Examination Practice Respecting
Medical Uses

PN 2013-04

June 10, 2013

To all examiners:

The present document is intended to build upon the guidance in section 17.02.03 (*Medical and surgical methods*) of the *Manual of Patent Office Practice* (MOPOP) and in PN 2013-02 (*Examination Practice Respecting Purposive Construction*).

MOPOP 17.02.03 can generally be relied on for guidance, however, the examination of medical use claims, including dosage regimens and dosage ranges, requires specific guidance in order to ensure efficient, predictable and reproducible examination of applications. The guidance in the present notice applies to a claim in the form "use of product X for treating disease Y" and may apply to claims such as "use of product X for the manufacture of a medicament for treating disease Y", or "product X for treating disease Y...", or a claim having similar language when construed to be a claim to the use *per se.*

To reflect decisions of the courts on medical use claims[1], the emphasis of the guidance provided herein relates to the examination of claims that recite dosage regimens or dosage ranges.

Practice Guidelines

A) Subject-matter

Section 2 of the *Patent Act* requires the subject-matter of an invention to fall within one of the categories of *invention*, *i.e.* an art, process, machine, manufacture, composition of matter, or an improvement in one of the foregoing.

Medical inventions, in particular, have been subject to a number of jurisprudential interpretations whereby certain types of matter have been found to fall outside the scope of section 2. For instance, it is well established that methods of medical treatment and surgery are not statutory subject matter and are excluded from the definition of *invention*.[2]

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[1] *Axcan Pharma Inc. v. Pharmascience Inc.,* 2006 FC 527; *Merck & Co., Inc. v. Pharmascience Inc.,* 2010 FC 510*; Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123 [*Janssen*]

[2] *Tennessee Eastman v. Commissioner of Patents,* 1972, 8 C.P.R. (2nd), 202 (S.C.C.); *Imperial Chemical Industries Ltd. v. Commissioner of Patents*, 1986, 9 C.P.R. (3rd), 289 (F.C.A.)

Medical use claims, however, are generally permitted as long as they do not equate to medical or surgical methods (*e.g.* do not include an active treatment or surgical step) and they satisfy all other requirements of patentability. The Federal Court has concluded, however, that inventions preventing physicians from exercising their skill and judgment in using a known compound for an established purpose effectively cover a method of medical treatment.[3]

In order to determine whether the subject-matter of a claim is statutory, examiners must take into account the guidance outlined in Patent Notice on *Practice Guidance Following the Amazon FCA Decision* [March 2013], which provides that an assessment for section 2 compliance should be based on the essential elements of the claim as determined by a purposive construction (see part B below).

The importance of a purposive construction approach is highlighted when assessing the patentability of claims that recite a dosage regimen or dosage range since the mere recitation of either of these does not necessarily mean the claim is non-statutory. If, however, it is determined after a purposive construction that a dosage regimen or dosage range is an essential element of a claim encompassing the use of a known compound in an established treatment, then the claim covers a method of medical treatment, and thus, is not compliant with section 2 of the *Patent Act*.

Where an essential element only serves to instruct a medical professional "how" to treat a patient,[4] rather than "what" to use to treat the patient, this will lead to the conclusion that the claimed use encompasses a method of medical treatment.

Therefore, essential elements that point to a limitation of a physician's professional skill or judgment include those that provide details of a dosing schedule, those that represent a range of potential dosages that a patient may receive (as distinct from a range of dosages forms), and those that narrow treatment to a patient sub-population (rather than bring treatment to a new population) or administration site.

B) Claim analysis

PN 2013-02 (*Examination Practice Respecting Purposive Construction*) mandates the use of purposive construction in place of other approaches to claim analysis.[5]

To perform a purposive construction, an examiner identifies the problem the inventors

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[3] *Janssen* at paragraphs 51-53

[4] *Apotex Inc. v. Wellcome Foundation Ltd.,* 2002 SCC 77 at paragraph 50 suggests that the "how" and "when" amounts to professional medical skill: "...How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession."

[5] In particular, the "contribution approach" set out in MOPOP Chapter 13 is not to be used.

set out to address and the solution disclosed. This exercise generally must be performed considering the specification as a whole recognizing that the description guides the identification of the problem and solution.

While an applicant is entitled to claim less than the entire invention if so desired,[6] a proper identification of the actual invention, grounded in a purposive construction of the claims, is nevertheless necessary in order to assess whether the claim is patentable.

Identifying the problem and solution

The identification of the *problem* faced by the inventors is guided by the examiner's understanding of the common general knowledge in the art and by the teachings of the description.

The *solution* is the element or set of elements essential to the successful resolution of the problem. Depending on what was disclosed in the description and what was commonly known in the art, the solution could be, for example, a new compound or new use of a compound; or it could be an improvement (*e.g.* refinement) of a known use.

It must be borne in mind that the applicant is not required to explicitly state the problem and solution as long as the description allows for their understanding (see paragraph 80(1)(*d*) of the *Patent Rules*). Where the applicant is explicit as to the nature of the problem, examination should generally proceed accordingly unless doing so would be unreasonable on an informed reading of the application in light of the common general knowledge.

In identifying the problem faced by the inventors, the examiner will consider what the inventors state about the background of the invention, their objectives ("objects of the invention"), any specific problems, needs, limitations or disadvantages known in the art or discovered by the inventors, etc.

For medical inventions, the problem faced by the inventor may relate to "what" to use for treatment. Generally the solution to such a problem will be provided by an element or set of elements in a claim that embody a treatment tool. This tool may include a compound, composition, formulation, or a dosage unit form.

Alternatively, where the emphasis is not on "what" to use but instead relates to "how" to administer or refine a treatment, the solution (as embodied by the essential elements of the claim) will likely place a limit on the professional skill or judgment of a physician. An emphasis on "how" (as distinct from "what") may include details of when or where a treatment is to be administered or who is to receive a treatment.

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[6]For example, an applicant may choose to limit the scope of a claim by adding a dosage range to a claim covering a "new use" of a product.

After identifying the problem and solution, a proper construction of the claims includes a determination of which elements in the claims are essential and non-essential to the solution. Having identified the essential elements, the subject-matter of the claim is then assessed for patentability (see part A).