

Manual of Patent Office Practice Updates
Chapter 9: Descriptions
Submissions of Eli Lilly Canada Inc. and GlaxoSmithKline Inc.

December 30, 2009

Attn: Chris Evans
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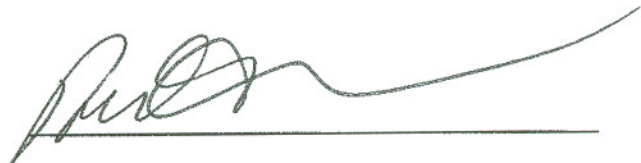
Dear Mr. Evans:

Please find attached the submissions of Eli Lilly Canada Inc. and GlaxoSmithKline Inc. in response to the request for feedback and comments on "Chapter 9 : Descriptions" of the Manual of Patent Office Practice.

Yours very truly,



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**Re: Manual of Patent Office Practice Updates
Chapter 9: Descriptions
Request for Feedback and Comments: November 16 – December 30, 2009**

Introduction

On behalf of Eli Lilly Canada Inc. and GlaxoSmithKline Inc., we are writing to provide our comments in connection with the proposed revisions to Chapter 9 of the Manual of Patent Office Practice (MOPOP), as published on the Canadian Intellectual Property Office (“CIPO”) website and released for comment on November 16, 2009.

As innovative pharmaceutical companies, we are highly dependent on patent protection. We are active participants in the patent prosecution process in Canada and internationally and feel that it is in the best interest of all stakeholders that the patent procedures and practices described in MOPOP support innovation and are consistent with Canadian jurisprudence and international patent practice.

Our comments primarily concern the proposed addition of Chapter 9.04 “Establishing Utility” to Chapter 9 of the MOPOP but are broadly applicable to other proposed amendments. Our comments fall into two categories and may be summarized as follows:

- I. **As presently proposed, Chapter 9.04 of the MOPOP exceeds statutory requirements and is not based on settled law.**
 1. ***The Statutory Basis for the Description Requirements.*** The description requirements set out in proposed Chapter 9.04 exceed statutory requirements under s. 27(3) of the *Patent Act*. Section 27(3) requires the inventor to correctly and fully describe the invention and its operation and use as contemplated by the inventor. It also requires the inventor to describe it in such full, clear, concise and exact terms as to enable a person skilled in the art to make or use the invention. Section 27(3) does not require the attributes of patentability for an invention (i.e. novelty, inventive step or utility, which are requirements for an “invention” under s. 2 of the *Patent Act*) to be substantiated in the patent specification as a description requirement.

2. ***The Legal Interpretation of the Description Requirements.*** Settled law¹ on the description requirement establishes that the disclosure of a “use” under s. 27(3) is different from and should not be confused with the “utility” requirement under s. 2 of the *Patent Act*. Only the disclosure of a credible “use” is required: the establishment of utility is considered under s. 2 and may be based upon a “sound prediction”. To the extent a sound prediction is relied upon, it relates to “Utility” and should be dealt with in Chapter 12 of the MOPOP.
3. ***Sound Prediction.*** Settled law^{2, 3} on “sound prediction” of utility says that there must be a factual basis for the prediction and the inventor must have an articulable and “sound line of reasoning” from which a desired result can be inferred. Nevertheless, as a matter of settled law, it has not been determined that the factual basis or the “sound line of reasoning” have to be disclosed in the patent specification as a disclosure requirement, and the inventor may submit evidence to support utility after the filing date of a patent application.
4. ***Selection Patents.*** Settled law⁴ on “selection” patents does not recognize a description requirement other than a simple statement of an advantage for the selected range, sub-genus or species. The proposed Chapter 9.04.02 of the MOPOP confuses this simple description of an advantage with resolution of the obviousness inquiry. Evidence of non-obviousness need not be included in the specification and the inventor may submit evidence to support non-obviousness after the filing date of a patent application. In any event, settled law is clear that “selection” is a part of the law of obviousness. This should be dealt with in Chapter 15 of the MOPOP.
5. ***Non-authoritative, Non-precedential Decisions.*** To the extent that relevant issues have not been fully argued exhausting all available routes of appeal, adjudications, not receiving such thorough judicial analysis, should not be relied upon. As such, typically proceedings under the *PM(NOC) Regulations* are non-authoritative and should not be the basis for changing the examination guidelines. Proposed requirements under Chapters 9.04.01, 9.04.01a and 9.04.01b, such as the inclusion of the factual basis for selections and utility and “sound prediction” in the patent specification, are based on *PM(NOC)* decisions where full judicial review was not available. They are not in accordance with Supreme Court principles. Moreover, they are not requirements under Section 27(3) of the Patent Act.

¹ *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504; (1981), 56 C.P.R. (2d) 145 (S.C.C.) [Consolboard].

² *Monsanto Co. v. The Commissioner of Patents* [1979] 2 S.C.R. 1108; (1979), 42 C.P.R. (2d) 161 [Monsanto]

³ *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153; 21 C.P.R. (4th) 499 (S.C.C.) [AZT].

⁴ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 [Sanofi].

II. As presently proposed, Chapter 9.04 of the MOPOP is inconsistent with practice in major examining authorities, international harmonization and treaty obligations.

1. ***MOPOP Inconsistent With Practice Guidelines in Major Examining Offices and International Harmonization:*** The proposed MOPOP guidelines under Chapter 9.04.01, 9.04.01a, 9.04.01b, and 9.04.02 are substantively different from the description requirements in The Guideline for Examination in the European Patent Office (“EPO”), The Manual of Patent Examination Procedure (“MPEP”) in the U.S. Patent and Trademark Office (“USPTO”), and require more disclosure than specified by the Regulations of The Patent Cooperation Treaty (“PCT”). This will lead to a lack of harmonization among the examining authorities since Canada will apply different standards. Accordingly, efforts to achieve efficiencies in international examination, such as the Patent Prosecution Highway, will be impaired, resulting in additional burden for examiners. In addition, patent applicants seeking patent protection in multiple jurisdictions may be prejudiced in Canada.
2. ***Treaty Obligations.*** Chapter 9.04 of the proposed MOPOP guidelines incorporate heightened disclosure requirements for “utility” and selection patents which are inconsistent with Canada's obligations under TRIPS, NAFTA, and the PCT. By incorporating heightened disclosure requirements for "utility" and selection patents, Canada prejudices certain types of inventions.

These points are more fully discussed in the sections that follow and specific concerns are set out in Appendix A.

I. Proposed Chapter 9.04 is Not Based on Settled Law

Canadian patent law is wholly statutory. Judicial decisions can interpret and apply statutory provisions but they cannot create or impose requirements that are not otherwise prescribed or contemplated by statute.

1. The Statutory Basis for the Description Requirement

Proposed Chapter 9.04 pertains to the patent description requirements as they relate to “utility”.

Section 2 of the *Patent Act*, defines an “invention” as “any new and useful art, process, machine, manufacture or composition of matter ...” or a new and useful improvement thereof. As a precondition to patentability, an invention must be new, inventive and useful. The concept of “utility” derives from the term “useful” under s. 2 of the *Patent Act*.

The substantive disclosure requirements for a patent specification are prescribed under s. 27(3) of the *Patent Act*. Paragraphs (a) and (b) provides:

27(3) 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. ...

When specifying requirements for a patent specification, proposed Chapter 9.04 of the MOPOP must ensure that there is a statutory basis for the requirements. A plain reading of the statute indicates that it only requires a description of the invention itself, its use, and how to make it. There is no requirement in the statute for disclosure of sound prediction, advantage, or evidence of utility or nonobviousness. Accordingly, with respect to proposed Chapter 9.04, disclosure requirements as to utility or selection inventions engraft new provisions on to the statutory requirements. The statutory provisions relating to utility, novelty and obviousness are dealt with in s. 2 and 27(3) of the Patent Act.

