CIPO’s Examination Guidelines for Medical Diagnostic Methods Turn Three

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This article provides a retrospective on three years of experience with the examination guidelines established by the Canadian Intellectual Property Office for patent applications filed for medical diagnostics inventions, including personalized medicine and *precision medicine technologies*.

June 29, 2018 marked three years from the publication of PN2015-02, a practice notice that established new examination guidelines to be followed by patent examiners of the Canadian Intellectual Property Office ("CIPO") for the assessment of claims to medical diagnostic methods, including *personalized medicine* and *precision medicine* technologies.[1] According to the practice notice, the so-called “essential elements” of a diagnostic claim are determined based on the identification of either a data acquisition problem or a data analysis problem in the state of the art. This problem is identified retroactively by an examiner, and only claim features that solve the delimited problem are deemed essential.

Thus, if the biomarker and the way of measuring it are determined to be “common general knowledge” ("CGK") and the correlation is discovered, CIPO states that there was no pre-existing problem relating to data acquisition. CIPO then finds that a data analysis problem was addressed, and limits the essential elements of the claim to the correlative features that directly address this problem. These are then said to be patent-ineligible mental steps.

In the alternative, CIPO will assert that a data acquisition problem was addressed, thereafter disregarding the correlation as supposedly “non-essential”. In this case, patent-eligible subject matter will be found, but, unless the analyte or means for its measurement are independently novel and inventive, what is left is the step of measuring a known analyte in a conventional way, unlimited by application. As will be seen, objections for lack of novelty and/or inventive step follow.

CIPO’s approach completely subordinates the claim language to a hindsight assessment of the point of discovery. This is inconsistent with jurisprudence from the Supreme Court of Canada ("SCC") concerning claims construction, which acknowledges the primacy of the claim language, and which determines essentiality based on material effects to the working of the invention.[2,3] The approach contravenes

the SCC on subject matter eligibility, and its pronouncement that the Commissioner of Patents is not permitted to refuse patents on the basis of public policy considerations independent of the *Patent Act*.[4,5]

The examination guidelines use the SCC-endorsed term “purposive construction” as labelling. The actual approach bears no resemblance whatsoever to the SCC’s purposive construction.[6] As discussed by UNB Professor of Law Norman Siebrasse in his blog post "Diagnostic Methods at CIPO", the meaning ascribed to a diagnostic claim by CIPO changes based on the inventive concept and therefore equates, in practical terms, to an older contribution analysis approach. This is starkly evident when one considers that two identically worded claims will be given interpretations that do not even overlap if the analyte is novel in one case, and known in the other.

The change in examination practice was not based on any change in the law, and has come in for criticism recently in the national press, including the *National Post* and *The Globe and Mail*.

Despite this, the examination guidelines were codified into Chapter 17 of CIPO's examination manual, the *Manual of Patent Office Practice* ("MOPOP") in November 2017.

Lessons from the Past Three Years

Three years have taught us a great deal about CIPO’s examination guidelines, including many details that are not apparent in official published texts.

Office actions have provided information about the practical application of the guidelines. One 2016 webinar involving CIPO representatives explained how some decisions about the analyte are made. In addition to this, material concerning the examination guidelines has been obtained through Canada’s *Access to Information Act* and has been posted online anonymously.[7] This includes CIPO training presentations, training manuals, bulletins, and internal emails, which together have illuminated many more aspects of the practice. Some of these points are discussed below, with hyperlinks to relevant source documents.

- **CIPO views SCC jurisprudence as inapplicable to examination** — As previously reported, slide 12 of a March 2017 training presentation (.pptx file) indicates that examiners are not required to follow the SCC on claims construction, including determinations of essentiality. In line with this, a revised version of CIPO’s Basic Training Manual for examiners released in November 2017 no longer references the landmark *Whirlpool* and *Free World Trust* decisions of the SCC for claims construction. Instead, version 12 indicates in Section 4.1 that essentiality is to be determined based on the problem-and-solution approach established by the examination guidelines (compare this to page 269 of version 11).[8]
- **Diagnostic methods are singled out for a special claims construction** — Slide 69 of CIPO’s fall 2015 training presentation states, “Any method of detection + correlation must be analyzed using this practice”.
- **Some elements of a diagnostic claim will always be found to be non-essential** — Practice Notice PN2015-02 states, “...it *may be appropriate* to consider that an inventor is generally looking to solve a ‘data acquisition problem’

