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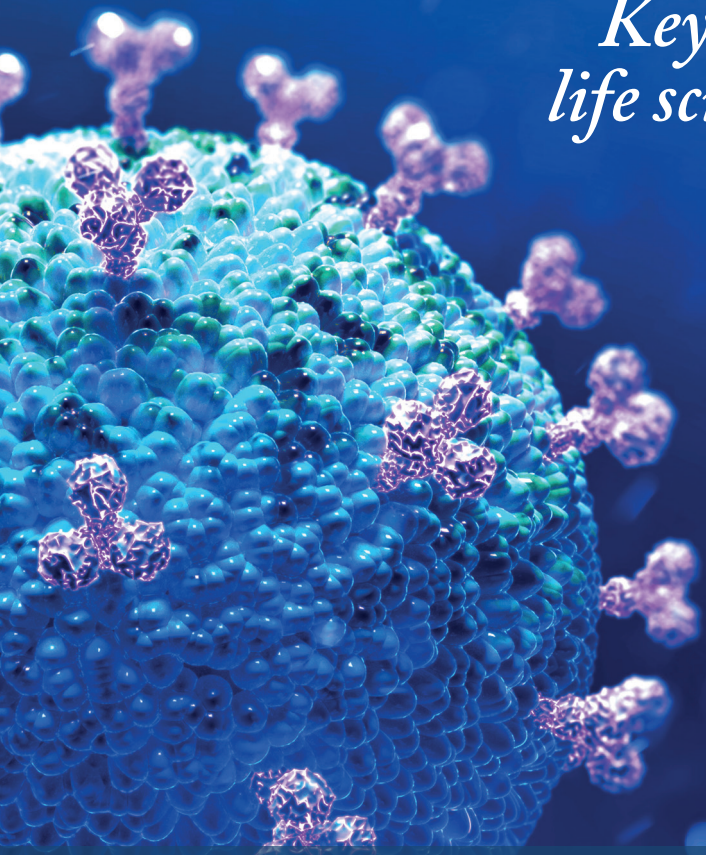

Patenting personalised medicine in Canada: navigating choppy waters

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Jennifer A Marles and Christina SW Kwok

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Patenting personalised medicine in Canada: navigating choppy waters

By **Jennifer A Marles** and **Christina SW Kwok**

Personalised medicine is the future of healthcare delivery, allowing healthcare practitioners to provide a targeted therapy regimen that is likely to be effective for a particular individual. Underpinning much personalised medicine are diagnostic methods which enable healthcare practitioners to evaluate the specific characteristics of a given patient and select a course of therapy accordingly. Personalised medicine often relies on establishing a correlation between one or more markers and the existence of a specific disease or a response to a particular treatment.

Encouraging investment in technologies that facilitate the delivery of personalised medicine through the patent system is key to ensuring that this field continues to grow and thrive. However, Canada falls short in this area due to the current administrative policies of the Canadian Intellectual Property Office (CIPO). It is therefore important to proceed cautiously in patenting such technologies in Canada. This chapter will guide the reader through the types of diagnostic method that are likely to be considered patentable under the current regime and which may potentially encounter patentability issues in Canada.

Protecting diagnostic methods

Regarding how problems with protecting diagnostic methods arise, methods of medical treatment have long been considered unpatentable in Canada. Although this prohibition originated from a now-repealed section of the Patent Act, Canadian courts have continued to refuse protection for methods that restrict a medical practitioner from determining how a particular therapy should be administered. The specific therapeutics themselves can be patented, including via first and second medical-use claims if the therapeutic is not novel. But methods of their administration that require any degree of skill and the judgement of a medical practitioner to implement (eg, selecting an appropriate dosage from a range or conducting a dosage titration regimen) cannot currently be patented.

Diagnostic methods originally escaped this prohibition on patenting methods of medical treatment precisely because they were diagnostic and not therapeutic in nature. For example, an early decision of the Patent Appeal Board found that a method of locating tumours using radiolabelled antibodies was patentable because the antibodies were diagnostic and not primarily therapeutic in nature. Following this reasoning, diagnostic method patents were previously granted in Canada.

However, in more recent years, this principled approach that limited the exclusion on patentability to therapeutic methods, thereby allowing the protection of diagnostic methods, has given way to a novel approach implemented by the CIPO that excludes protection for diagnostic methods wherein the invention resides in the way that data is analysed to arrive at a particular conclusion. Diagnostic methods that involve the detection of a novel analyte such as a new biomarker, or that relate to a new way of detecting the analyte, are still considered to be patentable under this regime. However, diagnostic methods that rely on new evaluations of known analytes may encounter difficulties in the Canadian patent system.

