen have stated that what is required is a "mere scintilla of utility" (see *Laboratoires Servier v. Apotex Inc.* 2008 FC 825 at para. 270 (July 2, 2008); *Lundbeck Canada Inc. v. Canada (Minister of Health)*, 2009 FC 146 at para. 134 (February 25, 2009); *Sanofi-Aventis Canada Inc. v. Apotex*, 2009 FC 676 at para. 145 (June 29, 2009); *Lundbeck Canada Inc. v. ratiopharm Inc.*, 2009 FC 1102 at para. 212 (November 23, 2009).

Furthermore, even where a patent specification includes a specific promise, that promise is satisfied where a mere scintilla of utility towards that promise can be shown (see *Laboratoires Servier v. Apotex Inc.* 2008 FC 825 at paras. 293 & 316).

Having regard to the jurisprudence on the issue, IPIC submits that Chapter 9.04 should include some commentary on the level of utility necessary for a patentable invention. In particular, only a scintilla of utility, even if it's promised utility, is required for patentability

9.04.01 Sound prediction

The law continues to develop in this area, as reflected by the many recent Federal Court judgments in prohibition applications under the *Patented Medicines (Notice of Compliance) Regulations*. These cases inevitably reference *Apotex Inc. et al. v. Wellcome Foundation Ltd. et al.* (2002), 24 CPR (4th) 499, the leading case from the Supreme Court of Canada on sound prediction. However, it will likely be many years before the full scope and meaning of the *Wellcome Foundation* case is explored by the lower courts, particularly any disclosure requirements for a sound prediction of utility.

As an introductory and parenthetical note, IPIC emphasizes that, in *Wellcome Foundation*, the Supreme Court was concerned with sound prediction in the context of a new use for a known compound, wherein the patentee's only contribution was the identification of the new use. See paragraph 52 of the judgment:

52 It is important to reiterate that the only contribution made by *Glaxo/Wellcome* in the case of AZT was to identify a new use. The compound itself was not novel. Its chemical composition had been described 20 years earlier by Dr. Jerome Horwitz. *Glaxo/Wellcome* claimed a hitherto unrecognized utility but if it had not established such utility by tests or sound prediction at the time it applied for its patent, then it was offering nothing to the public but wishful

thinking in exchange for locking up potentially valuable research turf for (then) 17 years. (emphasis in original)

and also paragraph 56:

56 Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if, *per* Pigeon J. in *Monsanto Co. v. Canada (Commissioner of Patents)*, [1979] 2 S.C.R. 1108 (S.C.C.), at p. 1117, the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, "[t]here is evidence of lack of utility in respect of some of the area covered". (emphasis added)

At paragraph 70, the Court sets out a three-component requirement for sound prediction, explaining that "[n]ormally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised..." but that in a case where all that is provided is a proposed new use for a known compound "...the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly":

70 The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In *Monsanto* and *Burton Parsons*, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice. Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. In *Monsanto* and *Burton Parsons*, the line of reasoning was grounded in the known "architecture of chemical compounds" (*Monsanto*, at p. 1119), but other lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised: H. G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th ed. 1969), at p. 167. It 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. In 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. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it. (emphasis added)

At paragraph 37, the Supreme Court cautioned that “[t]he patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures”, which in that case was the sound prediction that AZT was useful in the treatment of AIDS.

Thus, while it is acknowledged that the Federal Court has subsequently applied the three-component test for sound prediction from the *Wellcome Foundation* in other types of cases, clearly the Supreme Court was addressing the special situation of a proposed new use of a known compound, where the *only* contribution made was the new use.

Eli Lilly Canada Inc. v. Apotex Inc. 2009 FCA 97, referenced extensively in section 9.04, is a similar case, the patented invention again involving a new use for a known compound (use of the known compound raloxifene for treating osteoporosis in post-menopausal women), the Court finding that disclosure in the patent concerning predicted utility did not go beyond that in the prior art. See paragraph 17 of the judgment:

...the ‘356 Patent did not disclose any more than the Jordan article did, and as such, the person skilled in the art was given, by way of disclosure, no more than such a person already had available in the art.