and/or a ‘data analysis problem’,” (emphasis added), suggesting a degree of flexibility. However, experience of the practice indicates that only one of these two problems — never both together, and never a diagnostic problem — will *always* be identified for diagnostic claims. This means that only a subset of elements is ever considered to be essential for such claims. Examiner’s Bulletin 2015-P13-K confirms this implicitly in stating, “Claims that are determined to NOT be diagnostic method claims should not be split into data acquisition and data analysis components…”.

- **CIPO does not recognize diagnostic problems and solutions** — Slide 32 of the fall 2015 training presentation states, “Why is the problem not the *need for a diagnosis*?;The solution to the diagnosis is the correlation, not the data acquisition steps...” (emphasis original).
- **This is because CIPO views diagnostic methods as aggregations** — In training presentations, diagnostic methods are characterized as aggregative combinations of data acquisition and data analysis features, termed “building blocks”. The fall 2015 training presentation states on slides 8 and 9 that a combination of data acquisition (measurement) and data analysis (correlative) features usually has an aggregative nature, and not a cooperative one, because, “correlation of data with a disorder does not have a material effect on how the data is acquired”.[9] It is stated that this is, “Not a new use of an analyte, but a new use of the ‘information’ about that analyte”. Slide 71 states, “…the method cannot qualify as a use of the analyte because the analyte does not produce the material effect.” A training presentation from Oct-Nov 2017 (.pptx file) reiterates on slide 9, “Remember the aggregative nature of these claims.”
- **The examination guidelines do not only apply to method claims** — Despite the title of the original practice notice suggesting application to diagnostic methods only, the examination guidelines are applied to all claim types involving diagnostic-type correlations. Examiners’ Bulletin 2015-P13-K states that use, kit, and array claims are subject to the guidelines, and objections to apparatus claims have been observed in office actions. The bulletin states “...transforming a [diagnostic method] claim into a use claim does NOT transform the claim into a non-[diagnostic method] claim — in a purposive construction, the claim will include the same essential elements…”. Slide 69 of CIPO’s 2015 training presentation states that the guidelines also apply to non-medical fields.
- **However, screening methods are excluded from the examination guidelines** — Slide 12 of the Oct-Nov 2017 training presentation (.pptx file) explains that screening methods are exempt from the practice: “Screening methods or measuring methods generally feature practical steps that provide information; They include methods of determining the presence/absence of a substance, of measuring an attribute or of identifying a substance that has a particular property; When a claim is determined to be a screening or measuring method, the [diagnostic method] practice should not be applied.” The distinction between a diagnostic and screening methods apparently hinges on the presence or absence of an additional correlation step, as explained on slide 13: “Typically, a [diagnostic method] claim will include a further step where a correlation is made from the information; This is not a strict rule however — a claim may have an “if/then” statement and not be a [diagnostic method].” Slide 14 states, “There will be claims that fall in a ‘grey area’; Claim preambles can be misleading…”. Examiners are advised that, “It is valuable in these cases to consider [purposive construction] as if the method is a screening method and another as if the method is a [diagnostic method] to see if and how your conclusions would differ (but don’t put both in a report).”