2. Settled Law on the Description Requirements

The Supreme Court of Canada in *Consolboard Inc. v. Macmillan Bloedel (Saskatchewan) Ltd.*⁵ specifically considered the disclosure requirements under s. 36(1) of the *Patent Act*, now s. 27(3) of the *Patent Act*. Addressing the concept of “utility”, the Supreme Court of Canada set out the following principles concerning description requirements under section 36(1) of the *Patent Act*. Dickson J. wrote:

Section 36 of the Patent Act lies at the heart of the whole patent system. The description of the invention therein provided for is the *quid pro quo* for which the inventor is given a monopoly for a limited term of years on the invention. As Fox points out in *Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (1969), p. 163, the grant of a patent is in the nature of a bargain between the inventor on the one hand and the Crown, representing the public, on the other hand. The consideration for the grant is twofold:

... first, there must be a new and useful invention, and secondly, 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".

⁵ *Consolboard*, supra note 1.

The "description" to which Fox refers is that required by s. 36 of the *Patent Act*.⁶
[emphasis added]

Put another way, "Section 36(1) [now s.27(3)] seeks an answer to the questions: "What is your invention?: How does it work?"⁷

The Supreme Court of Canada further clarified that "... s. 36(1) [now s. 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention"⁸ and that:

Although (i) s. 36(1) requires the inventor to indicate and distinctly claim the part, improvement or combination which he claims as his invention and (ii) to be patentable an invention must be something new and useful (s. 2), and not known or used by any other person before the applicant invented it (s. 28(1)(a)), I do not read the concluding words of s. 36(1) as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.⁹ [Emphasis added]

Consolboard has not been overturned and is binding Supreme Court precedent on lower courts. These principles must be properly reflected in the proposed Chapter 9.04 of the MOPOP.

The description requirements set out under proposed Chapter 9.04.01 "Sound prediction" and Chapter 9.04.02 "Selection" exceed s. 27(3) of the *Patent Act* and the principles set out in *Consolboard* since it requires the invention to be described and further substantiated in the patent specification.

It is important to note that s. 27(3) of the *Patent Act* does not require that the patentability requirements of s. 2 of the *Patent Act*, namely: novelty, inventive step or utility, be set out in the patent description. On this issue, the Supreme Court of Canada in *Consolboard* wrote:

With respect, I agree with the submission of counsel for the appellant that the Federal Court of Appeal has confused the requirement of s. 2 of the *Patent Act* defining an invention as new and "useful", with the requirement of s. 36(1) [now s. 27(3)] of the *Patent Act* that the specification disclose the "use" to which the inventor conceived the invention could be put. The first is a condition precedent to an invention, and the second is a disclosure requirement, independent of the first. [Emphasis added]

The proposed amendments in Chapter 9.04 of the MOPOP if left to stand as currently drafted intermix these concepts. The proposed amendments should be re-drawn to remove this and ought not confuse s. 2 of the *Patent Act* with the disclosure requirements under s. 27(3) of the *Patent Act*.

⁶ *Consolboard*, *supra* note 1 at page 154-155.

⁷ *Consolboard*, *supra* note 1 at page 157.

⁸ *Consolboard*, *supra* note 1 at page 158.

⁹ *Consolboard*, *supra* note 1 at page 161.

3. The Settled Law on Sound Prediction

It is a well settled principle of Canadian patent law that a “sound prediction” of utility may satisfy the utility requirement of s. 2 of the *Patent Act*. “Sound prediction” is addressed in proposed Chapter 9.04.01 of the MOPOP.

Two primary Supreme Court of Canada cases consider sound prediction of utility: *Monsanto Co. v. The Commissioner of Patents*¹⁰ and *Apotex Inc. v. Wellcome Foundation Ltd* (“AZT”).¹¹

Monsanto is the foundational case in Canada establishing the principle of sound prediction. In formulating this principle, Pigeon J. adopted the British case of *Olin Mathieson*¹² quoting:

Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment this line was drawn properly by Sir Lionel when he very helpfully stated in the words quoted above that it depended upon whether or not it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so. Of course, in so doing he takes the risk that a defendant may be able to show that his prediction is unsound or that some bodies falling within the words he has used have no utility or are old or obvious or that some promise he has made in his specification is false in a material respect; but if, when attacked, he survives this risk successfully, then his claim does not go beyond the consideration given by his disclosure, his claim is fairly based on such disclosure in these respects, and is valid¹³. [Emphasis added]

Pigeon J. then wrote:

I have quoted again the passage quoted by the Board because I consider the last sentence of the paragraph of some importance as it does clearly indicate what is meant by a "sound prediction". It cannot mean a certainty since it does not exclude all risk that some of the area covered may prove devoid of utility. It thus appears to me that the test formulated by Graham, J., involves just two possible reasons for rejecting claims such as those in issue.

1. There is evidence of lack of utility in respect of some of the area covered;
2. It is not a sound prediction.¹⁴

The Court in *Monsanto* also addressed procedural aspects of the patent examination process in circumstances where the patent examiner was of the view that the prediction of

¹⁰ *Monsanto, supra* note 2.

¹¹ *AZT, supra* note 3.

¹² *Olin Mathieson Chemical Corp. et al. v. Biorex Laboratories Ltd. et al.* [1970] R.P.C. 157 (Ch. D.)

¹³ *Monsanto, supra* note 2 at page 175-176.

¹⁴ *Monsanto, supra* note 2 at page 176.

utility was unsound. Background information concerning the patent specification in issue in *Monsanto* together with aspects of the procedural history is set out in Appendix B.

Principles that can be distilled from *Monsanto* include:

- CIPO may only reject a patent claim encompassing unmade and untested compounds (based on a sound prediction) if there is evidence of lack of utility or if it is not a sound prediction.
- CIPO cannot refuse a patent because the inventor has not fully tested and proved it in all its claimed applications. Such a refusal must be supported by evidence of lack of utility or evidence that the prediction of utility is not sound and reasonable.¹⁵
- Affidavits from the inventor and from others may be submitted by the patent applicant and must be considered by CIPO when determining whether a patent application should be rejected. The affidavits can include fact information from the inventor to bolster utility, evidence as to common general knowledge of persons of skill in the art, and information or principles obtained from scientific publications not included in a patent specification.
- CIPO must justify a refusal based on lack of sound prediction with reasons. If affidavits are submitted, the inadequacy or non-acceptance of evidence contained in the affidavits must be addressed.
- In the absence of evidence of unsoundness of prediction, a claim cannot be limited to proved utility.¹⁶

It should be further noted that *Monsanto* does not require that the underlying factual basis for a prediction be apparent to a person skilled in the art nor does it prescribe specific disclosure requirements. Also, further information and explanation may be provided by to the examiner to establish the factual basis and sound line of reasoning.

AZT addresses “sound prediction” in the specific context of a new use for a known compound. As emphasized by the Supreme Court of Canada in *AZT*:

[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. ...

[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

¹⁵ *Monsanto*, *supra* note 2 at page 179.

¹⁶ *Monsanto*, *supra* note 2 at page 179: Pigeon J. wrote: “In the instant case, the Board, in spite of a complete absence of any evidence of unsoundness of the prediction, deny the claims and would in the end limit them to the area of proved utility instead of allowing them to the extent of predicted utility. In my view this is contrary to s. 42 of the Patent Act.

prediction based on the information and expertise then available.¹⁷

The Supreme Court of Canada in *AZT* clarified what was required for a sound prediction:

[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.¹⁸ [Emphasis added]

Explaining what it meant by "proper disclosure" in the above context, the Supreme Court of Canada continued in paragraph 70 of its Reasons for Judgment:

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.¹⁹

This statement is consistent with the principles set out in *Consolboard* regarding the requirements of s. 36 [now 27(3)] of the *Patent Act*. This discussion of disclosure requirements does not suggest that the factual basis or the sound line of reasoning must also be included in the disclosure as set out in proposed Chapters 9.01.01a and 9.01.01b and indeed "proper disclosure" is listed as a separate point from "factual basis" and "sound line of reasoning".

