

January 20, 2010

By Email: Barney.deSchneider@ic.gc.ca

Barney de Schneider
Assistant Commissioner of Patents
Canadian Intellectual Property Office
Patent Branch
50 Victoria Street
Gatineau, Québec
K1A 0C9

Dear Mr. de Schneider:

Re: Proposed Amendments to MOPOP Chapter 9

FICPI Canada wishes to thank the Canadian Intellectual Property Office for the opportunity to comment on the proposed revisions to Chapter 9 of the Manuel of Patent Office Practice which were released for public review on November 16, 2009.

As you know, FICPI (the Federation Internationale des Conseils en Propriété Industrielle), comprises more than 3500 intellectual property attorneys in private practice in over 80 countries. FICPI Canada is a self-governing national association of FICPI and represents the interests of Canadian patent and trade mark professionals. Our membership includes senior professionals at most major Canadian intellectual property firms. Our clients span all types and sizes of businesses, including multi-national corporations, small and medium size enterprises, and individuals.

We recognize that updating Chapter 9 of MOPOP represents an enormous effort and we commend the Patent Office for addressing this important project. It is crucial that MOPOP be kept up to date, and that it provide clear guidance to the examination staff in the Patent Office.

FICPI Canada's submissions are set out in the attached documents, which include a marked-up copy of the proposed draft of Chapter 9 containing recommended changes and notes.

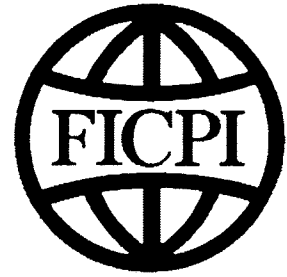
FICPI Canada wishes to thank the Canadian Intellectual Property Office for the opportunity to provide comments. If CIPO has any comments about our submissions, or if you consider it would be helpful to have a meeting with representatives from FICPI Canada, please do not hesitate to contact the undersigned.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Storey', with a long horizontal flourish extending to the right.

Robert B. Storey
President - FICPI Canada

cc Chris Evans, CIPO (by email at chris.evans@ic.gc.ca)



FICPI Canada Submission to CIPO

Re: Proposed Amendments to MOPOP Chapter 9

January 20, 2010

Submission

This submission is provided in response to a call for comments on a draft amended Chapter 9 of the Manual of Patent Office Practice (“MOPOP”) entitled “Descriptions”.

FICPI Canada shares the view that examiners should be provided with guidance when examining patent applications. Guidance documents generally provide greater objectivity and consistency in the examination of patent applications.

FICPI Canada supports CIPO's ongoing work in amending MOPOP and acknowledges the contribution of the individuals involved in this work.

Recommendations

Recommendation 1

FICPI Canada is of the view that some portions of the draft extend into areas already covered and best dealt by other chapters of the MOPOP. Such extension into overlapping chapters is not necessary for the purposes of Chapter 9. It is consequently recommended to delete portions of draft Chapter 9 and instead provide cross-reference to other MOPOP Chapters. Hyperlinks could be a convenient way for cross-referencing an online document.

Cross-reference is preferable since:

- it avoids inconsistencies within MOPOP on a given subject;
- it avoids having to rewrite more than one chapter of MOPOP when the law changes on a given subject;
- it avoids blending concepts which could lead to poorer understanding of description requirements;
- 9.01 of draft Chapter 9, entitled “Scope of this chapter”, deals with 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*. The scope should not extend to other concepts best dealt in other MOPOP chapters.

The approach of cross-referencing to other MOPOP chapters is consistent with the approach adopted by the Federal Court of Appeal in Pfizer vs. Ranbaxy case 2008 FCA 108:

[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

In the case, the Court of Appeal had to address, inter alia, allegations of "weak data" in the disclosure. The Court was clear that "weak data" was not an issue of sufficiency under 27(3) of the Act:

[51] These allegations, although placed under a heading entitled sufficiency in the NOA, have, in my respectful view, nothing to do with the disclosure requirement under subsection 27(3) of the Act. Rather, they are relevant to an analysis of the utility, novelty and/or obviousness of a patent.

This is clear from the first paragraph of the NOA cited above, according to which the disclosure does not support there being any novel or inventive aspect as claimed. What Ranbaxy is really challenging in its NOA under the heading of "sufficiency" is the fact that Pfizer obtained a selection patent without having provided reliable data showing that the narrow class of compounds selected was better than the compounds covered by the genus patent.

