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When it comes to what you can patent, patent offices don't always know best

APRIL 26, 2019 5 MIN READ

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When organizations invent something, they must decide whether to pursue patent protection. This decision is a consequential one, as patenting involves disclosing one's invention to the world, and obtaining patent protection may be necessary to secure a company's future. However, sometimes keeping an invention secret is the better approach, particularly where patent protection is unavailable. Guidance from national patent offices helps organizations determine whether or not to patent an invention by indicating what they perceive to be patentable subject matter.

Against this backdrop, the April 2019 decision of the U.S. Federal Circuit Court of Appeals in *Cleveland Clinic Foundation v True Health Diagnostics LLC* (Appeal 2018-1218) is of particular interest to a cross-border audience. In *Cleveland Clinic*, the Federal Circuit considered guidance on patentability rules issued by the United States Patent and Trademark Office (USPTO). The Court reaffirmed that it is not bound by patent office guidance when assessing a patent, even in a situation such as in *Cleveland Clinic*, where the claimed invention was clearly permissible under the USPTO's guidance.

The patents at issue in *Cleveland Clinic* disclosed diagnostic methods consisting of using known techniques to measure the amount of leukocyte and myeloperoxidase levels in blood in order to predict the likelihood of a patient developing or having cardiovascular disease. The Federal Circuit found the patents invalid as covering an ineligible natural law. The Court applied jurisprudence stating that the idea of testing for a naturally occurring bio-marker to predict the likelihood of a patient developing or having a particular disease condition was merely a principle and "[a] principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."

But what of the USPTO guidance suggesting that such an invention was patentable?

Cleveland Clinic had argued that the claims at issue were patentable subject matter based on an example of patentable subject matter including similar claim language contained within a USPTO guidance document. The Federal Circuit responded:

While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.

This case serves as a lesson to patent applicants that patent office policy is not the final word. Where applicants perceive a difference between court jurisprudence and patent office

guidance, the jurisprudence takes priority. Where a patent is issued based on erroneous guidance, as in *Cleveland Clinic*, the patent may not be enforceable in court. Conversely, where a patent is rejected based on erroneous guidance, the applicant may have recourse to challenge the patent office's decision in court.

As in the United States, Canadian courts are not bound by guidance documents issued by government agencies, such as the Canadian Intellectual Property Office (CIPO). Guidance documents are supposed to be consistent with Canadian jurisprudence, but there is often room for disagreement regarding what cases are controlling and how jurisprudence is to be applied in situations involving new fields of technology.

The current Canadian treatment of patentable subject matter for diagnostic methods flips *Cleveland Clinic* on its head. Canadian courts have issued no guidance regarding the subject-matter eligibility of patent claims to methods of medical diagnosis; however, CIPO has issued stringent guidance restricting approval of this claim type.

The CIPO guidance document PN2015-02 limits patentability of medical diagnostics to those that solve a "data acquisition problem" (i.e., new techniques for obtaining biological data) or a "data analysis problem" (i.e., new methods for analyzing biological data obtained using known techniques).

On its face, this guidance document construes patent eligibility more narrowly than the Supreme Court of Canada jurisprudence in *Shell Oil Co v Commissioner of Patents*, [1982] 2 SCR 536. In *Shell Oil,* the Supreme Court stated the following in deciding that a new use for a known compound constituted patentable subject matter under Canada's *Patent Act*:

The appellant's discovery in this case has added to the cumulative wisdom on the subject of these compounds by a recognition of their hitherto unrecognized properties and it has established the method whereby these properties may be realized through practical application. In my view, this constitutes a "new and useful art" and the compositions are the practical embodiment of the new knowledge.

Another criticism of the CIPO guidance has been that it approaches patent interpretation in a manner different from the Supreme Court's approach in *Free World Trust v Électro Santé Inc.*, 2000 SCC 66, by de-emphasizing essential elements of patent claims when considering subject-matter eligibility.

Over the past several years, as patent applications directed to medical diagnostics have languished at CIPO, applicants have argued that CIPO's guidance is overly restrictive and inconsistent with *Shell Oil* and other Supreme Court and appellate decisions. These arguments have been met with rejection and delay. To date, no patent applicant has challenged CIPO's decision in the courts.

The *Cleveland Clinic* decision should remind applicants that patent office guidance does not bind the courts, and that appeal of patent office decisions from time to time is necessary to generate the jurisprudence that allows the patent system to function smoothly. Nowhere would this be more helpful than for medical diagnostic patents, where new jurisprudence interpreting *Shell Oil* and the applicability of *Free World Trust* to questions of patentable subject-matter eligibility would be welcome to all.

Entrepreneurs who develop new and innovative medical diagnostics want fair patent protection in exchange for providing improved healthcare. This bargain is what the government intended to recognize by enacting the *Patent Act*. As technologies advance, patent law must be clear enough to enable entrepreneurs to understand when the patent bargain is available to them. Occasionally, when clarity is lacking, someone needs to rock the

boat.

For more information on Canadian patents in the life sciences, contact Nathaniel Lipkus or Yulia Konarski or another member of Osler's leading Life Sciences Intellectual Property team.