Evaluating patentability of diagnostic methods

The CIPO's current approach to evaluating the patentability of diagnostic methods is summarised in its Practice Notice Respecting Medical Diagnostic Methods (PN2015-02), released in June 2015 and now incorporated in Section 23.03.04 of the CIPO Manual of Patent Office Practice. In brief, the current guidelines provide that examiners must first identify the problem that the inventor is looking to solve and then determine from a purposive construction the essential elements of the claim. The essential elements are those that are required to solve the identified problem. If the examiner considers that the essential elements of the claim solve a "data acquisition problem", the claim is considered patentable subject matter. If the examiner considers that the essential elements of the claim solve a "data analysis problem", the claim is refused for being non-patentable subject matter (eg, in the nature of a disembodied idea).

It is clear in the foregoing analysis that the CIPO has tied the 'essential elements' of a patent claim to the 'inventive concept' of the claim. Essentially, its position is that if the inventive concept is merely informational, then the invention is not patentable, even if tangible and concrete steps may be used to implement that inventive concept. This is not consistent with Canadian case law, which supports a strong presumption that any element of a claim is essential, and which has found inventions such as the idea to use a known compound for a new use to be patentable.

Perhaps more problematically, as part of this analysis of identifying the essential elements of the claim, elements that do not solve the identified problem are not considered in evaluating the patentability of the claim. This applies both to determining whether the claim is directed to patentable subject matter and to determining whether the claim defines subject matter that is novel and inventive. In other words, if the examiner determines that the claims are directed to solving a data acquisition problem, then all the steps relating to acquiring the data will be considered to be essential elements of the claim, but any steps relating to how that data is analysed will be ignored in determining patentability. Likewise, if the examiner determines that the claims are directed to solving a data analysis problem, any steps relating to how the data is analysed (eg, the correlation between the presence of a particular biomarker and a disease state) will be considered to be essential elements of the claim, but any steps relating to how the data is acquired will be ignored in determining patentability.

This approach leaves the applicant with a dilemma for a diagnostic method where the novelty resides in how the data is analysed or in the conclusions drawn from that data. For such an invention, if the examiner determines that the claims are directed to a data analysis problem, then any physical steps of acquiring that data will be ignored, meaning that the examiner will conclude that the claim is directed to an unpatentable disembodied idea. However, if the examiner determines that the claims are directed to a data acquisition problem, then any steps relating to how the data is analysed or the conclusions that should be drawn from the data will be ignored, meaning that the examiner will conclude that the claim is directed to patentable subject matter, but is anticipated or rendered obvious by prior art relating to detection of the analyte in question. Indeed, most examiners' actions will set out both approaches in the alternative, so that the applicant is aware that changing the characterisation of the problem to be solved is unlikely to overcome an examiner's rejection of the claims.

Characterising the problem

So what is a patent applicant to do in the circumstances? The best option is to try (where feasible) to characterise the problem to be solved as a data acquisition problem that the CIPO will consider to be patentable subject matter. Examples of data acquisition problems include the discovery of a new analyte or a new method of acquiring data about a particular analyte. As used in the context of establishing patentable subject matter, the term 'new analyte' refers not only to an analyte that is novel (in the sense of not having been previously disclosed), but also one that does not form part of the "common general knowledge".

In Canada, the common general knowledge is a subset of prior art which is generally known and accepted by skilled persons. For example, something described in a single journal article would be part of the prior art (and therefore relevant to determining novelty or inventive step), but it would not form part of the common general knowledge until it had been reflected in multiple articles, a review article or a textbook on the subject, or in some other way become established as generally accepted in the field. Thus, a biomarker identified as being correlated

with pancreatic cancer in one single prior art reference would not be considered to form part of the common general knowledge in the process of evaluating whether a claim directed to a diagnostic use of such biomarker constitutes patentable subject matter (although the biomarker would no longer be novel, which could be problematic in establishing that the invention is novel and non-obvious).

The following factors are specifically listed in the CIPO's practice guidance as examples of indicia suggesting that an innovation is directed to solving a data acquisition problem. The term 'new' is not necessarily limited to 'novel', but also includes an analyte that does not form part of the common general knowledge, while the term 'known' refers to something that forms part of the common general knowledge:

- disclosure of a new analyte;
- disclosure of a new combination of biomarkers;
- disclosure of a new means to identify or quantify an analyte;
- disclosure that a known way to identify or quantify an analyte that can be applied to a sample or a subject population that is not standard to that analysis;
- disclosure that a known means to identify or quantify an analyte should be performed within specific constraints (eg, timing) that are not standard to that means;
- explicit statements that a specific problem or solution relates to how to identify or quantify a particular analyte;
- a significant level of detail devoted to describing technical details of how data about a particular analyte is acquired; and

Jennifer A Marles
Partner
jmarles@patentable.com

Jennifer Marles has an MSc in biochemistry and helps clients in the biotechnology, chemical and medical device industries build the value of their companies by securing patent protection in Canada, the United States and beyond. Ms Marles also assists clients with technology licensing, handling investor due diligence and evaluating their freedom to practise their technology. At all times, she remains aware of her clients' commercial goals and budgetary constraints, and she enjoys the rigours of learning about their new technologies. Ms Marles sits on the Patent Practice Committee, the Patent Agent Examination Board and is an adjunct professor at the Peter A Allard School of Law at the University of British Columbia.