Where "the new use" is the *gravamen* of invention, additional information may be required. However, on the particular facts of *AZT*, it was unnecessary for the Supreme Court of Canada to address this issue and accordingly, precise disclosure requirements were not prescribed:

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.²⁰

On the question of proof whether a sound prediction was made, the Supreme Court of Canada wrote:

¹⁷ *AZT*, *supra* note 3 at para. 55 and 56.

¹⁸ *AZT*, *supra* note 3 at para. 70.

¹⁹ *AZT*, *supra* note 3 at para. 70.

²⁰ *AZT*, *supra* note 3 para. 70.

[71] It bears repetition that the soundness (or otherwise) of the prediction is a question of fact. Evidence must be led about what was known or not known at the priority date, as was done here. Each case will turn on the particularities of the discipline to which it relates. In this case, the findings of fact necessary for the application of "sound prediction" were made and the appellants have not, in my view, demonstrated any overriding or palpable error.²¹ [Emphasis added]

Proposed Chapters 9.04.01a and 9.04.01b do not permit this evidence to come in after the filing date, but rather requires it to be a part of the initial disclosure.

Of note, the Supreme Court of Canada states that it is the "inventor" that must have an articulable and "sound" line of reasoning, in contrast to proposed Chapter 9.04.01b which states that the sound line of reasoning must be based on what the person skilled in the art would understand and not on proprietary knowledge possessed by the inventors themselves.

Principles that can be distilled from *AZT* include:

- For there to be a sound prediction, there must be a factual basis for the prediction, the inventor must have a sound line of reasoning from which the desired result can be inferred from a factual basis and there must be proper disclosure. Proper disclosure for a sound prediction is normally met with a full, clear and exact description of the nature of the invention and the manner in which it can be practiced. Additional information may be required where "new use" is the *gravamen* of the invention.
- The "soundness" of a prediction is a question of fact, to be determined on a case by case basis, depending on the nature of the invention.
- Evidence must be led as to what was known or not known as of the priority date of the application.

The principles provided by *Consolboard*, *Monsanto* and *AZT* provide guidance as to an appropriate procedure to be taken during the process of examination of a patent application in which a sound prediction has been made.

A patent specification may be filed that is directed to an invention having a "utility" in accordance with s. 2 of the *Patent Act* (*Consolboard*). The "utility" may be based upon a sound prediction (*Monsanto* and *AZT*). Only the disclosure of a credible "use" is required (*Consolboard*). Where a sound prediction is relied upon, there must be a factual basis for the sound prediction but it need not be set out in the specification so long as the inventor has an articulable and "sound line of reasoning" (*Monsanto* and *AZT*). The patent specification is also required to describe the invention (namely: "What is your invention?": *Consolboard*) and the "use" contemplated by the inventor (namely: "How does it work?": *Consolboard*) and provide sufficient details to enable a person skilled in the art to which the invention pertains to construct or use the invention when the period of monopoly expires (s. 27(3) of the *Patent Act*). The "use"

²¹ *AZT*, *supra* note 3 para. 71.

to be described under section 27(3) of the *Patent Act* is different from and not to be confused with the “utility” under s. 2 of the *Patent Act (Consolboard)*. There is no requirement for “utility” under s. 2 of the *Patent Act* (including the sound prediction thereof) to be substantiated in the description; it only has to be mentioned insofar as the invention is to be described under s. 27(3) of the *Patent Act* and *Consolboard*. Only when challenged is the inventor/patentee to provide proof of the soundness of the prediction of utility (*Monsanto* quoting *Olin Mathieson*, and *AZT*).

During examination in accordance with s. 35 of the *Patent Act* and s. 30(2)²² of the *Patent Rules*, if the examiner has reasonable grounds to believe that the application does not comply with the *Patent Act* or *Rules*, for example, the prediction is not sound as required under s. 2 of the *Patent Act*, the examiner may requisition the applicant to provide support. In response, the patent applicant may submit arguments as to why the application complies. From *Monsanto*, the patent applicant may submit an explanation together with affidavit evidence setting out facts or other information to support the factual basis and sound line of reasoning for the sound prediction. If, after considering the applicant’s information, the examiner is still of the view that the prediction is unsound, the examiner may reject the patent application on the basis that the prediction is unsound upon providing reasons to justify the refusal, in accordance with *Monsanto*. Alternatively, if, after considering the applicant’s information, the examiner is satisfied that the application complies with the *Patent Act* and *Rules*, the application may proceed to allowance in accordance with s. 30(1) of the *Patent Rules*.

The proposed Chapter 9.04 of MOPOP, at page 9-10 to 9-11, describes different disclosure requirements and procedures depending upon whether the utility of an invention is established by demonstration or by sound prediction.

In cases of demonstrated utility, the proposed Chapter 9.04 states that “the factual basis that constitutes the demonstration must have existed at the filing date but need not have been included in the description”. When challenged, the applicant is permitted to establish the factual basis by affidavit.

In cases where the utility of an invention is based upon a sound prediction, proposed Chapters 9.04.01, 9.04.01a and 9.04.01b require the patent specification to disclose facts that substantiate the soundness of a prediction of utility under s. 2 of the *Patent Act*, in excess of what is required under s. 27(3) of the *Patent Act* as interpreted by the Supreme Court of Canada and do not permit a patent applicant to establish by affidavit that a factual basis pre-existed the filing date of the patent application.

These proposed provisions conflate “utility” under section 2 of the *Patent Act* with disclosure of “use” under s. 27(3) of the *Patent Act*. This is contrary to *Consolboard* and *Monsanto*. In any

²² *Patent Act*, s.30(2): “Where an examiner examining an application in accordance with section 35 of the Act or the Act as it read immediately before October 1, 1989 has reasonable grounds to believe that an application does not comply with the Act or these Rules, the examiner shall inform the applicant of the application's defects and shall requisition the applicant to amend the application in order to comply or to provide arguments as to why the application does comply ...”

event, the requirements for a sound prediction are properly addressed under Chapter 12 of the MOPOP “Utility and Subject Matter”, not under the Chapter 9 of the MOPOP on “Description”.

Regardless, and with respect, the proposed MOPOP provisions ought to treat the “utility” requirement in the same manner whether based on demonstrated utility or on a sound prediction of utility. There are no statutory provisions or principles from the Supreme Court of Canada that sanction, or even suggest, differential treatment.

Proposed Chapter 9.04 of the MOPOP further provides that “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”.

This proposed procedure is contrary to *Consolboard*, *Monsanto* and *AZT*. These proposed provisions permit an examiner to object without having reasonable grounds to believe that the prediction is not sound or reasonable, contrary to s. 30(2) of the *Patent Rules*. *Consolboard* is clear that a patent specification is addressed to a person skilled in the art to which the invention pertains. Accordingly, the MOPOP needs to be revised to remove the suggestion that a higher standard of disclosure is required, namely: that the “examiner” has to be satisfied that there is a factual basis for a sound prediction, as this higher standard is improper.

Taking these principles as provided by *Consolboard*, *Monsanto* and *AZT* we have further considered them in the light of the proposed amendments and provide further comments on specific wording and set them out in Appendix “A.”

4. Settled Law on Selection Patents

There are no special disclosure requirements for selection patents other than a description of its use and an advantage to its use, if there is one. Selection patents do not in their nature differ from any other patent and simply represent the application of the general criteria for patentability in a particular fact situation (i.e. typically where the patent at issue claims a species of a previously disclosed genus). Like any other patent, a selection patent is subject to the same standards for patentability – it must be new, useful and unobvious.

There is nothing in the *Patent Act* that recognizes a different approach to determine the patentability of selection patents.

In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*²³ (“*Sanofi*”) the Supreme Court of Canada upheld the selection of clopidogrel (an enantiomer) from a previously disclosed racemate. In concluding that the selection of clopidogrel was an unobvious selection, the Court examined the inventiveness of clopidogrel using the following four-part obviousness test:

²³ *Sanofi*, *supra* note 4.