In view of the above, the cross-referencing approach for Chapter 9 allows focusing on written description requirements for achieving sufficiency of description as per the Act and Rules while directing the reader to other chapters for subject matter eligibility, utility, novelty and/or obviousness.

Query whether Chapter 9 would be even more clearly presented if split in (i) formal requirements and (ii) substantive requirements, with respective reference to relevant sections of the Act and Rules.

Recommendation 2

It is understood and acknowledged that patent description requirements will vary according to individual fact scenarios. For example, description requirements will vary depending on the field of technology or the basic knowledge of those skilled in the particular art of the invention. Furthermore, description requirements will vary depending on the nature of the inventive contribution. Differences exist between inventions based on selection of species from a broader genus, inventions based on synergistic combinations of known elements, inventions involving sound prediction of utility, inventions directed to software implementations, methods, systems or new uses. Thus the description requirements are intimately linked to patentability requirements. FICPI Canada recommends that this be acknowledged in Chapter 9 and that Examiners are specifically instructed to refer to other chapters of the MOPOP for patentability requirements that may impact on description requirements.

* * *

FICPI Canada's recommendations are embodied in the attached marked-up version of draft Chapter 9. As part of the same document, notes and suggestions are also provided for improved reference to case law and concepts.

Respectfully submitted,

A handwritten signature in black ink, appearing to be a stylized representation of the names Robert Storey, Alain Leclerc, Stephen Perry, and John Knox. The signature is written in a cursive, flowing style with a long horizontal line extending to the right.

FICPI Canada

Per Robert Storey, Alain Leclerc, Stephen Perry and John Knox.

Chapter 9 - Descriptions

DRAFT

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.

Chapter 9

Descriptions

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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 [Footnote 3 should avoid reference to Apotex v. Sanofi which does not address sufficiency of disclosure, see para [26]]

In *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.*, Dickson J. further 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 [Footnote 5 should also refer to Pioneer Hi-Bred, SCC and Ranbaxy, FCA] 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

[Note: the last quotes are peculiar to the facts of that the Radio Corp v. Raytheon case where the applicant had substituted the claims of a competitor's corresponding US patent while clearly not having the required support in its own disclosure. The quoted phrases of Thorson P. have not been adopted in other jurisprudence as a pronouncement as to the general law for description adequacy. FICPI urges that MOPOP should refer only to the more definitive quote from Thorson P. provided below.]

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

[Note: the Consolboard decision cited above appears to have tempered the above statements. Query if more emphasis should be given to Consolboard rather than Minerals Separation.]

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.

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 [Suggestion: add mention that response to Office Action including sworn or unsworn declarations or affidavits referring to available documentation, such as textbooks or scientific literature can be considered by examiners to establish the skillset of the person skilled in the art.]

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 [Footnote 22 should refer to AlliedSignal Inc. v Dupont Canada Inc (1995), 61 C.P.R (4th), FCA rather than Free World Trust]

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

9.02.04 Misleading or erroneous statements

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

[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.

[Note: the following passages are redundant with MOPOP Chapter 15]

~~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 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 [...]~~

Descriptions

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

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

Claim:

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

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

9.02.06 Theory of the invention

As a general proposition, it is not necessary for the description to provide a theory as to why the invention operates as it does.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

[Note: the following section is redundant with MOPOP Chapter 12]

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*.

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.

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.

9.03.01 — Essential elements

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.

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.

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.~~

~~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.~~

~~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.~~

~~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.

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.

[Note: the above passages suggest that the Examiner take a different perspective than the courts in determining essential elements of a claim. This is better dealt with in MOPOP Chapter 11 under a heading entitled "claim construction", also the above passages are not supported by caselaw]

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 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.⁴⁴~~

[Note: portions of the above are not supported by caselaw]

9.04 Establishing utility

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 [Suggestion: direct examiners to 17.03.03 for the requirements for establishing utility via sound prediction]

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.~~

[NOTE: the following passages are not appropriate in that obviousness is another issue. Furthermore the last sentence appears to be in error. It is common for preferred embodiments to be asserted in claims so as to overcome prior art objections.]

9.04.01 Sound prediction