Christina SW Kwok
Associate
ckwok@patentable.com

Christina Kwok joined Oyen Wiggs in 2014 as an articled student and has continued with the firm as an associate lawyer since 2015. Before studying law, Ms Kwok obtained a BSc in biotechnology and worked as a research associate at a local biotechnology company. She works with a wide array of clients, ranging in size – from start-ups to more established companies and universities – and industries, including the life sciences, chemical and mechanical technologies. She assists clients with all aspects of identifying, protecting and benefiting from their intellectual property, including patents, trademarks, industrial designs, copyright and domain names.

"Inventions that are likely to be construed as solving a data analysis problem may face intractable hurdles in examination"

- an emphasis on the challenges or deficiencies of prior means to identify or quantify a particular analyte.

Patentable diagnostic methods

Thus, based on the CIPO's administrative guidelines, as reinforced by recently granted Canadian patents including diagnostic method claims that were allowed while these guidelines were in effect, the following types of technology are likely to be considered by the CIPO to be patentable subject matter:

- the analysis of a new biomarker not previously understood to play a role in a disease or condition;
- the development of a new agent for detecting a biomarker (eg, a novel antibody or a novel nucleic acid probe);
- the development of a new way of detecting or quantifying a biomarker (eg, use of a novel group of aptamers that each have a different affinity for a particular protein that serves as a biomarker for a disease process);
- the analysis of a new group of biomarkers that have not been previously analysed together, even if the biomarkers themselves may be known (eg, evaluating multiple gene signatures to arrive at a prognostic or predictive determination);
- the analysis of a biomarker only within a specific patient subpopulation (eg, a biomarker that was known to be indicative of cancer may be newly discovered to be indicative of a different type of cancer – caution is advised regarding the fact that inherent anticipation may be a problem where many patients, including this patient subpopulation, have been previously screened for the biomarker);
- the analysis of the biomarker in a specific sample (eg, if a biomarker was previously known to be present in one bodily fluid such as blood, but it has now been discovered unexpectedly that the biomarker can be detected in urine, or if the biomarker was previously assayed in one type of tumour, but is found to be useful in providing prognostic or diagnostic guidance in a different one); and
- the analysis of a biomarker with a temporal limitation on when the biomarker is assayed (eg, assaying for the biomarker starting a specific time period after kidney injury, or at specific time intervals after kidney injury).

Anecdotally, incorporation of detailed data acquisition steps in the claims of an application may sometimes help to secure allowance, although this strategy is not widely successful and is inconsistent with the approach set out in the CIPO's administrative guidelines.

Data analysis problems

While diagnostic innovations that meet the guidelines are likely to be protectible in Canada (provided that the requirements for novelty and inventive step can be satisfied by the data acquisition steps of the claim alone), other types of diagnostic invention are difficult to protect under the current administrative regime. In particular, inventions that are likely to be construed as solving a data analysis problem may face intractable hurdles in examination. An example of a data analysis problem could include the discovery of a new diagnostic correlation between a condition and an analyte that forms part of the common general knowledge (referred to here as a 'known analyte'). Example diagnostic innovations that are not considered patentable under the CIPO's current practice include inventions relating to new uses of known biomarkers, where no distinguishing novel characteristic (eg, sample type, patient subpopulation or timing of conducting the assay) is available. Because methods for assaying for the biomarker will be part of the common general knowledge, the CIPO will characterise such inventions as solving a data analysis problem.

Indicators set forth in its practice guidance that the CIPO may rely on to indicate that the problem or solution relates to a data analysis problem include:

- explicit statements suggesting the problem to be solved is a data analysis problem, or at

least something other than a data acquisition problem;
- emphasising the discovery of a new correlation between a condition and a known analyte with a relative absence of technical details pertaining to how to acquire data about the analyte; and
- indicators or explicit statements that known means can be used to acquire data about a particular analyte or an absence of any explicit indication that practical problems were overcome relating to how to acquire data about a known analyte.