- (a) Identify the notional “person skilled in the art” and the relevant common general knowledge of that person;
- (b) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (c) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed; and
- (d) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?²⁴

The invention was clopidogrel and the inventive concept was its advantages. The advantages of clopidogrel were considered as part (c) and (d) of the obviousness inquiry.²⁵

The proposed amendment to Chapter 9.04.02 states that “...the accepted requirements of a selection are...” and then list the 3 criteria as set out in *I.G. Farbenindustrie*²⁶. Although the *I.G. Farbenindustrie* criteria were historically applied to selection inventions more recently the Supreme Court of Canada in *Sanofi* has signalled a move away from the strict application of the *I.G. Farbenindustrie* criteria. For instance, in *Sanofi* Rothstein J. referred to the *I.G. Farbenindustrie* criteria but noted that the *I.G. Farbenindustrie* criteria are “a useful starting point for the analysis to be conducted in this case”.²⁷ Justice Rothstein then determined the validity of the clopidogrel patent by applying the general law of novelty and obviousness. He never applied a separate test of “invalid selection”.

Moreover, the *Sanofi* approach has also been followed and applied in recent Federal Court decisions involving selection patents. For example, Justice Hughes of the Federal Court has emphasized that selection patents are really nothing more than a way of approaching obviousness:

In other cases, I have already expressed the view that an attempt to create a special category for “selection” patents is really nothing more than a way of approaching an issue of obviousness. The question generally stated is, if a class of compounds has been discovered, is it obvious that a particular member or group within that class will have the same or different properties, and, if different, how different?²⁸

This [*I.G. Farbenindustrie* criteria] was a useful starting point for Rothstein J. as he wrote in paragraph 11. What is really being said is, if a patent claims to have “selected” a particular member from a previously disclosed larger group, then to be an unobvious selection, the selected member or group should have previously undisclosed (i.e. not

²⁴ *Sanofi*, *supra* note 4 at para. 67.

²⁵ *Sanofi*, *supra* note 4 at para. 111.

²⁶ *Re I.G. Farbenindustrie A.G.’s Patents* (1930), 47 R.P.C. 289.

²⁷ *Sanofi*, *supra* note 4 at paras. 9-11.

²⁸ *Ratiopharm Inc. v. Pfizer Limited*, 2009 FC 711 at para. 175

anticipated) and unexpected (i.e. not obvious) advantages over what was previously disclosed.²⁹

Therefore, while the *I.G. Farbenindustrie* criteria have historical significance, they are not to be applied as a separate and distinct test. The proper application of the *I.G. Farbenindustrie* case is in the same manner as Justice Rothstein in *Sanofi*.

Proposed Chapter 9.04.02 provides that: “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. 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.”

Contrary to the suggestion in proposed Chapter 9.04.02, the proposed description requirements of the advantages of the selection do in fact go beyond what was required by other types of inventions and exceed the requirements set out by the Supreme Court of Canada in *Sanofi*. In the case of selection patents, a patent applicant is required to disclose the advantages conferred by the selection. However, this requirement does not require a patent applicant to provide data to prove the advantage or to complete the assessment of obviousness. In *Sanofi*, the Supreme Court of Canada stated that a patent applicant is required to define in clear terms the nature of the characteristic possessed by the selection. However, it is clear that only a simple statement of advantages is necessary. On the particular facts of the case, in *Sanofi*, two sentences stating the advantages were adequate.³⁰

...it is necessary that the specification of the selection patent define in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection for which he claims a monopoly. See *I. G. Farbenindustrie*, at p. 323. Here the ‘777 specification satisfies this requirement by providing, at p. 1:

In an unexpected manner only the dextro-rotatory enantiomer Id exhibits a platelet aggregation inhibiting activity, the levo-rotatory enantiomer II being inactive. Moreover, the inactive levo-rotatory enantiomer II is the less well tolerated of the two enantiomers.

If, during examination, in accordance with s. 30(2) of the *Patent Rules*, an examiner on reasonable grounds believes that a patent specification directed to a selection is deficient for non-compliance with the *Patent Act* or *Rules*, the examiner may requisition the patent applicant to provide support. In response, the patent applicant may submit arguments demonstrating compliance by the patent specification, including by submitting evidence and explanation³¹, in this example, demonstrating the advantage.

The proposed Chapter 9.04.02 then states that for, a selection patent, utility must be established by demonstration or sound prediction and that the description must contain more than statements

²⁹ *Bristol-Myers Squibb Canada Co. v. Apotex Inc.*, 2009 FC 137 at para. 183

³⁰ *Sanofi*, supra note 4 at para. 114.

³¹ Such as was done in *Monsanto*. See Appendix B

of advantages or improvements (page 9-14, lines 6-11). These proposed provisions do not reference statutory requirements. Rather, only decisions stemming from *PM(NOC)* cases are referenced. As discussed immediately below, such decisions are not reliable for patent principles unless the parties and the judiciary have had the opportunity to fully argue and consider the issues and principles involved (as was the case in *Sanofi*).

The proposed Chapter 9.04.02 also states 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”. As a practical matter, it is not possible to apply this criteria. It is often impossible to determine what exactly would be meant by “comparison to the entire group”. In terms of “testing”, the question as to how many, which compounds, and other such factors, would be indeterminate, impractical, ambiguous and subjective. The only practical way to deal with the comparison is to compare with the closest prior art such as outlined in the discussion below under the subject of selection patents under the EPO Guidelines and MPEP. By testing a “few isolated members” that represent the closest prior art, that should be sufficient.

The proposed Chapter 9.04.02 conflates “advantage” and “utility”³² as it pertains to the invention under section 2 of the *Patent Act* with the description of the invention as required under section 27(3) of the *Patent Act*. Section 27(3) of the *Patent Act* does not require a patentee to prove or substantiate that an invention has been made, to back up the invention by adding data in a patent description, or to otherwise meet the obviousness test for a selection patent. This statement is clear from *Consolboard*, where the Supreme Court of Canada wrote:

Nor is it any objection to the sufficiency of 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.³³

Thus, there are no heightened disclosure requirements for selection inventions. In fact, the addition of increased disclosure requirements as set forth in proposed Chapter 9.04.02 oversteps the *Patent Act* and decisions of the Supreme Court of Canada.

Proposed Chapter 9.02 of the MOPOP should be removed and selections should be dealt with under Chapter 15 of the MOPOP in connection with obviousness. The proposed amendments should also remove all references to utility and indicate that selection patents are to be evaluated under obviousness using the guidance set out by the Supreme Court of Canada in *Sanofi*.

³² It is worth noting that insofar as the selection has the same "use" as the prior art genus, "utility" has already been shown. Any advantage necessarily goes to inventive step or obviousness.

³³ *Consolboard*, *supra* note 1 at 161.

5. Non-authoritative, Non-Precedential Decisions

The MOPOP should not prematurely rely upon unsettled, non-authoritative judicial decisions to define practices and procedures.

Proposed Chapter 9.04 relies extensively upon jurisprudence decided according to the *Patented Medicines (Notice of Compliance) Regulations* (“PM(NOC) decisions”). Footnotes 43, 45-50, 53 and 55 of the proposed Chapters 9.04 to 9.04.02 of MOPOP cite PM(NOC) decisions.

Such jurisprudence is not authoritative, precedential or reliable for the purpose of establishing foundational patent principles.

Proceedings under the *PM(NOC) Regulations* (“PM(NOC) proceeding”) are summary proceedings undertaken for a limited, administrative purpose, namely: to determine whether the Minister of Health may grant regulatory approval by issuance of a Notice of Compliance (“NOC”) under the *Food and Drugs Act* to permit the marketing of a generic drug product in Canada.

The issues at play in these proceedings are limited by the manner in which they are framed by the generic company in the Notice of Allegation (“NOA”). The grounds put forward may not be clearly or precisely defined and significant considerations may be overlooked or intentionally omitted. Furthermore, the NOA cannot be changed during the course of the proceeding.

