

Canadian Intellectual Property Office (CIPO) Publishes Diagnostics Patent Notice

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On June 29, 2015, CIPO publicly released a brief Patent Notice to Examiners regarding examination of medical diagnostic methods (*Examination Practice Respecting Medical Diagnostic Methods – PN 2015-02*). This Practice Notice provides some long-awaited guidance for Examiners on how to construe diagnostic method claims. CIPO undertook a review of its diagnostics examination practices following the Federal Court of Appeal decision in the business methods patent case *Canada v Amazon.com Inc.*, 2011 FCA 328. Prosecution of some diagnostics applications had been postponed. CIPO intends to give priority to those applications which have been waiting the longest for a response, now that the Patent Notice is in effect.

Consistent with previous guidance documents, Examiners are to purposively construe the claimed subject matter with involves using a problem-solution approach and determination of the essential elements of the claims. Claims are then assessed to see if they represent statutory subject matter.

The Notice directs Examiners to identify the problem to be solved, guided by the description as well as their understanding of the common general knowledge (“CGK”) in the art (and not by reference to the closest prior art). PN 2015-02 also introduces that it may be appropriate to consider the problems generally sought to be solved in diagnostic methods as: 1) “data acquisition problems” and 2) “data analysis problems”. Factors in the description are to be assessed to identify whether the problem is a data acquisition problem (e.g. a *non-CGK* analyte and method of identifying or quantitating the analyte is a data acquisition problem) or a data analysis problem (e.g. an emphasis on the discovery of an allegedly new correlation between a condition and an analyte that is CGK with a relative absence of technical details pertaining to how to acquire the data about the analyte is a data analysis problem). An indication in the application that practical problems were overcome relating to how data about a CGK analyte is obtained can suggest that the problem is a category 1) data acquisition problem and the absence thereof is suggested as an indication that the problem is a category 2) data analysis problem. However as noted “CGK that suggests that the problem was something different than emphasized in the application must be considered by the examiner when identifying the *actual problem solved by the invention*. This seems to suggest that an Examiner may be able to identify a different problem than the problem identified in the application.

Once the problem is identified, Examiner is to identify the solution to the problem. For example the solution for a “data acquisition problem” can be provided by elements that provide a means to acquire data about the analyte such as directed to detecting a protein in a sample or measuring a concentration of a substrate.

The solution for a “data analysis problem” can be provided by elements that relate to the analysis of acquired data for the purpose of providing diagnostic meaning for example relating the presence of protein X from said test sample to a diagnosis of whether the test sample is from a subject suffering from disease Y.

Once the problem and solution are identified, the Examiner is to use purposive construction to determine the meaning of the elements and whether the elements are essential. The Examiner is then directed to consider which elements are essential to the solution identified and whether all of the elements required for providing the solution are included in the claim.

A problem solution approach is not clearly grounded in Canadian law and directing Examiners to use a problem-solution approach may be contrary to the principles affirmed in *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 (CanLII), which asserts that claim language should have primacy and components of a claim are presumed to be essential unless the contrary is indicated in the patent.

It would also seem clear that data acquisition problem solutions are more likely to be patentable: “[w]here a physical step of data acquisition is identified as an essential element of the construed claim, the claimed subject-matter will likely be statutory”. In contrast, “a diagnostic method claim construed as consisting solely of essential elements that are disembodied (e.g. mental processes lacking physicality, no practical application, etc.) will be identified as defective” and not patentable subject matter.

This threshold could be positive for diagnostics patenting, compared to the US environment, if interpreted reasonably and fairly to

Applicants. Physical steps for data acquisition appear to be important for to patent eligibility. Diagnostics claims could also be considered unpatentable if they contain patent-eligible subject matter, but also include non-permissible matter, such as a method of 'surgery' or medical treatment step. How this Notice will be interpreted in practice remains to be seen but as examination of postponed diagnostic method applications is expected to be prioritized, a clearer understanding of what types of claims the patent office is willing to allow should be available soon.