As a matter of basic principles, it is difficult to see why a patent claiming an invention that:

- (1) is indeed useful and falls within one of the statutory classes of “art”, “process”, “machine”, “manufacture”, or “composition of matter” thus complying with section 2 of the *Act*;
- (2) is novel and thus complies with section 28.2 of the *Act*;
- (3) is unobvious and thus complies with section 28.3 of the *Act*; and
- (4) is described in the patent specification in sufficient detail that the skilled person is enabled to make and use the invention and thus complies with section 27.3 of the *Act*;

could nevertheless fail on the basis that the patent specification does not itself provide evidence that the invention does in fact operate as fully described and claimed.

Nowhere does the *Act* make any mention of such a requirement. Indeed, such a patent, enabling the public to make and use a new, useful and unobvious invention, would appear to meet the requirements for payment of the “hard coinage” of disclosure, described in *Wellcome Foundation*.

Furthermore, various international treaties relating to patents, of which Canada is a member, do not elevate the description requirement in this way.

For example, Article 29 of the TRIPS Agreement provides, in pertinent part, that:

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. (emphasis added)

Similarly, Article 5 of the PCT requires only that:

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

These provisions of TRIPS and the PCT are remarkably similar to the test for sufficiency of disclosure set forth in *Consolboard* and *Pioneer Hi-Bred*.

Most Canadian patent applications are drafted for filing first in another jurisdiction, such as the United States, Europe, or Japan. Indeed, under the PCT, a single specification must be prepared that meets the substantive requirements for patentability in all contracting states.

It would be inefficient, impractical and unnecessary to have a separate Canadian standard for disclosure.

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 17.03.02 of this manual]:⁴⁴

- (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 make the sound line of reasoning clear to the person skilled in the art.⁴⁵

The above statement “...must be sufficient to make the sound line of reasoning clear to the person skilled in the art” is not supported by the cited cases. *Eli Lilly Canada Inc. v. Apotex Inc.* 2009 FCA 97 instead states at paragraph 18 far more broadly that:

...the patent must provide a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, soundly predicted that the invention would work once reduced to practice.

The disclosure must support a sound prediction, not “make the sound line of reasoning clear”.

See also, the decision of the Federal Court in *Pfizer v. Apotex* (2007) 59 CPR 4th 183 (FC) which describes the disclosure requirement quite broadly, where after reciting the test in *Wellcome* the Court states, in regards to the disclosure requirement, that the patent must “provide an adequate description of the invention and how it works” (para. 39 & 71).

The recent decision of *Sanofi-Aventis v. Apotex* (2009), 77 CPR (4th) 99 (FC) also is relevant. Discussing sound prediction, Justice Snider makes clear that:

In assessing sound prediction, we are not confined to examining the invention through the eyes of a person skilled in the art. Rather, the knowledge, activities and endeavours of the inventors themselves must be considered.

Thus, it may be that the sound line of reasoning must have been clear to the inventors and the facts and reasoning disclosed. However, the person skilled in the art is not inventive or imaginative, so it is questioned whether the sound line of reasoning need be clear to the skilled person.

As a minor point, the citation for the *Eli Lilly v. Novopharm* case appears to be wrong. Paragraph 102 merely sets out the questions the Court intends to address. Paragraphs 101-108 appear to be the relevant paragraphs.

