Patenting Diagnostic Methods in Canada: A Glimmer of Light From our Southern Neighbours?

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Personalized medicine, where prevention, diagnosis, and/or treatment of disease is tailored to a particular individual, is becoming more and more prevalent as scientists uncover new connections between biomarkers and illnesses. However, developments in the Canadian Intellectual Property Office (CIPO) over the last several years have made it increasingly difficult to patent technologies related to molecular diagnostics. This article reviews the current position of CIPO with respect to diagnostic patent claims and looks at recent developments in the United States.

At issue are patent claims directed to methods of diagnosing a particular disease in a subject where the inventors have identified a new association between a known biomarker and the disease. Such claims are now routinely objected to by Canadian patent examiners as being directed to non-patentable subject matter, despite meeting the other requirements for patentability, namely novelty, non-obviousness and utility.

The Canadian Patent Act defines an invention in section 2 as “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter”. A statutory exception is set out in section 27(8) of the Patent Act, which provides that a patent shall not be granted for “any mere scientific principle or abstract theorem”.

The patent eligibility of various types of subject matter has also been considered by the Canadian courts over the years. However, there have been no decisions specifically speaking to the patent eligibility of molecular diagnostic methods. Rather, current Canadian Examination practice with respect to diagnostic methods is based on a series of Practice Notices released by CIPO starting in 2013.

Practice Notice 2013-02 was published in 2013 following a Federal Court of Appeal case related to the patent eligibility of business methods (Amazon.com v. Attorney General (Amazon.com)), and provides guidance on the purposive construction of patent claims. The 2013 Practice Notice describes using a “problem-solution” approach to inform a purposive construction of the claims, including limiting the essential elements of the claims to those that solve the identified problem.

In June 2015, CIPO published a Practice Notice setting out procedures for examiners to follow when considering the patent eligibility of diagnostic method claims (Practice Notice 2015-02). This Practice Notice has now been incorporated into the Canadian Manual of Patent Office Practice (MOPOP).

Both the 2015 Practice Notice and MOPOP (referred to herein as the “diagnostic guidelines”) instruct examiners to identify the problem the inventors set out to solve and the solution provided by the invention and determine whether elements in the claims are essential (provide a solution to the identified problem) or non-essential (do not provide a solution to the identified problem). If the essential elements are required solely to solve a “data analysis problem” as opposed to a “data acquisition problem”, the claim will be refused as directed to non-statutory subject matter. Examples of “data analysis” problems include the identification of a new and non-obvious correlation, for example between a known biomarker and a disease state.

The identification of essential elements by way of a problem/solution analysis is generally considered to be inconsistent with the teachings of the Supreme Court in Free World Trust v. Électro Santé Inc. (Free World Trust) and Whirlpool Corp. v. Camco Inc. (Whirlpool). These cases confirmed the legal principles of claim construction in Canada including a single,
purposive approach to claim construction. Under a purposive claim construction, adherence to the language of the claims is promoted, while recognizing that the claims must be read in an informed and purposive manner.

The “data acquisition/data analysis” division which is emphasized in the diagnostic guidelines also has no basis in Canadian case law. Arguably, as long as the test for statutory process under section 2 of the Patent Act is met, then the subject-matter must be considered patent eligible, irrespective of any notion of “data acquisition” or “data analysis”.

Practically, the diagnostic guidelines direct Canadian patent examiners to reject most patent claims directed to diagnostic inventions and has made it difficult to secure patent protection for novel, non-obvious and useful diagnostic inventions in Canada.

Diagnostic claims in the United States also encounter similar challenges to those in Canada. Indeed, the dearth of Canadian case law, and the close timeline between the United States and Canadian prohibitions against patenting medical diagnostics have led some commentators to suspect that CIPO’s policy is informed at least in part by the position of the United States.