- **Applicants may face alternative objections that reach opposite conclusions** — For diagnostics inventions in which the analyte is not *per se* novel, examiners typically conduct the analysis from the perspective of a data analysis problem first, and raise subject matter eligibility objections. However, Examiners' Bulletins 2015-P13-K and 2016-P5-B advise that the analysis should also be conducted from a data acquisition viewpoint if an applicant insists a problem involving measurement of the analyte was addressed. Applicants will now routinely see both types of objections — reaching opposite conclusions for essentiality, subject matter eligibility, and novelty and inventiveness — in a single office action.
- **Patent-eligible subject matter may be found if a claim involves a "non-CGK" sample type, a "non-CGK" combination of known biomarkers, or a "non-CGK" selection from a public database** — In a June 2016 webinar, CIPO representatives stated that measurement of a known analyte in a "non-CGK" sample context could lead to identification of a data acquisition problem, and to a finding of patent-eligible subject matter. The same was stated of a "non-CGK" combination of biomarkers. The latter point has a basis in slide 68 from the fall 2015 presentation. Slide 17 from the Oct-Nov 2017 training presentation (.pptx file) states that the key considerations for combinations of biomarkers are, "(A) whether a means for measuring all of the markers together was CGK; (B) whether it was CGK to specifically acquire data about those markers (and disregard data about all other markers)." Slides 19 and 20 indicate that disclosure of SNPs or gene sequences in a database does not automatically render a feature "CGK" according to CIPO because "A database does not teach looking specifically at particular genes or SNPs (or a subset thereof)."
- **However, a finding of subject matter eligibility usually results in prior art objections** — When a data acquisition problem is identified, prior art objections usually follow because the correlative features are excluded from consideration, leaving measurement of the analyte unlimited by any application. Therefore, a finding of subject matter eligibility generally results in a simultaneous finding of anticipation and/or obviousness. Slide 72 of CIPO's fall 2015 training presentation states two alternatives: "Data analysis: non-[statutory] and not compliant with Section 2 [of the *Patent Act*]" and "Data [acquisition]: statutory, but patentable only if the steps [of acquiring data] by themselves are novel and inventive." Slide 24 of the Oct-Nov 2017 training presentation (.pptx file) states regarding obviousness, "Where the examiner has concluded there is a data acquisition problem, no data analysis elements will be part of the [inventive concept] (and *vice versa*)." Again, the solution equates to the inventive concept. Slide 67 from the fall 2015 training presentation instructs examiners to assume that a "borderline CGK" reference is not CGK, but then adds, "But then consider if it is inventive." Bulletin 2015-P9-H states that acceptance of a reference as non-CGK, "will likely result in a strong obviousness argument as you will likely have found several relevant prior art documents."
- **Unless an applicant has discovered an analyte or means for its measurement, examination will be difficult.** It is worth highlighting the above-noted phrase, "patentable only if the steps of acquiring data by themselves are novel and inventive". CIPO requires an inventive data acquisition feature in order to sustain a simultaneous finding of patent-eligible subject matter and inventiveness. Indeed, Example 1 of its fall 2015 training presentation, in which patent-eligible subject matter is identified, involved a scenario in which the inventors had discovered an analyte. Allowance of a diagnostic claim therefore signals that, at minimum, the step of measuring the analyte is probably

independently patentable. Therefore, applicants who achieve allowable diagnostic claims should consider if it is also worthwhile claiming the analyte or the means for its measurement outright.