9.04.01a Disclosure of the factual basis

The factual basis needed to render the line of reasoning sound must be clearly identified. If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified.⁴⁶ Any necessary facts that are not otherwise publicly available must be included in the description.⁴⁷

It is not clear what is meant by the statement that the “factual basis must be clearly identified”. This language does not find basis in the cases cited in [FN 46]. If CIPO is suggesting that the specification must explicitly refer the skilled reader to the certain disclosed facts that lead to the sound line of reasoning, this is not supported by the decided cases. It is noted that in the case law concerning sound prediction, expert evidence is often provided as to the “factual basis” and “sound line of reasoning”. The Court reviews the specification, as a whole, for the factual basis and sound line of reasoning.

The second and third sentences above also appear to be broad overstatements. The cited *Eli Lilly* "Hong Kong" reference cases noted above do not stand broadly for the proposition stated here, that publicly available documents relied upon to support a sound prediction must be “properly identified”.

Furthermore, what if certain elements of the factual basis are within the common general knowledge (i.e. in a publicly available document) — is there really a need to refer explicitly to these or to include these facts in the description?

The *Eli Lilly* situation, wherein the “Hong Kong study” — which did not form part of the patent application and was held to be pivotal to the issue of sound prediction — cannot be extrapolated so generally.

A factual basis does not by necessity mean only experimental data.⁴⁸ 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 word “only” should be struck from the first sentence as it gives the appearance that: (1) experimental data is the preferred means to establish a factual basis and (2) other factual basis alongside experimental data can provide a factual basis. The cases cited use broad language: “...other factual underpinnings, depending on the nature of the invention, may suffice.”

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.⁴⁹ 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”.

This paragraph is problematic and does not find basis in the cases cited in [FN49]. It is not understood what is meant by “simple, unsubstantiated statements” nor why prophetic examples have little value.

Consider the Wright brothers’ hypothetical patent example given by the Supreme Court in *Wellcome Foundation*. This hypothetical example arguably would contain “unsubstantiated statements” as to how the machine could be made to fly (i.e. how the airfoil creates “lift”). Does this mean the statements are not “sound” at the time of filing? The SCC does not appear of this view in stating:

If the essentials of the heavier-than-air flying machine were set out with sufficient precision to allow the reader actually to make a flying machine that flies, it is hard to accept the “hypothetical” that experts would continue to insist, after it had been flown, that the prediction was unsound.” (emphasis added)

The Supreme Court did not require the Wright brothers’ flying machine either to have been constructed or flown before the filing of the patent application. In what sense was this disclosure not “prophetic”? Irrespective of whether the flying machine had been built or tested, there was

still a factual basis, sound line of reasoning and disclosure.

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.

Looking at criteria (i) and (ii), for example, a broad claim in an emerging field will generally require significantly more support than a narrow claim in a developed field.

These factors appear to come from Chapter 17.03.02a. The basis for this list is not clear, nor is it clear that they are correct. A sound prediction is just that. Indeed it will be determined on a case-by-case basis, but to say generally that “a broad claim in an emerging field will generally require significantly more support than a narrow claim in a developed field” seems to be an over-generalization not supported by citation of appropriate authority.

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.⁵⁰

Here again, the description must provide any explanation necessary to supplement the common general knowledge of the person skilled in the art such that they would have a reasonable expectation, on the factual basis provided, that the invention will have the utility proposed.

Again, this paragraph mischaracterizes and overstates the requirements through use of the language “any explanation necessary”. As above, the courts have not said that the elements of sound prediction must be spelled out in this way in a patent specification provided the factual basis, articulable and sound line of reasoning and disclosure are present.

Care should be taken not to give the appearance that there is a requirement that the specification lead the reader through the three components of sound prediction.

The sound line of reasoning will usually involve an understanding at some level of the theory of the invention, 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.

Note that the sound line of reasoning must be based on what the person skilled in the art would understand and not on expert or proprietary knowledge possessed by the inventors themselves.

These paragraphs seem to suggest that a theory of the invention must be disclosed. Again as noted above, it is cautioned that the Supreme Court stated in *Wellcome Foundation* that "It is generally not necessary for an inventor to provide a theory of *why* the invention works" and in *Consolboard* that "If an inventor has adequately defined his invention, he is entitled to its benefit even if he ... cannot give the scientific reasons for them."

