

CIPO releases revised guidelines for subject matter eligibility

November 05, 2020

Good news for diagnostics, less so for computer-implemented inventions

On Nov. 3, 2020, the Canadian Intellectual Property Office (CIPO) released revised guidelines¹ and examples² for the assessment of patentable subject matter in Canada. Released without prior consultation, the guidelines explain how claims to computer-implemented inventions, medical diagnostic methods, and medical “uses” are to be examined in light of recent jurisprudence from the Federal Court of Canada (FCC).

The guidelines begin by following the Supreme Court of Canada (SCC) on claims construction. However, they cast the result of purposive construction aside in favour of an assessment of a so-called “actual invention” – a concept that excludes any essential claim element CIPO deems not to co-operate with other elements or not to have a material effect on the working of the invention. In some cases, an essential element is excluded from the “actual invention” if it is used in a well-known manner.

The new guidelines continue a tradition, started in 2009, of CIPO assessing something different to what is claimed.

The practical result of the new approach appears to be good news for medical diagnostic methods, while computer-implemented inventions continue to face the same challenges applicants faced under CIPO’s previous approach.

Background

In August 2020, the FCC struck down CIPO’s “problem-and-solution” approach to claims construction.³ Under this previous approach, CIPO routinely read out claim features as purportedly non-essential if they did not form part of a “solution” to a “problem” defined by common general knowledge. For many years, this resulted in rejection of claims to computer-implemented inventions and diagnostics as allegedly limited to disembodied mental steps, contrary to the requirements of Section 2 of the *Patent Act*.

In *Choueifaty*, the FCC found that CIPO's approach to claims construction was inconsistent with SCC jurisprudence, in particular with the test for essentiality of claim elements. The FCC directed CIPO to follow the SCC. The government did not appeal this decision. As a result, CIPO issued new guidelines for its patent examiners.

The new guidelines

The new guidelines state that the "problem and solution" approach should no longer be followed, and that claims should be construed in accordance with the principles set out by the Supreme Court in *Free World Trust v Électro Santé Inc*⁴ and *Whirlpool Corp v Camco Inc.*⁵

The guidelines acknowledge the importance of the intent of the inventor and indicate, consistent with the SCC jurisprudence, that "all elements set out in a claims are presumed essential unless it is established otherwise or is contrary to the language used in the claim."

The guidelines place new emphasis on a statutory prohibition under subsection 27(8) of the *Patent Act*, which indicates that, "No patent shall be granted for any mere scientific principle or abstract theorem."

The guidelines also introduce the concept of an "actual invention," which is different to what is claimed:

An element of a claimed invention that is identified as essential for establishing the fences of the monopoly under purposive construction is not necessarily part of the actual invention. For example, an element may be an essential element of a claim only because the applicant intended to limit the scope of the monopoly being claimed to less than what the applicant actually invented. An element may thus be an essential element of the claim because the applicant intended it to be essential even though it has no material effect on the working of the invention. Such an element would not form part of the actual invention because the fact that it has no material effect on the working of the invention means it does not cooperate with other elements of the claimed invention.

Under new guidelines, it is CIPO's "actual invention" and not the "claimed invention" that must meet subject matter eligibility requirements.

This dichotomy could be seen to fit with jurisprudence insofar as a patentee is not required to claim its entire invention. However, the concept of an "actual invention" is not part the SCC's purposive construction, and is difficult to reconcile with the SCC's fundamental principle that the claims define the invention.

CIPO's scrutiny of the "actual invention" against subject matter eligibility requirements also strikes at the SCC's affirmation, in *Shell Oil*, that valid patent claims can be based on a patent-ineligible abstract idea:

A disembodied idea is not *per se* patentable. But it will be patentable if it has a method of practical application.⁶

Computer-implemented inventions

CIPO's new guidelines continue the tradition of omitting computing elements from subject matter eligibility considerations. Purposively construing a computer element as an essential element of a claim is not enough, under the new guidelines, to make the computer part of the "actual invention" to clear the subsection 27(8) hurdle:

The mere fact that a computer is identified to be an essential element of a claimed invention for the purpose of determining the fences of the monopoly under purposive construction does not necessarily mean that the subject-matter defined by the claim is patentable subject-matter and outside of the prohibition under subsection 27(8) of the *Patent Act*. In such a case, it is necessary to consider whether the computer cooperates together with other elements of the claimed invention and thus is part of a single actual invention and, if so, whether that actual invention has physical existence or manifests a discernible physical effect or change and relates to the manual or productive arts.

CIPO indicates that co-operation with other elements is also not enough to make the computer part of the "actual invention" if the computer is merely used in a well-known manner:

In addition, the fact that a computer is necessary to put a disembodied idea, scientific principle or abstract theorem into practice does not necessarily mean that there is patentable subject-matter even if the computer cooperates together with other elements of the claimed invention. **If a computer is merely used in a well-known manner**, the use of the computer will not be sufficient to render the disembodied idea, scientific principle or abstract theorem patentable subject-matter and outside the prohibition under subsection 27(8) of the *Patent Act*. [emphasis added]

The guidelines also continue to restrict computing elements based on "problem" and "solution" considerations, renewing aspects of purportedly abandoned practice, despite the earlier indication in the guidelines that the "problem and solution" approach is not to be followed:

In the case of a claim to a computer programmed to run a mathematical algorithm, if the computer merely processes the algorithm in a well-known manner and the processing of the algorithm on the computer **does not solve any problem** in the functioning of the computer, the computer and the algorithm do not form part of a single actual invention **that solves a problem** related to the manual or productive arts. If the algorithm by itself is considered to be the actual invention, the subject-matter defined by the claim is not patentable subject-matter or is prohibited under subsection 27(8) of the *Patent Act*. [emphasis added]

CIPO's example analyses show that the "problem and solution" approach is very much alive for computer-implemented inventions. In one example, a computer is deemed to form part of the "actual invention" because, in combination with an algorithm, it solves a computer problem. However, an example claim limited to steps of receiving data, processing data, and displaying results is said not to address a computer problem. The "actual invention" is stated to be an algorithm that contravenes the requirements subsection 27(8) of the *Patent Act*.