- **Claims are always construed with an eye to the prior art** — The training material differentiates between CGK and prior art, stating that CGK must be widely accepted (*e.g.*, see slide 10 of the Oct-Nov 2017 training presentation and Examiners' Bulletin EB 2015-P9-H). However, the distinction is rendered quite meaningless by the prescribed approach. The examiner's assessment so-called "CGK" focuses on claim sub-quantities (measurement of the analyte and the correlation). This approach *never* considers what is widely accepted in the actual medical diagnostic field of the invention, and therefore always equates to a much more expansive search of prior art that is undertaken with full knowledge of the invention and all its features. Therefore, claims are always construed based on the prior art, in contravention of the SCC.[10] In an email dated April 2014, first reported by IPKat, the Assistant Commissioner of Patents wrote, "…for me the line between CGK and prior art is artificial (risk for inconsistencies [sic] in examination) to make a determination on [Section 2 of the *Patent Act*]...".
- **The asserted POSITA for diagnostic inventions is a hindsight assemblage that negates the possibility of inventive work** — It is common for applicants to face problematic definitions of the notional person of ordinary skill in the art ("POSITA"). Example 1 of MOPOP 17.03.04e states, "The POSITA is a team including an oncologist, an endocrinologist, a geneticist, a molecular biologist and a medical technologist." Examiners often assert that the notional POSITA is a team that includes a clinician working on the *specific* disease, a scientist working on the *specific* analyte, and one skilled in the art of laboratory test development. Not only is the POSITA a team, but the combined specific knowledge of each team member is then considered together to define the problem. Bearing in mind that diagnostic inventions *by definition* associate that which was previously unassociated, the aggregate POSITA with its CGK fusion is unrealistic. To use a simple scenario, the clinician would more realistically be thinking, "I wonder what genetic defect causes this disease." The molecular biologist would be thinking, "I wonder what the function of this gene is within the cell." Depending on the perspective, each faces a different problem. CIPO's definitions are only relevant with a hindsight view of things and appear to nullify the possibility of diagnostic inventions.
- **An applicant's own disclosure is routinely cited against it** — Slide 40 of the fall 2015 training presentation provides the following tip: "If the applicant has not done any work or invested any effort in the 'data acquisition side' of the diagnostic method, it is not likely that is a problem that is being solved." Example 2 of the fall 2015 presentation considers a situation in which the inventors disclosed use of an existing commercial test, and ultimately concludes that no data acquisition problem was addressed. Applicants will often see passages of their own disclosures cited to support allegations that their claims are patent-ineligible because data acquisition must have been routine (and therefore "CGK") if it could be carried out in the various ways described. Alternatively, the references in the applicant's disclosure — despite this being drafted by the inventors *with* after-the-fact knowledge of the invention — will be interpreted as direct admissions of "CGK", as CIPO understands it.
- **CIPO's advice to its examiners has changed over time** —The fall 2015 training presentation a model argument on slide 22 reading. On the subject of essentiality, the argument read in part, "The steps are not **essential** to solve the problem defined above, they are only **required** for its operation" (emphasis

original).This curious statement, differentiating essential from required, appeared in stock wording in office actions from 2015 to 2017 before suddenly vanishing. Slide nine of the training presentation from Oct-Nov 2017 (.pptx file) explains why this is so, stating, “The term ‘required’ should not be used in [diagnostic method] reports to describe the elements of the alternate problem; If you’re focusing on the data analysis problem, the elements of the data acquisition are NOT ‘required but non-essential’ and vice-versa.”

- **CIPO’s official position is that “a very small subset” of applications is impacted** — On March 23, 2018, the Assistant Commissioner of Patents wrote an email to the acting head of the Canadian Institutes of Health Research ("CIHR"), the major federal funding agency for health and medical research. The assistant commissioner stated, "Applying CIPO's framework for examination to diagnostic methods does mean that some of the methods are not patentable... **In a very small subset of methods** it could also arise because the diagnostic method relies on the discovery that result of a previously known diagnostic test are now applicable to a different disease" (emphasis added). The statement is difficult to reconcile with experience, and with informal statements from CIPO employees indicating that no diagnostic claims are to be allowed. The email discusses novelty and inventiveness requirements, but does not acknowledge the *entirely unconventional* prior art objections raised only to diagnostic methods under CIPO’s examination guidelines under the “data acquisition problem” approach.
- **Some CIPO policymakers expressed concerns about the impact of patents on existing diagnostic tests** — The March 2018 email from the Assistant Commissioner, noted above, stated of situations in which the analyte was previously measured for some other purpose, “In such a case the discoverer has not invented a diagnostic test since the particular test is already known and may already have been commercially developed.” The Assistant Commissioner uses the measurement of the analyte alone for judging equivalency between tests. Similar views were expressed in 2013 discussions, in which one CIPO employee stated, “Did the inventor do her own work or did she simply look at a database exploiting the work of others?” In deliberations, this employee suggested considering “reverse infringement” and “inherent anticipation” of claims by a preexisting diagnostic test. Another employee was described as having, “issues with what happens in the marketplace if two patents issue where the same marker is used to detect different diseases…”.
- **However, most CIPO employees were apparently opposed to the premise of the current examination guidelines**— Excerpts from the material obtained under the *Access to Information Act* ("AIA") show that in November 2011 it was noted that examiners in the biotechnology and chemistry divisionals and their section heads were not in agreement with CIPO’s interpretation of case law. In 2012, a member of the Patent Appeal Board asked, “Why is [it] that [CIPO] must have the liberty to create new legal principles?” The AIA material shows strong concerns expressed by several individuals in 2013 and 2014. The Division Chief for biotechnology wrote in 2014 of an example scenario in which a method involving known biomarker was said to be patent-eligible, “...I'm happy... to read that a diagnostic method that relies on a known diagnostic tool (marker) for a first disease is patentable subject matter when the method is directed to diagnosing a second (or subsequent) disease... This has been my point in the meetings we had on diagnostic methods and is the position of the biotechnology division and those in the chemical division who work with diagnostic tools and methods. It is not, and never has been, exclusively my position or my approach — it is the