Furthermore, consider the consequences. Does this mean a "sound prediction" cannot be made if it goes against what is generally thought by a person skilled in the art? Recall that inventors are by definition imaginative while the hypothetical skilled person is not.

Note that *Wellcome Foundation* states at paragraph 70 that:

"Secondly, the inventor must have at the date of the patent application an articulable and 'sound' line of reasoning..." (emphasis added)

See also e.g. *Sanofi-Aventis v. Apotex*, (2009) 77 CPR (4th) 99 at paragraph 151:

In assessing sound prediction, we are not confined to examining the invention through the eyes of a person skilled in the art. Rather, the knowledge, activities and endeavours of the inventors themselves must be considered. (emphasis added)

Presumably sound prediction can be based on expert or proprietary knowledge possessed by the inventors provided this knowledge is disclosed.

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.

It appears the last sentence should read "...on the basis of the description as filed and the common general knowledge."

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:⁵¹

- (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 special quality or character common to the whole selection.

This paragraph does not fully recite the requirements for a proper selection as enunciated in *Sanofi-Synthelabo*. In particular, point (i) fails to recognize that the selection can be based on a substantial “disadvantage to be avoided”; point (ii) fails to recognize that there may be “a few exceptions here and there”; and point (iii) uses the word “common” rather than “peculiar”. CIPO should adhere to the language of the Supreme Court of Canada.

It is important to note that the advantage must be in comparison to the entire group from which the selection has been made, and not simply with respect to a few isolated members of that group.⁵²

The expression “must be in comparison to the entire group” improperly implies that a comparison must be made to the entire genus class of compounds. This is not the test. The test is “sufficient representative testing” (see *Eli Lilly v. Novopharm*, 2009 FC 1018 at para. 120 citing *GSK*, 2008 FC 593). The selection patent need not actually compare the selected compounds to all of the genus compounds.

The newly discovered and unexpected advantage is what provides to the selection the utility and inventive step upon which its patentability rests.⁵³ 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”.⁵⁴

It is not clear that the above comments concerning novelty are correct (nor that they belong in this chapter concerning sufficiency of description). The SCC in *Sanofi-Synthelabo* repeated the passage from *I.G. Farbenindustrie*, but did not express any view on its correctness. The SCC appears to have found that novelty resided in the fact that the prior patent did not disclose the special advantages of the selection.

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.⁵⁵ 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”.⁵⁶

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 is not sufficient to meet the requirements of an inventive selection.⁵⁷

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”.⁵⁸ Such a result may conveniently be termed a “unitary” result.⁵⁹

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.⁶⁰

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”,⁶¹ or simply as an “aggregation”, to distinguish it from a true combination.

The cited *Solvay* case [FN61] did not concern the issue of uninventive aggregations of elements. *Solvay* instead involved the listing of a combination patent on the Patent Register. The Court recognized that eligibility issues may arise in respect of whether a combination patent allows for separate administration of the components of the composition. The Court noted that the issue is not trivial because “at some point the composition will inevitably start to resemble a mere aggregation that may not be patentable.”

As such, *Solvay* is not an appropriate case for the above proposition and [FN61] should be removed. The leading cases pertaining to the law of combinations include *Domtar Ltd. v. MacMillan Bloedel Packaging Ltd.* (1977), 33 C.P.R. (2d) 182, affirmed (1978), 41 C.P.R. (2d)

182 and *Crila Plastic Industries Ltd. v. Ninety-Eight Plastic Trim Ltd.* (1986), 10 C.P.R. (3d) 226, affirmed (1987), 18 C.P.R. (3d) 1.

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, it is only necessary to establish that the combination works to produce that result.