Once a NOA has been served, the brand name company is required to commence proceedings by way of a notice of application under the *Federal Courts Rules*. The issues are constrained by the manner in which they were framed by the generic company. Evidence is tendered in writing by way of affidavits. There are no discoveries. While cross-examination of a deponent of an affidavit by an opposing party is permitted, such cross-examination is limited to matters raised in the affidavit and to test credibility. A hearing involving submissions by counsel is held over a period of days without any witnesses. A lower level of proof is involved; the PM(NOC) proceeding seeks only to determine, on a balance of probabilities, whether the factual and legal bases of the allegations of invalidity or non-infringement raised in the NOA are not justified. This determination turns on whether allegations by the generic drug manufacturer are sufficiently substantiated to support a conclusion for administrative purposes that a patent is valid and would not be infringed if the generic company’s product is put on the market.

This is in contrast to patent infringement/impeachment proceedings that proceed by way of an action under the *Federal Court Rules*. The parties are obligated to identify in pleadings all issues to be tried. The opposing party may seek particulars to more clearly define the issues. In discoveries, the parties are obligated to disclose all relevant documents including those that tend to adversely affect their own case and relevant documents in the possession of third parties. The parties submit to oral discovery addressing any issues raised in the pleadings. Discovery of third parties having relevant information is also available. The discovery process helps the parties to fully understand the issues and evidence, and to avoid surprise. At trial, the parties are able to fully present and argue their cases, to canvass the issues and to introduce all relevant evidence through witnesses providing the Court with an opportunity to ask questions to clarify and understand the facts in evidence and to assess credibility.

A finding of patent invalidity in a patent impeachment action is *in rem* and the judgment is registered in the Patent Office³⁴.

A finding of patent invalidity in a *PM(NOC)* proceeding is not even binding as between the parties. For example, in *Janssen-Ortho Inc. et al. v. Novopharm Ltd. et al.*³⁵ Justice Mosley dismissed Janssen-Ortho's application for an Order of Prohibition in respect of the drug ofloxacin. In the subsequent infringement proceeding, Justice Hughes found the patent in question valid and infringed.³⁶ In proceedings relating to the drug amlodipine the opposite occurred. In two different *PM(NOC)* proceedings the Court granted Orders of Prohibition.³⁷ Subsequently, ratiopharm was successful in an impeachment action in respect of the patent covering the drug amlodipine.³⁸

The proposed Chapter 9.04 of MOPOP cites the *PM(NOC)* decision of *GlaxoSmithKline Inc. v. Pharmascience Inc.* [2008] FC 593 in footnotes 47 and 52. The parties are now involved in a full patent infringement/impeachment action involving the same patent. A different result together with different jurisprudence may follow.

Significantly, decisions from *PM(NOC)* hearings are often not permitted to be appealed. This is because these proceedings are solely about the administrative decision to issue, or not issue, a NOC. Once a NOC issues, all further proceedings are held to be moot. This can and has allowed errors of fact, of law and of mixed fact and law to stand without correction. If incorporated into the MOPOP, it further propagates these errors.

Where a right to appeal from a Federal Court decision is available and is exercised, that indicates that errors of fact or of law may have been committed, which is subject to adjudication by an appellate court.

In *Pfizer Canada Inc. v. Ranbaxy Laboratories Limited*³⁹, a case where an appeal from the *PM(NOC)* decision was permitted, the Federal Court of Appeal reversed the *PM(NOC)* hearing judge's decision. This case is an example involving disclosure requirements under s. 27(3) of the *Patent Act*.⁴⁰

The persuasiveness or precedential value of judicial decisions arising from these proceedings were recently commented upon by the Federal Court of Appeal in *Eli Lilly Canada Inc. v. Novopharm Inc. et al.*. Justice Sexton wrote:

³⁴ S. 62 *Patent Act*

³⁵ *Janssen-Ortho Inc. et al. v. Novopharm Ltd. et al.* (2004), 35 C.P.R. (4th) 353 (F.C.)

³⁶ *Janssen-Ortho Inc. et al. v. Novopharm Ltd.* (2006), 57 C.P.R. (4th) 6 (F.C.)

³⁷ *Pfizer Canada Inc. v. ratiopharm Inc.*, 2006 FC 220; *Pfizer Canada Inc. v. Pharmascience*, 2008 FC 500.

³⁸ *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711.

³⁹ *Pfizer Canada Inc. v. Ranbaxy Laboratories Limited*, 2008 FCA 108.

⁴⁰ In *Pfizer*, the Federal Court of Appeal wrote in paragraph 56: "...Whether or not a patentee has obtained enough data to substantiate its invention is, in my view, an irrelevant consideration with respect to the application of subsection 27(3). An analysis thereunder is concerned with the sufficiency of the disclosure, not the sufficiency of the data underlying the invention. Allowing Ranbaxy to attack the utility, novelty and/or obviousness of the '546 patent through the disclosure requirement unduly broadens the scope of an inventor's obligation under subsection 27(3) and disregards the purpose of this provision."

[41] NOC proceedings were never intended to be substitutes for an infringement action: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.) at 319 (leave to appeal to the S.C.C. dismissed [1994] S.C.C.A. 330); *Pfizer*, supra at paragraph 17. **Similarly, it is inappropriate to rely on NOC proceedings to set binding precedent on controversial and uncertain questions in patent law** (see *Sanofi-Aventis*, supra, at paragraph 49). NOC proceedings are supposed to be summary in nature and do not lend themselves to such determinations.⁴¹ [Emphasis added]

Decisions rendered under the *PM(NOC) Regulations* do not set binding precedent and are not authoritative. Such summary proceedings do not have the benefit of full evidence and argument and are often not appealable as would be the case in a patent infringement or impeachment action. Thus, it is improper for the MOPOP to rely on these cases to define patent procedures and practices.

II. Inconsistent with Practice in Major Examining Authorities, International Harmonization and Treaty Obligations

1. MOPOP Inconsistent with Practice Guidelines in Other Major Examining Offices

A. Proposed MOPOP Inconsistent with European Practice

i. Description

Sufficiency of disclosure falls under Article 83 EPC and requires that the "European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." Clearly, the disclosure requirement is on how to make and use the invention, similar to the statutory language in Canada.

The EPO Guidelines note two circumstances in which a European application disclosure is insufficient. The first is where the successful performance of the invention is dependent on chance. The second instance is where performance of the invention is impossible because it violates the laws of physics e.g. a perpetual motion machine. In the second instance the application is objected to under Article 83 and Article 52(1) (industrial applicability).⁴² However, an application cannot be rejected for providing insufficient disclosure *of its industrial applicability*;⁴³ insufficient disclosure arises only in relation to the question whether the invention can be put into practice.

In contrast to the practice under the EPO, the proposed Chapter 9.04 of the MOPOP clearly requires different disclosure requirements and permissible manner of proof depending upon

⁴¹ *Eli Lilly Canada Inc. v. Novopharm Inc. et al.*, 2007 FCA 359.

⁴² Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 4.11.

⁴³ This is consistent with *Consolboard*, supra at 1, page 161.

whether the utility of an invention is established by demonstration or by sound prediction.⁴⁴ Such a requirement does not exist under EPO practice.

ii. Industrial Applicability/Sufficiency

The European patent system under the EPC does not contain a concept of utility but rather uses the phrase “susceptible to industrial applicability”, which is consistent with TRIPS. Under Article 57 EPC an invention shall be regarded as having industrial application “if it can be made or used in any kind of industry, including agriculture.”⁴⁵ The EPO Boards of Appeal has held that the concept of “industry” in Article 57 EPC is to be given a broad construction involving most activities carried out for financial (commercial) gain.⁴⁶

There are two main fields in which the EPO have found that claimed inventions are not capable of industrial application: those contravening the laws of physics and those involving personal, non-commercial activity.