position of the examination divisions that work with diagnostic method applications as represented by the section heads in these divisions." However, for a similar scenario in which patent-ineligibility was found, the Division Chief stated, (as reported in *The Globe and Mail*) of "There is absolutely no basis in law for this and no reason why CIPO should take this approach. It is unexplainable, unsustainable and contrary to the decision of the Supreme Court in [*Shell Oil*]."

- **Final Actions are rare** — Despite the intransigent nature of objections raised under the examination guidelines, the author is not aware of any Final Actions having issued at the time of writing.

The Impact of CIPO's Examination Guidelines on Healthcare Innovation in Canada

At best, CIPO's guidelines create unnecessary uncertainty for business. At worst, they remove Canadian patents from the equation completely for an entire sector of health care. With little prospect of a proprietary position in the Canadian market, domestic innovators and start-ups are disadvantaged and face the daunting prospect of commercializing in an unfamiliar foreign market first. Foreign innovators, meanwhile, must decide whether Canada is worth their investment, for instance, to meet regulatory requirements.

In June 2015, CIPO provided an Advice to the Deputy Minister of Industry, in which it was stated that any party that disagreed with its then forthcoming practice notice was free to challenge it in court. Three years on, it would be unfortunate for Canadians if CIPO still perceives a court challenge to be necessary for the correction of errors. Of course, final actions would also be required before any such process could commence, meaning that CIPO is the gatekeeper of which applications may come before the courts.

Meanwhile, Canadians are funding research initiatives that appear to be undermined by the guidelines, including CIHR's recent $2 million "Antimicrobial Resistance: Point of Care Diagnostics in Human Health" and $4.5 million "Research Projects on Personalized Medicine" funding opportunities. Both include commercialization aims. Both will yield innovations that cannot easily be commercialized under CIPO's examination guidelines. Two branches of government therefore seem to be at cross purposes, to the detriment of the taxpayer. It is also unclear how the policy making of CIPO — a program within Industry, Science, and Economic Development ("ISED") Canada — fits into that ministry's wider Innovation Agenda, and with Canada's Intellectual Property Strategy announced this past April.

Hope on the Horizon

On April 6, 2018, the Intellectual Property Institute ("IPIC") of Canada, under the guidance of President Grant Lynds, announced that IPIC and CIPO had agreed to initiate a joint working group to further study the issues around medical diagnostic patent claims. This is a welcome development for patent applicants, who have waited for a fair examination in Canada since 2009, when CIPO first invented contribution analysis. It is hoped that these joint efforts will mean that the current examination guidelines for medical diagnostic methods do not see another birthday.

[1] The term “diagnostic method” will be used throughout as an umbrella term to encompass any claim involving measurement of an analyte and correlation to a biological trait.

[2] *Whirlpool Corp. v. Camco Inc*., 2000 SCC 67 [*Whirpool*].

[3] *Free World Trust v. Électro Santé Inc*., 2000 SCC 66 [*Free World Trust*].

[4] *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 SCR 536.

[5] *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76 at par 144.

[6] The author's review article is available at https://ssrn.com/abstract=2809891

[7] https://ipflyonthewall.wordpress.com/

[8] *Free World Trust* is referenced in Section 4.15.4.2 of version 12, but merely to say that interpretation of claims, for computer-related inventions, cannot begin and end with the claim language.

[9] That this is true of any method involving *ordered* steps is not addressed.

[10] *Supra* note 2 at para 49.

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