In certain combinations, however, compounds having known activity are combined and jointly applied to their known purpose in order to achieve a synergistic result. That is, the activity or effect of the combination as a whole is greater or otherwise better than the expected additive result of its individual components. In order to establish that a synergistic effect has been produced, it is necessary for the person skilled in the art to be aware of the point of reference (the additive result of 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].

9.05 Special topics

The following sections set out practice in respect of certain specific topics which give

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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 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.⁶² 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, where it has been discovered that the combination of a particular drug with any non-steroidal anti-inflammatory (NSAID) compound leads 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.

A discussion on "Functional limitations" seems more appropriate for a chapter on claims than here in the chapter on description. The discussion of this topic here becomes confusing: seeming to imply that an objection might be made to the description for using functional language, even where that functional language does not appear in the claims. Surely this cannot be the intent. If the Office continues to see some value in the inclusion of this section in this chapter, we suggest that this section could be amended to clarify that it is an issue arising from the claim language.

That being said, we note that the statutes and the case law clearly state that the claims must be directed to the invention. The claims are entitled to encompass the scope of what has been invented. If the invention lies in the solution to a particular problem, then the Applicant is entitled to claim that solution. If the invention lies in the discovery that a certain family of compounds have certain beneficial properties, then the Applicant is entitled to lay claim to that family of compounds. The point of the "bald man" example in *Free World Trust* is that there may be other solutions to the "bald man" problem, and the Applicant is not entitled to monopolize those solutions – he must be limited to his own solution, though he is entitled to claim his solution broadly. There is substantial case law holding that the Applicant is only required to describe one example of how to implement the claimed invention – not all possible examples. We believe the case law shows it is sufficient to describe "few or only one" way of implementing the claimed invention.

Paragraph 9.05.01 could more clearly address acceptable uses of functional language to describe known elements. We are concerned about statements such as "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."

One of the greatest advantages of functional language is the ability to encompass anything that would satisfy an element of the invention that is not by itself novel. The NSAID example in 9.05.01 almost addresses this, but frames acceptability in terms of the scope of the limitation being clear. Examiners should be instructed to be liberal about allowing phrases like "capable of supporting," "driving mechanisms", etc. as acceptably and unambiguously defining the element, even though the term used may encompass all such things, as long as novelty and utility are present in the claim overall.

In other words, if it doesn't matter what is used to cut, "cutting means" or "capable of cutting" etc. should be acceptable descriptors for both the description and the claims. Perhaps more examples would make this clear.

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.⁶³

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 of art that is contrary to the usual meaning of the term, 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 acceptable if, for the purposes of expediency and without sacrificing clarity, it narrows the scope of a term of art. It would be acceptable, for example, to define 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.

Paragraph 9.05.03 seems to be supporting the more recent practice of the Office to object to lexicon statements. In the past, objections to such statements were not raised but objections are certainly now more common. The courts have long endorsed and understood that the specification is a lexicon for the claims and the MOPOP has no authority to vary the instruction of the courts.

The MOPOP should indicate that the case law holds claims to be read:

1. “in the context of the specification as a whole” (*Camco Inc. et al. v. Whirlpool Corp. et al.*, 9 C.P.R. (4th) 129, Supreme Court of Canada, December 15, 2000);
2. “by a mind willing to understand, not by a mind desirous of misunderstanding” (*Baldwin International Radio Co. of Canada v. Western Electric Co.*, [1934] S.C.R. 94 at 105-106; and
3. if a claim may be construed in a number of ways, the courts shall “adopt that construction which supports an invention” (*Wandscheer et al. v. Sicard Ltd.*, 8 C.P.R. 35, Affirming 4 C.P.R. 5, Supreme Court of Canada, December 22, 1947).

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.

It would be useful to mention here that it is permissible under section 38.2 of the *Patent Act* to amend the description to include the wording of the claims as originally filed.

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.⁶⁴

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 misleading or incorrect in the context of Canadian law. Where this is the case, the statement must be removed in order that the description be “correct” and comply with subsection 27(3) of the *Patent Act*.