Under the EPO Guidelines, industrial applicability is one of the four basic conditions for patentability of an invention (Article 52(1) EPC⁴⁷). In contrast, sufficient disclosure is a technical requirement for a European patent application (Article 83⁴⁸).

Furthermore, for applications where utility is based on a sound prediction, proposed Chapter 9.04.01 of the MOPOP proposes that the description, when read in view of the common general knowledge must be sufficient to render the sound line of reason clear to the person skilled in the art.⁴⁹ This is again inconsistent with the EPO Guidelines as it incorporates a sufficiency requirement into utility. The EPO Guidelines are clear that industrial applicability (“does it work”) is separate and distinct from sufficiency (“can one put it into practice”). In addition, proposed Chapter 9.04.01 of the MOPOP goes further and suggests that the factual basis for the sound prediction as well as the sound line of reasoning for the sound prediction must be disclosed in the application or available from the common general knowledge.

iii. Selection Patents

The EPO has formulated its own Guidelines⁵⁰ for the treatment of selection patents. Under the EPO Guidelines selection patents are considered under novelty⁵¹ and/or inventiveness.⁵² The EPO Guidelines do not consider selection inventions under utility or industrial applicability. Consequently, inclusion of selection under the presently proposed Utility of Chapter 9.04 of the MOPOP is inconsistent with the EPO Guidelines.

⁴⁴ See for example the following statements in proposed Chapter 9.04 of the MOPOP, p. 11 in 7-13.

⁴⁵ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 5.1.

⁴⁶ For example see decisions T 144/83 and T 870/04.

⁴⁷ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 1.1.

⁴⁸ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 1.2.

⁴⁹ See for example the following statements in proposed Chapter 9.04.02 of the MOPOP, p. 11 in 38-40.

⁵⁰ Guidelines for Examination in the European Patent Office.

⁵¹ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 9.8.

⁵² Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 11.11.

Under novelty, the EPO Guidelines⁵³ state that a selection is novel if the selected elements have not been disclosed in an individualised (concrete) form in the prior art (see T 12/81, OJ 8/1982, 296).

Under obviousness, the EPO Guidelines indicate that a selection patent is inventive if the selection differs from the closest prior art, the selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection. For inventive step, the examiner must consider whether the skilled person would have made the selection in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer to this question is “no”, the invention is unobvious.⁵⁴ In considering whether a patent application involves an inventive step the EPO permits the applicant to rely upon evidence taken from the originally-filed patent application or submitted by the applicant during prosecution.⁵⁵

The EPO Guidelines also provide the following example of an unobvious selection: “a selection invention is unobvious if the invention consists in selecting particular chemical compounds or compositions (including alloys) from a broad field, such compounds or compositions having unexpected advantages”.⁵⁶

As the above clearly shows, utility and/or industrial application have no bearing on the assessment of patentability of selection patents.

In addition, the proposed amendments to Chapter 9.04.02 of the MOPOP suggest that the advantage for a selection invention 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 groups⁵⁷. This is clearly inconsistent with the EPO Guidelines which states that the advantage comparison is between the selection invention and the “closest prior art.”⁵⁸

B. Proposed MOPOP Inconsistent with United States Practice

i. Description

In the U.S., the description requirement is encoded in 35 U.S.C 112 para. 1, and it requires that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The requirement is generally regarded as having three parts – a written description of (i) the invention, (ii) the manner of making and using it, and (iii) the best mode of practicing the

⁵³ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 9.8(ii).

⁵⁴ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 11.11.

⁵⁵ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 11.10.

⁵⁶ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, Annex, section 3.2.

⁵⁷ Proposed Chapter 9.04.02 of the MOPOP p. 13 ln 27-29.

⁵⁸ Guidelines for Examination in the European Patent Office, Part C, Chapter IV, section 11.11.

invention. The focus is clearly on the invention and making and using it, as well as providing support for the claims. Moreover, "[c]ompliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis."⁵⁹ The requirement is analogous to s. 27(3) in Canada, but it is applied differently than the current amendments to MOPOP Chapter 9.04 with regard to utility and selection inventions.⁶⁰

ii. Utility

Under the U.S. Manual of Patent Examining Procedure ("MPEP") an applicant's assertion of utility creates a presumption of utility that is sufficient to satisfy the utility requirement.⁶¹ To overcome the presumption of truth in an assertion of utility, the USPTO must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e., "question") the truth of the statement of utility. This is consistent with the Supreme Court of Canada in the *Monsanto* case. In contrast, the proposed Chapter 9.04 amendments do not permit the applicant to rely upon any presumption of utility.

In appropriate situations, the USPTO may require an applicant to substantiate an asserted utility for a claimed invention. Requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility (e.g., if the asserted utility is not consistent with the evidence of record and current scientific knowledge). As the Federal Circuit recently noted, "[o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility."⁶²

It is important to emphasize that the requests from the USPTO for more evidence can happen after the patent is filed; therefore the data is not required as part of the originally filed specification.

iii. Selection Patents

The MPEP considers selection inventions as part of the obviousness analysis.⁶³ Under the MPEP, a selection invention may be *prima facie* obvious based on structural similarity.⁶⁴ This can be rebutted by proof that the claimed compounds possess unexpected advantages or superior properties. In contrast to the proposed guidelines, such proof may be submitted during

⁵⁹ MPEP s. 2163; *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

⁶⁰ "It is important to recognize that 35 U.S.C. 112, first paragraph, addresses matters other than those related to the question of whether or not an invention lacks utility. These matters include whether the claims are fully supported by the disclosure, whether the applicant has provided an enabling disclosure of the claimed subject matter, whether the applicant has provided an adequate written description of the invention and whether the applicant has disclosed the best mode of practicing the claimed invention." MPEP 2107.01 General Principles Governing Utility Rejections.

⁶¹ MPEP s. 2107. Guidelines for Examination of Applications for Compliance with the Utility Requirement.

⁶² *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995).

⁶³ MPEP 2144.08, Obviousness of Species When Prior Art Teaches Genus.

⁶⁴ MPEP 2144.09 VII.

prosecution,⁶⁵ and it is not part of the description requirement for the initial application. For example, *In re Papesch*,⁶⁶ affidavit evidence showing that the claimed triethylated compounds possessed anti-inflammatory activity, whereas the prior art trimethylated compounds did not, which was sufficient to overcome the obviousness rejection.

Like the EPO Guidelines, the MPEP does not scrutinize a selection invention under utility. Accordingly, treating selection patents under the presently proposed utility section 9.04 of the MOPOP is inconsistent with US and European practice.

Finally, the MPEP, like the EPO Guidelines, states that in assessing the unexpected advantage of a selection invention the examiner must compare the closest disclosed prior art species to the claimed selection invention.⁶⁷ This is inconsistent with the proposed amendments to Chapter 9.04 which suggest that the advantage for a selection invention “must be in comparison to the entire group from which the selection has been made, and not simply with respect to a few isolated examples”.⁶⁸

2. Proposed MOPOP Guidelines Inconsistent with PCT, TRIPS and NAFTA

A. PCT

i. Description

Article 5 of the PCT sets out the requirements for sufficient disclosure. Article 5 provide as follows:

Article 5 The Description

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.

Rule 5 of the PCT Regulations sets out the formal requirements for the contents of an international patent application. As regards disclosure, Rule 5.1(a)(iii) PCT Regulations provides further that the description shall:

⁶⁵ "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to >render obvious< the claimed invention." MPEP 2142.

⁶⁶ *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

⁶⁷ MPEP 2144.08, Ascertain the Differences Between the Closest Disclosed Prior Art Species or Subgenus of Record and the Claimed Species or Subgenus; See also, MPEP 2145, Consideration of Applicant's Rebuttal Arguments.

⁶⁸ Proposed Chapter 9.04.02 of the MOPOP p. 13 ln 27-29.

“disclose the invention, as claimed, in such terms that the technical problem (even if not stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art.”