In two decisions, Mayo Collaborative Servs. v. Prometheus Labs., Inc (Mayo)[3] and Alice Corp. Pty. Ltd. v. CLS Bank Intl (Alice)[4], the US Supreme Court developed a two-step test to determine patent eligibility. Step one of the test asks whether a patent is directed to ineligible subject matter, namely a law of nature, natural phenomenon, or abstract idea. If it is, then the second step determines if the patent contains an element or combination of elements sufficient to establish that the claim as whole amounts to “significantly more” than the judicial exception.

Diagnostic method claims have faced challenges in the wake of the Mayo and Alice decisions with courts holding that a correlation between a biomarker and a disease state is an ineligible “law of nature”. Claims are only held to be patent eligible where they include additional limitations that add “significantly more” to the abstract idea, namely activities that are not well-understood, routine and conventional in the field.

Within the last year however, there have been some early indications that the landscape in the United States with respect to diagnostic claims may be changing.

In a recent decision, Vanda Pharmaceuticals v. West-Ward Pharmaceuticals (Vanda)[5], the United States Federal Circuit held that a diagnostic claim which also recited an administration step was patent eligible. The Court held that while the inventors recognized relationships between a drug and a biomarker, what they claimed was an application of these relationships. Following the Vanda decision, the United States Patent and Trademark Office (USPTO) issued a memo to examiners providing that method of treatment claims that apply natural relationships should be considered patent eligible and that it is not necessary for the method of treatment to include non-routine or unconventional steps to be patent eligible[6].

Including a treatment step in a diagnostic claim could also be a useful approach for trying to overcome subject matter objections in Canada, although a few caveats exist. First, as methods of medical treatment are not patentable in Canada, such a claim would need to be carefully drafted to avoid any active steps of medical treatment. In addition, a diagnostic claim that also includes a treatment step will likely be of lower value to a patentee given that divided infringement is an open question in Canada. In particular, it is unclear whether a claim that includes steps of both diagnosis and treatment would be infringed in Canada when two different parties perform each of the steps (divided infringement is also an issue in the United States, although there has been some recent US case law that may make it easier to establish a case for divided infringement).

Another positive development in the United States is the case of Berkheimer v. HP Inc (Berkheimer)[7] involving a computer implemented invention. Here, the Federal Circuit held that when analyzing the second step of the Alice/Mayo test, the question of whether the elements of a claim in addition to those reciting judicial exceptions represent “well-understood, routine, conventional activity” raises a disputed issue of fact. A subsequently issued memo to examiners from the USPTO sets out that in light of Berkheimer, a conclusion of “routine and conventional” can only be reached where the elements at issue are “widely prevalent or in common use in the relevant industry” and not merely found in the prior art[8]. The teachings of Berkheimer could also potentially be useful in Canadian prosecution to rebut objections from Examiners that claimed steps of “data acquisition” are simply part of the common general knowledge, and therefore not relevant to a determination of subject matter eligibility.

Further, the Director of the USPTO recently made remarks stating that new guidance on subject eligibility may be coming
Director Iancu spoke against the conflation of patent eligibility with the other patentability requirements of novelty and nonobviousness, noting that the "proposed new guidance would explain that Supreme Court jurisprudence taken together effectively allows claims that include otherwise excluded matter as long as that matter is integrated into a practical application". Most recently, two US senators have invited a number of companies, industry groups and intellectual property experts to a closed-door meeting in mid-December to discuss possible legislation to reform the standards for patent eligibility in the US.

While a precedent-setting case on diagnostic methods would be the ideal way to clarify the patent eligibility of diagnostic method claims in Canada, such a case is not currently on the horizon. In the meantime, it is hoped that CIPO will act to either amend or rescind the diagnostic guidelines. If the present trend in the United States towards enlarging the scope of patent eligibility of diagnostic claims continues, it may be more likely that CIPO will reconsider their current position to bring the office more in line with other jurisdictions. This would be welcome news for those trying to bring new and potentially life-saving diagnostic tests to the Canadian market.

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[1][2000] 2 SCR 1024.


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