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 should be removed.

Statements regarding the rights of foreign governments to the invention may also be misleading, and should be removed.

The above wording is too strong. It implies that a patent is somehow defective if it issues with such statements – and this is not the case.

We suggest "should be removed" rather than "must be removed". Certainly the Examiner may ask that they be removed, but the MOPOP should not imply that their inclusion is “misleading or

incorrect”. Elsewhere in the MOPOP, case law is cited which requires the patent to be “correct” in a more critical sense. Clearly, the “incorrectness” of a foreign patent reference is not fatal to a patent and, therefore, the language here warrants tempering.

9.06 Form of the description

The form a description should take is set out in section 80 of the *Patent Rules*.⁶⁵ 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 of technology to which the invention pertains. A title such as “flame-retardant rigid polyurethane foam” is acceptable, whereas “foam” is not.⁶⁶

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.⁶⁷

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,⁶⁸ 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.⁶⁹

9.07.02 Drawings, graphics and tables

In accordance with section 74 of the *Patent Rules*, the description shall not contain drawings⁷⁰ but may contain chemical or mathematical formulae or the like.⁷¹ For greater clarity, a chemical formula may be presented in the description in graphical form (i.e. as a structure).⁷² 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.⁷³ Otherwise, subsection 75(1) of the *Patent Rules* provides that pages of the description must be used upright (i.e. in portrait format).⁷⁴

Graphical representations of data, such as graphs, histograms, pie charts, and spectra, are not considered to be drawings and should be included in the description.

Schematics that illustrate a process, such as flow-charts, are considered to be drawings.

Paragraph 9.07.02 introduces a complete departure from standard international practice by suggesting that graphical representations of data are to be included in the description rather than the drawings. Enforcement of this proposed practice would lead to needless amendment of patent applications to move such graphical representations, often introduced as drawing figures, to the description. This means more chance of errors being introduced and clerical burden. It is suggested that any reference to graphical representations in the preceding paragraph be deleted or identified as being appropriate for inclusion in either the drawings or 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.⁷⁵ 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.⁷⁶

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.⁷⁷ The Office requires that each trade-mark be identified in an appropriate manner at least once, preferably at its first appearance.

Paragraph 9.07.03 is welcomed and should ease the identification of trade-marks when the same mark appears many times throughout the description.

Use of the words “trade-mark” in parentheses, of the designation TM, 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.⁷⁸

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 typically not published and may not be referred to by their application

numbers.⁷⁹

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 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”).

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 “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.

For clarity, we suggest that the words in bold be added to the following sentence of this paragraph: “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

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↳ 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.

~ Corrections to formatting requirement defects should not be requisitioned by examination support staff, although such defects could be identified by examination support staff in order to expedite advancing the application to allowance.

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 [(2002), 21 C.P.R. (4th), 499 (S.C.C.)] at paragraph 37
3. *Leithiser v. Pengo Hydra-Pull of Canada Ltd.* [(1974), 17 C.P.R. (2nd), 110 (F.C.A.)] at pages 113 and 114. This view appears to have been confirmed indirectly in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* [2008] SCC 61, e.g. at paragraph 26. Note that the Supreme Court was here discussing prior disclosure requirements for the purposes of anticipation, rather than of sufficiency of description.
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. *Radio Corporation of America v. Raytheon Manufacturing Co.* [(1957), 27 C.P.R. (1st), 1 (Ex.Ct.)] at page 14
9. *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.
10. 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 [(2000), 9 C.P.R. (4th), 129 (S.C.C.)] at paragraph 53; *Consolboard* (supra at 4) at page 160
11. *Free World Trust v. Électro Santé Inc.* [2000] SCC 66 [(2000), 9 C.P.R. (4th), 168 (S.C.C.)] 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 10) at paragraph 49, citing *Lister v. Norton Brothers and Co.* [(1986), 3

