The Canadian Patent Office Releases New Guidelines: The Diagnostics Industry Should Be Cautiously Optimistic

November 4, 2020

By Patricia Folkins, Melanie Szweras, Sandra Marone and Iris Cheung

The Federal Court in the recent decision *Yves Choueifaty v Attorney General of Canada* held that CIPO's "problem-solution" approach in claim construction was "incorrect in law".[1] The Court made clear that determination of subject matter must be based on a purposive construction of the patent claims. The decision was seen as pro-innovation and welcomed by patentees, as CIPO's problem-solution approach created great difficulty for patenting computer-based and medical diagnostic inventions (see our report here).

In response to *Choueifaty*, CIPO has published a guidance document for patent examiners on purposive construction and patentable subject matter. In the guidance document, CIPO focuses in on three particular areas: computer-implemented inventions, medical diagnostic methods and medical uses. In this article, we review the medical diagnostics and medical uses guidance.

In the guidance document, CIPO states, correctly, that the first step to determine subject matter patentability is to construe the claim and it was this step where CIPO had previously gone astray. The guidance makes clear that patent examiners must construe the claim based on purposive construction, which involves identifying the elements of the claimed invention as either essential or non-essential, as set out by the Supreme Court of Canada.[2] Importantly, CIPO explicitly states that all elements set out in a claim are presumed essential, unless it is established otherwise or is contrary to the language used in the claim. Furthermore, where an invention consists of a combination of elements cooperating together, all of the elements of the combination must be considered as a whole when considering whether there is patentable subject matter.

This updated approach is important from the point of view of inventions directed to medical diagnostics. Applying CIPO's now defunct problem-solution approach, patent examiners often determined that the innovation was directed to the discovery of a correlation between a genetic alteration, or a level of an analyte, and a disease or other medical condition. This approach resulted in patent examiners effectively ignoring the elements of measuring or detecting the genetic alteration or analyte, finding those elements to be "inessential". The remainder of the claim was then alleged to be directed to a disembodied idea (i.e. a mental process or having no practical application). Consequently, many worthy diagnostic claims were excluded from patentability. Following the updated guidance, patent examiners will now have to consider all steps identified in a claim to be essential, unless the language indicates otherwise and suggests that for diagnostic methods, the data acquisition and the correlation steps will both be considered when assessing patentable subject matter.

This guidance on diagnostic method claims is bolstered by the examples provided. The first example provided is directed to a claim for a method of diagnosing risk of developing cancer comprising measuring the level of X and comparing the level of X to a reference. CIPO considers this exemplary claim to be patentable subject matter under the updated approach. The rationale is that the measuring element, comparing element and correlation element must cooperate together for the invention to work, and the measuring element satisfies the physicality requirement of patentable subject matter. However, the guidance contrasts this example with one that would not meet the requirement. In the non-patentable example, the first step no longer measures the level of X but instead "receives a report" regarding the level of X. Since the first step no longer has any physicality to it, both steps or elements of the claim could be mental steps, or "disembodied ideas".

The guidance document also goes on to consider the patentable subject matter in relation to medical uses. In Canada, it is well established that methods of medical treatment are not patentable, but medical uses are. A claim that is directed to the use of compound X to treat disease Y is therefore patentable (this is similar to the first example claim provided in the guidance). Patentees, however, must be aware that claims that are directed to a dosage range may be construed to be a method treatment if professional skill and judgment is required to determine the dosage. This is consistent with the decision of *AbbVie Biotechnology Ltd v Canada (Attorney General)* which made it clear that the proper approach is to determine whether the exercise of professional skill and judgment is involved[3] This is not new and is unrelated to the *Chouiefaty* decision. However, the second example claim provided by the guidance document, is a claim that depends on the first example claim and recites a dosage range for compound X. The guidance determines that this necessarily involves the professional skill and judgment of a medical professional and thus the claim is found to be unpatentable.[4] This is contrary to the Office's previous guidance on such claims construed under the problem-solution approach. However, we do not agree that this is necessarily the correct conclusion. As the second example claim depends on a patentable use claim it may be considered a voluntary limit on the "fences of the monopoly" by the patentee as, for example, in *Shire Biochem Inc v Canada (Minister of Health)*.[5]

Choueifaty and the resulting update on guidance on patentable subject matter by CIPO are clearly a win for the diagnostic industry in Canada. However, this may be a step backwards for innovations in respect of medical uses that include dosage regimens.

---

1 *Yves Choueifaty v Attorney General of Canada*, 2020 FC 837 [*Choueifaty*].

2 *Free World Trust v Électro Santé Inc*, 2000 SCC 66; *Whirlpool Corp v Camco Inc*, 2000 SCC 67.

3 *AbbVie Biotechnology Ltd v Canada (Attorney General)*, 2014 FC 1251 [*Abbvie*].

4 The argument in the guidance document is that the claimed dosage range is a limitation that "amounts to a titration regime since the medical professional is expected to monitor individual patients and make adjustments to the dosage and/or dosage period". Here the Office may be improperly reading limitations into the claim as set out in Commissioner's Decision No. 1409. As this issue relates to the separate matter of what claim limitations monopolize the activities of a physician, and thus constitute methods of medical treatment, we have not addressed it in detail in this article.

5 *Shire Biochem Inc v Canada (Minister of Health)*, 2008 FC 538.