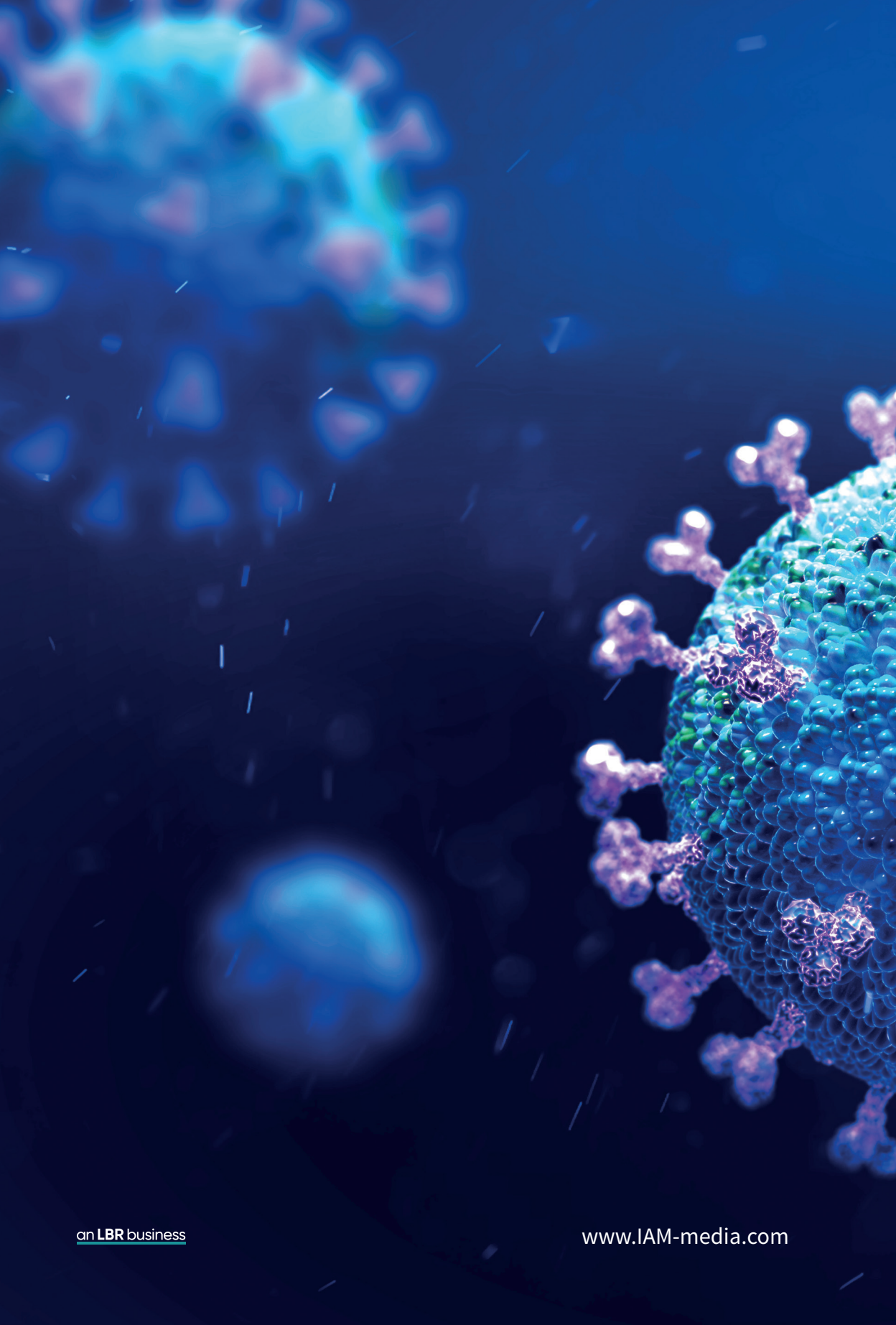
Strategies for drafting applications that are likely to be found to define patentable subject matter under the current administrative guidelines include:
- incorporating – in both the description and the claims – details on each step of the method, including the specifics of the sample to be collected and the experimental details;
- focusing on novel aspects relating to the analyte itself;
- focusing on novel aspects of the way in which the analyte is detected or quantified; and
- focusing on the novelty of the patient population, sample source or timeline according to which the assay is practised.

Looking forward

The uncertainty in the diagnostics space is worrying for companies seeking legal protection in Canada. Unfortunately, there are no cases currently pending before the Canadian courts to challenge the CIPO's guidelines and it is expected that the *status quo* is likely to prevail for the foreseeable future. Thus, to the extent that innovations can be characterised to fall within the CIPO's examination guidelines, it will remain desirable to do so.

Despite the uncertainty, we still recommend filing for important diagnostic inventions in Canada. Canada has a deferred examination system. This means that a patent application can remain patent pending in Canada for many years, even before the application will be taken up for examination. A pending application acts as a deterrent for competitors in Canada. We remain hopeful that the present uncertainty will be resolved at some point, meaning that by the time applications which are filed now are subject to examination, there will be greater clarity in this area. *IAM*

Oyen Wiggs Green & Mutala LLP
480 The Station
601 West Cordova Street
Vancouver BC V6B 1G1
Canada
Tel +1 604 669 3432
Fax +1 604 681 4081
Web www.patentable.com



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