From a practical viewpoint, the new guidelines appear to preserve the *status quo* at CIPO as far as subject matter eligibility of computer-implemented inventions is concerned.

Medical diagnostic methods

Under its old approach, CIPO would routinely assess medical diagnostic claims from the perspective of either a “data acquisition problem” or a “data analysis problem,” the result being a set of essential elements that was always less than what was claimed. In contrast, the new guidelines indicate all elements set out in a medical diagnostic claim are presumed essential at the outset.

The new guidelines acknowledge that many diagnostic methods specify a physical step of testing or quantifying an analyte. The guidelines state that these elements may co-operate with a correlation feature to form a single “actual invention” that constitutes patentable subject matter. This contrasts favourably with CIPO’s previous approach, which usually held such combinations to be non-co-operative aggregations.⁷

In line with this, two example claims provided distinguish between a step of *measuring* an analyte and a step of merely *receiving information* about the analyte. The former is recognized as a physical step that renders the claim patentable subject matter, while the latter is said to lack required physicality.

On its face, the approach appear to accept, as patentable subject matter, claims routinely objected to under previous practice.

Medical uses

Canada has a judicially created exclusion on the patentability of methods of medical treatment.⁸ This exclusion was established under a compulsory licensing regime that is no longer in force and persists, despite the SCC’s subsequent confirmation of the patentability of medical “use” claims.⁹ At least one commentator has called the distinction between methods of medical treatment and medical “uses” unprincipled and confusing,¹⁰ and the Federal Court of Appeal has twice called for the issue to be reviewed.^{11, 12}

Within this framework, certain lower court decisions have construed medical “use” claims having particular limitations to be impermissible methods of medical treatment. For example, “use” claims limited by dosage ranges have been struck down because they allegedly require the professional skill or judgement of a physician.^{13, 14} However, in recent jurisprudence, claims limited by discrete dosage amounts have been upheld because no choice is required.¹⁵

The new guidelines indicate that mere presence of a dosage (or time) range or amount within a claim is not, by itself, determinative, and state that “[i]t is also necessary to consider whether the exercise of professional skill and judgment of a medical professional is part of the actual invention.”

The presence of dosage range or time period within a claim is said to restrict, prevent, interfere with, or require the exercise of the professional skill and judgment of a medical

professional. On this basis, a dependent “use” claim comprising these features is interpreted as a method of medical treatment that contravenes the judicial exclusion. Whereas CIPO’s previous practice permitted such features in dependent claims, the new practice does not. The basis for this change is unclear.

Summary

Much will be learned in the coming months as CIPO examiners interpret and apply the new guidelines.

Taken at face value, the new guidelines appear to continue the *status quo* for medical “use” claims, and to maintain the difficult and questionable state of examination practices for claims to computer-implemented inventions.

As far as claims to medical diagnostic claims are concerned, the guidelines affirm their subject matter eligibility when a physical step of data acquisition is included in the claim. If borne out in practice, this change should be welcome news to an industry that has faced significant patenting challenges at CIPO since at least 2009.

[BLG’s intellectual property professionals](#) can answer questions regarding how the revised CIPO guidelines may affect your business. Reach out to any of the key contacts below for assistance.

¹ Government of Canada, CIPO (November 3, 2020). [Patentable Subject Matter under the Patent Act.](#)

² Government of Canada, CIPO (November 3, 2020). [Examples of Patentable Subject-Matter Analysis.](#)

³ *Choueifaty v. Canada (Attorney General)* 2020 FC 837 [*Choueifaty*].

⁴ *Free World Trust v Électro Santé Inc* 2000 SCC 66.

⁵ *Whirlpool Corp v Camco Inc* 2000 SCC 67.

⁶ *Shell Oil Co v Commissioner of Patents* (1982), 67 CPR (2d) 1 (SCC) at p14. [*Shell Oil*]

⁷ Boocock, G.R.B. (July 12, 2020). [CIPO’s Examination Guidelines for Medical Diagnostics Claims Turn Three.](#)

⁸ *Tennessee Eastman Co et al v Commissioner of Patents* (1972), 8 CPR (2d) 202 (SCC).

⁹ *Apotex Inc v Wellcome Foundation Ltd* 2002 SCC 77.

¹⁰ Siebrasse, N. (January 19, 2015). [A Rule Without a Principle: Patentability of Methods of Medical Treatment.](#)

¹¹ *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research* 2020 FCA 30 at para 53.

¹² *Cobalt v Bayer* 2015 FCA 116 at para 101.

¹³ *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527, 50 CPR (4th) 321.

¹⁴ *Janssen Inc. v Mylan Pharmaceuticals ULC*, 2010 FC 1123, 88 CPR (4th) 359.

¹⁵ *Merck & Co v Pharmascience Inc* (2010 FC 510).

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