Section 4.02 of the PCT Guidelines state that the content of the description are set out in Rule 5. The purpose of Rule 5 is to:

- (i) to ensure that the international application contains all the technical information required to enable a skilled person to put the invention into practice; and
- (ii) to enable the reader to understand the contribution to the art which the inventor has made.⁶⁹

Under the PCT there is no requirement to disclose facts supporting the utility of the invention as suggested by proposed Chapter 9.04. Similarly, the PCT does not impose a different disclosure requirement for patent applications based on a sound prediction of utility. Consequently, the description requirements under proposed Chapter 9.04 are inconsistent with those under the PCT.

ii. Industrial Applicability/Sufficiency

The PCT, like the EPO, TRIPS and NAFTA uses the term “industrially applicable”. The requirement, in so far as it relates to international applications under the PCT is contained in Article 33(4) which states: “a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry...”

Industrial applicability is elaborated upon in the Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications Under the Patent Cooperation Treaty (‘the PCT Guidelines’) at Chapter 14.⁷⁰ Chapter 14.01 notes that “industrially applicable” and “utility” may be deemed synonymous by some offices and *cf.* TRIPS Article 27(1) and NAFTA Article 1709(1).

Utility, according to the PCT Guidelines, has three requirements. The utility must be (1) specific, (2) substantial and (3) credible. According to the PCT Guidelines, the utility is credible *unless* (i) the underlying logic is seriously flawed or (ii) the facts upon which the assertion is based are inconsistent with the underlying logic. Unlike the proposed amendments to MOPOP,⁷¹ neither of these possibilities require proof of utility to be contained in the patent application.

⁶⁹ Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications Under the Patent Cooperation Treaty Chapter 4.02.

⁷⁰ Industrial applicability is elaborated upon in the Guidelines for the Processing by International Searching and Preliminary Examining Authorities of International Applications Under the Patent Cooperation Treaty Chapter 14.01.

⁷¹ See for example, p. 11 ln 7-11, p. 12 ln 4-16, ln 35-41.

Under PCT Guidelines, utility is a completely separate requirement from sufficiency of disclosure.⁷² The requirement of utility under the PCT does not require any specific level of proof. Where the patent application contains an assertion of invention together with details from which that assertion may logically follow, the requirement of utility is satisfied, notwithstanding that the application may leave out direct proof that that invention works or can exist.

Although the Guidelines are not binding on national offices such as CIPO, it is clear that the disclosure requirement for sound prediction proposed by amended Chapter 9.04 is well above that required under the PCT Guidelines.⁷³ As a result, the proposed amendments to MOPOP would force applicants for Canadian patents to face significantly more stringent disclosure requirements than those applying for international patents or for patents in other countries, contrary to the purpose of the PCT and contrary to the interests of Canadian national applicants. Furthermore, the coherency of patent applications would be substantially undermined if the requirements for applications under MOPOP differ significantly from the requirements for applications under the PCT, especially upon entry into the national phase in Canada.

The proposed amendments to the MOPOP also differ from PCT in respect of the type of proof that the Office will accept in assessing utility. The proposed amendments suggest that the factual basis or sound line of reasoning must be *in the description* or based on common general knowledge at the filing date.⁷⁴ In fact, Article 27(2)(ii) PCT clearly contemplates the submission of documents during prosecution to substantiate allegations in the application that may require additional evidence or proof:

(2) The provisions of paragraph (1) [do not] preclude any national law from requiring, once the processing of the international application has started in the designated office, the furnishing: ...

(ii) of documents not part of the international application but which constitute proof of allegations or statements made in that application...

This provision makes it clear that supporting evidence of allegations and statements made in a PCT application are to be supplied when, and if, requested during the prosecution of the patent application. In the notes on Article 27(2)(ii) accompanying the text of the PCT in the Records of the Washington Conference, 1970, it is stated that “Allegations or statements to be proved may relate...to the fact that the invention is usable or operational for certain purposes...The documents supporting such allegations may be affidavits...laboratory notes, etc.” This Article and the accompanying explanatory notes make it abundantly clear that the framers of the PCT never envisaged that such information was meant to be included in an application as originally filed, as suggested in MOPOP 9.04.

⁷² Article 5 of the PCT states: 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. Rule 5.1(a)(iii) of the PCT Regulations provides that the description shall: [D]isclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art. This is consistent with s. 27(3) of the *Patent Act* and s. 80(1) of the *Patent Rules*.

⁷³ See for example, p. 11 ln 7-11, p. 12 ln 4-16, ln 35-41.

⁷⁴ See for example p. 11 ln 38-40, p. 12 ln 4-7, ln 13-18, ln 38-41, p. 13 ln 6-8.

B. TRIPS and NAFTA

The proposed amendments to Chapter 9.04 of MOPOP impose a higher disclosure standard for utility than that prescribed in Article 27(1) of TRIPS and Article 1709(1) of NAFTA.

The criteria for patentability under Article 27(1) of TRIPS and Article 1709(1) of NAFTA is quite clear, that is, patents shall be available for any inventions which are :

- (1) new (novel);
- (2) involves an inventive step (unobvious); and
- (3) is capable of industrial application (useful).⁷⁵

“Capable of industrial application” is clearly a fact based criterion to be evaluated on the evidence. To put it simply, these treaties do not impose any disclosure requirement in the context of utility, and so to superimpose such a requirement as is now advanced in the proposed MOPOP guidelines would render Canada non-compliant with its treaty obligations under both TRIPS and NAFTA.

3. Proposed MOPOP Inconsistent with Canada’s Harmonization Efforts

Canada is a part of the larger international patent community and has progressively worked toward the harmonization of its patent laws. As part of this effort, Canada has signed and agreed to be bound by several international intellectual property rights treaties. In 1925 Canada signed the *Paris Convention for the Protection of Industrial Property*. As a member of the World Trade Organization (“WTO”), Canada agreed to be bound by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In 1989, Canada rewrote its patent laws switching from a first-to-invent to a first-to-file system to align itself with the majority of countries in the world. In the early 90’s Canada implemented and incorporated into Canadian law the *Patent Cooperation Treaty* (“PCT”) and, in 2002, CIPO became an International Searching Authority (“ISA”) and International Preliminary Examining Authority (“IPEA”) under the PCT.

Canada has also taken other steps to harmonize its patent regime with that of its trading partners. For example, CIPO’s Strategic Plan, “Strategic Direction C - Administrative Framework for IP”, notes:

A modern, internationally competitive IP framework creates conditions for entrepreneurship, innovation, investment and competitiveness. While Canada’s IP framework is generally aligned with the IP regimes of its key trading partners, there are outstanding issues. Closing these gaps would create a more efficient, effective IP regime in support of the modernization of CIPO products and services. CIPO is committed to working effectively with our IP partners and stakeholders to achieve a world-class IP regime, for the benefit of Canada. [Emphasis added]

More recently, Canada implemented initiatives with Patent Offices in the United States, Japan,

⁷⁵ The W.T.O.’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This same requirement is repeated at Rule 5.1(a)(vi) of the *PCT Regulations*.

Denmark and Korea. The Patent Prosecution Highway (“PPH”) pilot programs seek to help accelerate patent examination in Canada by allowing patent applicants whose patent applications have been allowed or granted in those jurisdictions to obtain a corresponding Canadian patent more quickly and efficiently.

Even prior to the PPH pilot, the substantive patent examination process in Canada placed great weight on examination results from foreign counterpart patent applications, particularly from the PCT, the United States Patent and Trademark Office (“USPTO”) and the European Patent Office (“EPO”). This expedites and streamlines the Canadian examination process.

One reason that CIPO has sought harmonization is that it recognizes that significant advantages flow from such efforts, including strengthening Canada’s IP regime, fostering innovation and entrepreneurship, improving Canada’s administrative efficiencies, improving patent quality and improving Canada’s position in the world.

