PERSONALIZED MEDICINE: Patent and Regulatory Frameworks in Canada

"Personalized medicine", or perhaps more accurately “precision medicine” (“PM”) has been described as the next revolution in healthcare and the “coolest part of medicine.” Generally speaking, PM refers to the tailoring of medical interventions to individual (“personalized”) and/or disease (“precision”) characteristics. PM promises to radically improve patient care by making medicine more predictive, preventive and precise. Accordingly, there is a strong desire for protecting and commercializing PM innovations. The following provides a brief review of some Canadian specific scenarios under the current legal regimes that may influence development of PM technologies.

**Patent Framework**

Claims define the scope of patent protection and PM innovations can be protected by a variety of claim types. Examples of claim types include prognostic method type claims (e.g. that extract baseline patient/disease characteristic information that can affect outcome regardless of treatment) and companion diagnostic method type claims (e.g. that identify whether a patient is more or less likely to benefit from a specific treatment or intervention). A generalized example could be a method of predicting a likelihood of developing disease Y (e.g. prognostic) or responding to a particular treatment (e.g. companion) for disease Y in a patient comprising: i) detecting a mutation in ABC; and ii) identifying the patient with a greater likelihood of developing disease Y or responding to a particular treatment for disease Y if the mutation in ABC is detected. Assuming such claims meet the requirements for patentability, including novelty, non-obviousness and utility, such claims can generally be obtained.

Method of treatment claims would seem to be a useful category of claim type to protect PM innovations as PM tests can be used to identify a patient sub-population that, for example, is more likely to respond to a treatment. However, Canadian Courts have clearly established that methods of medical treatment claims do not constitute patentable subject matter. The decision is based on the principle that inventions should not prevent physicians from exercising their skill and judgement while delivering a medical treatment.

It is generally possible to convert traditional method of treatment claims into use claims (e.g. use of compound X for treating disease Y, a.k.a. “Canadian method of treatment claims”), though the drafter must remain mindful to remove all elements that may be construed as limiting the skill and judgement of a physician. A patent examiner will consider a use claim not patentable if an essential element only serves to instruct a medical professional “how” to treat a patient (e.g. dosing schedule, administration site or narrowing treatment to a patient sub-population), rather than “what” to use to treat the patient (e.g. compound, composition, dosage form). The question that arises is ‘does inclusion of “how” elements equate to a patentability bar for personalized medicine Canadian style treatment claims?’

Recently the Canadian Intellectual Property Office (CIPO) released a practice notice entitled Examination Practice Respecting Medical Uses and Examples of purposive construction analysis of medical use claims for statutory subject-matter evaluation. One of the examples describes use of a known compound X to treat a disease Y in a specific patient population having the gene mutation ABC, and finds that the claim is not patentable because the invention is directed to “how” to treat and restricts the choices of the physician on how to use X. Moreover, the example states that the invention does not qualify as a “selection” patent because in a selection all of the range claimed must be novel and in this case in the population already treated, some patients already had the ABC gene mutation, and therefore treating the sub-population with X for Y is not novel. The example notes that if the solution was to provide a different formulation of X to patients with ABC mutation, for example a lower dose unit, then such a claim could be statutory. No case law is cited to support the lack of patentability and although several court decisions have considered the patentability of...
dosage ranges whose selection relies on the skill of a physician, no cases have specifically considered the scenario provided in the ABC mutation example.10

As mentioned above, meaningful protection is still available in the form of prognostic/diagnostic claims. However, medical use claims may have advantages not shared by prognostic/diagnostic type claims. For example, a patent with a claim for the use of a medicinal ingredient, where the use has been approved through the issuance of a Notice of Compliance in respect of the submission would be eligible for listing on the Patent Register under the Patented Medicines (Notice of Compliance) Regulations and periods of exclusivity therein provided.14 Such benefits are not available for patents directed to prognostic/diagnostic claims.