R.P.C. 199 (Ch.D.)] at page 203

12. *Free World Trust* (supra at 11) at paragraph 44
13. 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 10 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.
14. *Bayer Aktiengesellschaft v. Apotex Inc.* [(1995), 60 C.P.R. (3rd), 58 (On.Ct.G.D.)] at page 79
15. *Servier Canada Inc. v. Apotex* [2008] FC 825 at paragraph 99
16. *Servier Canada Inc. v. Apotex* [2008] FC 825 at paragraph 254
17. *Axcan Pharma Inc. v. Pharmascience Inc.* [2006] FC 527 at paragraph 38
18. *Bayer AG* (supra at 14) 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
19. In respect of applications filed on or after October 1, 1996.
20. 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.
21. 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
22. *Free World Trust* (supra at 11) at paragraph 54. Note that the Supreme Court was here concerned with claim construction, and not enablement.
23. *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 37. During examination, such obvious errors should be corrected whenever identified.
24. *TRW Inc. v. Walbar of Canada Inc.* [(1991), 39 C.P.R. (3rd), 176 (F.C.A.)] at page 197
25. *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
26. *Rice v. Christiani & Nielsen* [1929] Ex.C.R. 111 at paragraph 9, rev'd on other grounds
 27. H.G. Fox, *Canadian Law and Practice Relating to Letters Patent for Inventions* [(1969), 4th Ed.]
 28. *Janssen-Ortho Inc. v. Novopharm Ltd.* [2004] FC 1631 [(2004), 35 C.P.R. (4th), 353 (F.C.)] 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
 29. *Pfizer Canada Inc. v. Canada (Minister of Health)* [2006] FCA 214 [(2006), 52 C.P.R. (4th), 241 (F.C.A.)] at paragraph 24
 30. *Janssen-Ortho Inc. v. Apotex Inc.* [2008] FC 744 at paragraph 111
 31. *Apotex* (supra at 2) at paragraph 70
 32. *Apotex* (supra at 2) at paragraph 70
 33. *Apotex* (supra at 2) at paragraph 37
 34. *Norac Systems International Inc. v. Prairie Systems & Equipment Ltd.* [(2002), 19 C.P.R. (4th), 360 (F.C.T.D.)] at paragraph 16, rev'd in part on other grounds [2003] FCA 187 [(2002), 25 C.P.R. (4th), 1 (F.C.A.)]
 35. see, e.g., *Halford v. Seed Hawk Inc.* 2004 FC 88 and *Jules R. Gilbert Ltd. v. Sandoz Patents Ltd.* [(1970), 64 C.P.R. (1st), 14 (Ex.Ct.)]
 36. *Halford v. Seed Hawk Inc.* 2006 FCA 275 [(2006), 54 C.P.R. (4th), 130 (F.C.A.)] at paragraph 14, referring to *Free World Trust* (supra at 11) at paragraph 20
 37. *Free World Trust* (supra at 11) at paragraphs 55 to 59
 38. *Dimplex North America Ltd. v. CFM Corp.* [2006] FC 586 [(2006), 54 C.P.R. (4th), 435 (F.C.)] at paragraph 80, aff'd [2007] FCA 278 [(2007), 60 C.P.R. (4th), 277 (F.C.A.)]; citing *Norac Systems* (supra at 34)
 39. Fox (supra at 27) 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 [(2007), 58 C.P.R. (4th), 214 (F.C.)] 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
40. *Norac Systems* (supra at 34) at paragraph 41; *Almecon Industries Ltd. v. Anchortek Ltd.* [(2001), 17 C.P.R. (4th), 74 (F.C.T.D.)] at paragraph 45, aff'd [(2003), 25 C.P.R. (4th), 129 (F.C.A.)], citing *Consolboard* (supra at 39) at page 216
 41. *Metalliflex Ltd. v. Rodi & Wienenberger Aktiengesellschaft* [(1960), 35 C.P.R. (1st), 49 (S.C.C.)] at pages 53-54
 42. *Apotex* (supra at 2) at paragraph 46
 43. see, e.g., *Pfizer Canada Inc. v. The Minister of Health* [2008] FC 13 at paragraphs 99 and 118
 44. *Apotex* (supra at 2) at paragraph 70
 45. *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 102
 46. *Eli Lilly Canada Inc. v. Apotex Inc.* [2008] FC 142 at paragraphs 163-164; *Eli Lilly v. Apotex* (supra at 45) at paragraph 12
 47. *Eli Lilly v. Apotex* (supra at 45) 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 Inc. v. Pharmascience Inc.* [2008] FC 593 at paragraph 71
 48. *Apotex* (supra at 2) at paragraph 70; *Pfizer Canada Inc. v. Canada (Minister of Health)* [2007] FCA 209 at paragraph 152
 49. *Pfizer Canada Inc. v. Apotex Inc.* [2007] FC 26 [(2007), 59 C.P.R. (4th), 183 (F.C.)] at paragraphs 66-70; aff'd [2007] FCA 195 [(2007), 60 C.P.R. (4th), 177 (F.C.A.)] - 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."
 50. *Servier Canada Inc. v. Apotex* [2008] FC 825 at paragraph 379; *Eli Lilly v. Apotex* (supra at 45) at paragraph 18; *Eli Lilly v. Novopharm* (supra at 45) at paragraphs 101 and 107; *Merck & Co. v. Apotex Inc.* 2005 FC 755 at paragraphs 125-126