Having a strong, reliable and robust patent system promotes economic and entrepreneurial growth, enhances Canada’s reputation and image abroad, and is in Canada’s best interest. Unfortunately, the proposed amendments to Chapter 9.04 of the MOPOP threaten to undermine Canada’s harmonization efforts by introducing much stricter disclosure requirements as compared to those of the USPTO, EPO and PCT.

4. Proposed MOPOP will have Negative Effect on Canada’s Patent System

For Canada’s patent system to work effectively while still meeting its international obligations, it is critical that Canada properly apply the rules and procedures that have been commonly agreed upon by all member countries. Prejudice flows from deviations.

To provide an illustration reflecting practical realities, it is noted that a patent applicant rarely seeks patent protection in Canada alone. When a patent application is prepared, one patent specification is drafted in accordance with the patent requirements of that person’s home jurisdiction. Since most patent jurisdictions are based upon a first to file system, there is added impetus for a patent applicant to file a patent application as soon as practicable. The proposed amendments run counter to this by requiring applicants to delay filing in Canada as specialized Canadian patent applications are prepared.

If, as is presently proposed under Chapter 9.04 of the MOPOP, the description requirements in Canada deviate substantially from other countries, prejudice will ensue. For example, in Canada, the ability of a patent applicant to adapt the patent specification to the peculiar disclosure requirements now proposed is restricted by s. 38.2 of the *Patent Act*, which may be prohibited as constituting new subject matter. Proposed Chapter 9.08 of the MOPOP appears to take a restrictive view of what constitutes new subject matter and may foreclose amendment of the description to include information that is now proposed to be required under Proposed Chapter 9.04 of the MOPOP. It is conceivable that a patent applicant may be denied patent protection in Canada, while obtaining protection elsewhere, all based on the same international patent application.

Such prejudice may deter foreign patent applicants from seeking patent protection in Canada to

the detriment of the Canadian public, depriving Canadians from access to innovative products and technology. Where the deviations have a discriminatory effect on a class of patentable subject matter, such as to pharmaceuticals, this may also lead to disciplinary or retaliatory action from Canada's trading partners.

When Canadian patent law is out of step with those of other jurisdictions, that negatively affects Canada's reputation and prominence of the international stage and standing as a leading player in WIPO. Discordance with foreign substantive law increases the burden on CIPO during the examination process, affects patent quality and the delivery of services, and undermines initiatives such as the Patent Prosecution Highway.

Ensuring that Canada's substantive patent law remains in step and in alignment with those of its trading partners is beneficial to patentees and to the Canadian public, to CIPO and to Canada as a whole.

Conclusions

For the foregoing reasons, we submit that the proposed amendments to the MOPOP disclosure requirements be reconsidered and amended to comply with the *Patent Act and Rules*, the decisions of the Supreme Court of Canada, and be consistent with Canada's international obligations and harmonization efforts. None of this governing law requires the description to contain the information required by the proposed amendments to the MOPOP regarding utility and selection inventions.

Appendix A - Specific Concerns in Chapter 9.04.01 to 9.04.01b of MOPOP

9.04.01: “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”.

- No statutory basis; not based on Supreme Court of Canada principles
- *AZT* states that the “inventor” must have the sound line of reasoning. This does not follow that the sound line of reasoning must be disclosed as clear to the person skilled in the art.

9.04.01a: “The factual basis needed to render the line of reasoning sound must be clearly identified.

- No statutory basis; not based on Supreme Court of Canada principles
- *Monsanto* suggests that that the inventor must have the factual basis. Affidavit evidence from the inventor was admissible and considered.
- *AZT* does not require disclosure of the factual basis in the disclosure.

9.04.01a: “If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified.

- No statutory basis; not based on Supreme Court of Canada principles
- *Monsanto* suggests that affidavit evidence including information not disclosed in a patent specification may be considered

9.04.01a: “Any necessary facts that are not otherwise publicly available must be included in the description”.

- No statutory basis; not based on Supreme Court of Canada principles
- *Monsanto* suggests that affidavit evidence including information not disclosed in a patent specification may be considered

9.04.01a: “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”.

- No statutory basis; not based on Supreme Court of Canada principles
- *Monsanto* suggests that affidavit evidence including information not disclosed in a patent specification may be considered
- *AZT* states that the “inventor” must have the sound line of reasoning. This does not follow that the sound line of reasoning must be disclosed.

9.04.01b: “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”.

- No statutory basis; not based on Supreme Court of Canada principles

9.04.01b: “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”.

- No statutory basis; not based on Supreme Court of Canada principles

9.04.01b: “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”.

- No statutory basis; not based on Supreme Court of Canada principles
- Contrary to *Monsanto* and to *AZT*

Appendix B – Background Information Concerning Patent Specification and Prosecution History in *Monsanto*

The facts underlying the patent at issue in *Monsanto* are set out in the Federal Court of Appeal decision under appeal and may briefly be set out as follows.

In *Monsanto*, two claims were rejected under *inter alia* s. 36 of the *Patent Act* by the examiner for covering subject-matter beyond what was invented. Claim 9 was directed to a class of compounds defined by a general formula. Claim 16 claimed 126 species of compounds (three of which were made and tested). Thus, the utility of the broad class of compounds claimed in claim 9 and 123 species claimed in claim 16 were based on a sound prediction of utility.

The extent of the patent disclosure together with the specific reasons for the rejection by the examiner in part is as follows:

These product claims are much too broad in view of the disclosure which only discloses the preparation of three of the compounds being claimed. Product claim 16 is directed to 126 species altogether; they are just recited from the disclosure. As previously mentioned only the preparation of three of these species is exemplified and have a physical constant (melting point) and elemental analyses (for two species only). There is no way of proving that all these species have been prepared for there are no methods of preparation, physical constants and/or elemental analyses results given. ... In order to sustain claims to a broad group of compounds, the specification must illustrate with reasonable certainty that all members of the group are capable of being prepared by the disclosed process of preparation and have the same utility (inhibiting premature vulcanization) upon which their patentability is based. ...⁷⁶

In response to the examiner's rejection, Monsanto submitted two affidavits of its employees, one of whom was a named inventor and the other whom the Patent Appeal Board accepted as a person of skill in the art to which the invention pertains. The affidavits showed that Monsanto had only prepared three of the compounds before the application was filed, that other compounds were prepared later, that the directions in the specification were adequate so they could have prepared all the compounds covered by the claim, and that it would have been apparent to them what utility the compounds would have possessed.⁷⁷ The affidavits included "detailed references to authoritative scientific publications" and were "based on scientific principles".

⁷⁶ *Monsanto Co. v. Commissioner of Patents* (1997), 34 C.P.R. (2d) 1 (F.C.A.) at page 6.

⁷⁷ *Monsanto Co. v. Commissioner of Patents* (1997), 34 C.P.R. (2d) 1 (F.C.A.) at pages 6 to 8.

The Supreme Court of Canada overturned the decisions of the Federal Court of Appeal and the Commissioner of Patents and directed that the patent be issued with claims 9 and 16. The Supreme Court of Canada observed that the Board:⁷⁸

... gives no indication of the reasons for which it was not satisfied of the soundness of the prediction of utility for the whole area covered by claim 9. Evidence had been submitted in the form of affidavits based on scientific principles, it does not take issue with those principles, it just says: "We are not satisfied that this is adequate". In my view this is insufficient because, if accepted, it makes the right of appeal illusory. In this respect it is important to note that s. 42 of the Patent Act reads:

42. Whenever the Commissioner is satisfied that the applicant is not by law entitled to be granted a patent he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of such refusal and of the ground or reason therefor.

I have emphasized by law to stress that this is not a matter of discretion: the Commissioner has to justify any refusal. As Duff, C.J., said in *Vanity Fair Silk Mills v. Commissioner of Patents*, [1938] 4 D.L.R. 657, [1939] S.C.R. 245 at p. 246:

No doubt the Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation.

⁷⁸ *Monsanto*, *supra* note 2, page 173.