The Canadian position also stands in contrast to our neighbours to the south. Notably, the breadth of prognostic/diagnostic claim types allowed by CIPO is far greater than what is currently allowable by the United States Patent and Trademark Office (USPTO) in light of recent case law and a USPTO guidance document that have significantly diminished the breadth of protection available to prognostic/diagnostic type claims.12 Interestingly, although patenting PM technologies and particularly prognostic/diagnostic method type claims have faced mounting hurdles in the United States, method of treatment claims are a category of claim that is generally available for personalized medicine type claims.

**Regulatory Framework**

Under Canada’s Constitution, legislative powers are divided between federal and provincial governments and as such, ‘diagnostic’ tests may fall under federal or provincial regulations depending on whether they are sold as a kit or delivered solely in a laboratory.13 In vitro diagnostic tests (“IVDs”) are regulated under the *Medicines Devices Regulations* pursuant to the Food and Drug Act, while laboratory-delivered tests (“LDT”) are subject to provincial regulations.

In vitro diagnostic tests are defined in the *Medicines Devices Regulations* as a medical device intended to be used in vitro for the examination of specimens taken from the body, and genetic testing is defined as the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission.19 Therefore, they do not fall within the scope of the *Medical Devices Regulations* or the *Food and Drug Act*. They are regulated by provincial regulations relating to laboratory safety and quality. Accordingly, all laboratories offering diagnostic testing are required to obtain an operation licence issued by the provincial Minister of Health, as well as self-regulated accreditation and quality controls. Because each province has its own regulations relating to medical laboratories, these rules have been shown to vary considerably from one provincial jurisdiction to another.18 In some provinces, there is a lack of binding rules whereas other provinces have developed elaborate legal frameworks.19

Given that diagnostic testing is offered predominantly as a laboratory service, and given the variations between provincial regulations on LDTs in Canada, harmonized oversight of diagnostic tests has been proposed, particularly for high risk LDTs. At present, LDTs that are considered as posing a high individual risk (i.e. equivalent to Class III devices) are not required to comply with Health Canada regulations which may be more stringent. Interestingly, this concern was expressed by the United States Food and Drug Agency (“FDA”) which regulates IVDs (much like Health Canada), and has suggested that the FDA oversight be based on the risk level to patients, and not on whether the diagnostic test is made by a conventional manufacturer or in a single laboratory.20 Although the FDA has historically exercised enforcement discretion over LDTs, it has recently taken steps to ensure that diagnostic tests provide accurate, consistent and reliable results by publishing a Draft Guidance entitled *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*. LDT providers who were not required to provide clinical study data to support their tests may now be urged to conform to FDA guidelines.

**Conclusion**

As innovators continue to invest heavily in PM, it is expected that PM technologies promising to revolutionize health care will continue to emerge. Patient and regulatory challenges remain. Methods of treatment are not per se patent eligible subject matter in Canada although protection for some therapeutic methods and meaningful protection for prognostic/diagnostic claims is available. It remains to be seen if the courts will endorse CIPO’s example relating to subpopulations. The Canadian regulatory frameworks relevant to PM technologies are complex owing in part to the division of powers between the federal and provincial governments. Whether regulatory harmonization is on the horizon, and whether harmonization would address the regulatory challenges, remain to be seen.

**References:**

2. Peter Byers, MD, director of the new Center for Precision Diagnostics at the University of Washington, calls it “the coolest part of medicine.” UW Medicine 2014 Annual Address: Precision Medicine. Ibid.
6. Ibid. 4, at page 2.
7. Ibid. 4.
9. Ibid, see section 7. Known compound, for a specific group of patients, Example 7.1 sub-patient population.
12. USPTO, Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products. The Guidance document at the time of writing was under public consultation and it is expected that changes will be released shortly.
13. Constitution Act
17. Ibid. 14, section 32.
20. FDA News Release, FDA takes steps to help ensure the reliability of certain diagnostic tests (July 31, 2014), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm407321.htm

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