51. *I.G. Farbenindustrie A.G.'s Patents* [(1930), 47 R.P.C. 289] at pages 322 to 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.
52. *GlaxoSmithKline* (supra at 47) citing at paragraph 51 *Dreyfus and Others Application* [(1945), 62 R.P.C. 125 (H.L.)] at page 133; *Farbenindustrie* (supra at 51) at page 327
53. *Pfizer Canada Inc. v. Canada* 2006 FCA 214 at paragraph 4
54. *Apotex v. Sanofi-Synthelabo* (supra at 3) at paragraph 9; *I.G. Farbenindustrie* (supra at 51) at page 321
55. *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
56. *Farbenindustrie* (supra at 51) at page 323
57. see, e.g., *Eli Lilly Canada Inc. v. Novopharm Ltd.* (supra at 39) at paragraph 162, *Pfizer Canada Inc. v. The Minister of Health* (supra at 43) at paragraphs 115-116; note the similarity to the comments rendered in *Pfizer v. Apotex* (supra at 49) at paragraphs 66 and 69
58. *The King v. American Optical Co.* [(1950), 13 C.P.R. (1st), 87 (Ex.Ct.)] at page 98
59. *The King v. American Optical* (supra at 58)
60. *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
61. *Solvay Pharma Inc. v. Apotex Inc.* [2008] FC 308 at paragraph 128; *Bergeon v. De Kermor Electric Heating Co.* [1927] Ex. C.R. 181 at paragraphs 29 and 81
62. *Free World Trust* (supra at 11) at paragraph 32
63. *Minerals Separation North American Corp. v. Noranda Mines, Ltd.* [(1952), 15 C.P.R. (1st), 133 (P.C.)] at pages 144-145
64. *Free World Trust* (supra at 11) at paragraph 31
65. 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.
66. 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*.

67. This practice was first communicated in the practice notice *Title of Invention* [C.P.O.R. Vol. 137, No. 4, January 27, 2009].
68. 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.
69. There is no such requirement in the *Patent Rules* governing applications filed prior to October 1, 1996.
70. 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.
71. 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*.
72. 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.
73. 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.
74. 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.
75. No such explicit provision exists for applications filed prior to October 1, 1996.
76. 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.

77. 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.
78. 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.
79. 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.