How well does Canadian law protect information products? The case of patents over diagnostic methods

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Precision medicine — tailoring medical treatment to a patient's genetic characteristics — has the potential to greatly improve health care. Researchers and life sciences companies are committing significant resources to developing therapies whose success turns on the presence of biomarkers identified with diagnostic tests. Oncology is one field where these investments are widespread, with researchers seeking to bring insight into the genomic mutations that drive cancer.

Protecting the technical contributions of inventors, and encouraging such valuable investments, is the main purpose of patent law. However, a 2021 Australian case, *Ariosa Diagnostics, Inc. v Sequenom, Inc.* (*Ariosa Diagnostics*), illustrates the difficulties of enforcing patents over diagnostic methods.[1] The Australian court held that Sequenom's invention over a method for detecting fetal DNA in a maternal blood sample was eligible for patent protection, but it was not infringed by a competitor who made the patented test available to Australians but carried out the diagnostic method outside of the country.

The patentee Sequenom may well have fared better in Canada. Recent Canadian legal developments broadening patentable subject-matter have gone a long way toward protecting diagnostic inventions. Moreover, the Supreme Court has endorsed the view that Canadian patent law should prohibit acts that deprive patentees of the benefit of their invention. On these grounds, Canadian patent law appears well tuned to balance effective patent protection for diagnostic method inventions with countervailing policy objectives such as preventing patents from pre-empting entire fields of scientific research.

The challenge of enforcing patents over diagnostic methods

In the late 1990s, Sequenom developed and patented a method for detecting fetal DNA in maternal blood samples. In *Ariosa Diagnostics*, the Full Court of the Federal Court of Australia held that the claims in Australian Patent No. 727919 (AU 919) fell within the concept of a manner of manufacture, being an artificially created state of affairs of economic utility and therefore patentable subject-matter.[2] Fetal DNA is a naturally occurring phenomenon but, in the Court's view, a method for identifying and discriminating between maternal and fetal nucleic acid went beyond a mere discovery of a naturally occurring phenomenon.[3]

The Full Court was also called upon to decide whether the defendant Ariosa Diagnostics infringed AU 919 by practising the gene-based diagnostic method. The evidence showed that health care professionals drew blood samples from pregnant women in Australia to be analyzed by laboratories in the United States where the invention could not be patented.[4] The defendant reported on the tests' results to Australian patients by way of an electronic

report downloadable from a file sharing platform.[5] It was conceded that if the laboratory testing was performed in Australia, the defendant would infringe AU 919.[6]

The Full Court concluded that the defendant was *not* liable for patent infringement. Under Australia's *Patents Act 1990*, the issue turned on whether the test results provided to Australian patients were a "product" resulting from the use of the patented method. [7] As the act did not define this term, the Full Court reasoned that "product" should not be interpreted as extending to information, which could not itself constitute patentable subject-matter.[8] Holding that mere information is not a product, the appellate court concluded that AU 919 was not infringed.[9] The implication of *Ariosa Diagnostics* is that an Australian patentee may be unable to enforce its patent against competitors outside the jurisdiction when only information is imported into Australia.

Sequenom may well have fared better in Canada

And what about Canada? While every patent's validity turns on the language of its claims, recent case law supports the view that diagnostic methods are eligible for patent protection in Canada. In the 2020 case of *Choueifaty v. Canada (Attorney General)*, the Federal Court rejected the Canadian Commissioner of Patents' "problem-solution" approach to interpreting patent claims, and re-emphasized that patent claims must be interpreted using purposive construction for all purposes, including assessing subject-matter eligibility.[10] In response to *Choueifaty*, the Canadian Intellectual Property Office (CIPO) published a guidance document outlining an updated approach to analyzing medical diagnostics inventions.[11] A diagnostic method claim that defines a combination of elements that cooperate together to form a single actual invention that includes physical means for testing or for identifying, detecting, measuring, etc. the presence or quantity of an analyte in a sample is patentable subject-matter. Unlike in the United States, where the patentability of diagnostic methods faces significant hurdles,[12] Sequenom's invention was likely patentable in Canada (and a patent issued for it).[13] But could it be enforced successfully on the facts of the Australian *Ariosa Diagnostics* case?

Canadian patents cannot be infringed outside the country, but whether infringement requires that *all* claim steps be put into effect in Canada has not yet been settled.[14] Canadian courts have long held that a process patent can be infringed by the importation of a product made abroad using a patented process because this conduct deprives the inventors of the full enjoyment of their monopoly.[15] This "Saccharin doctrine" may apply even if material changes are made to the article produced by the patented process prior to importation of the ultimate product. It is simply necessary that the patented process play an important part in the manufacture of the imported product. Whether this Canadian theory of infringement also applies to defendants whose *only* commercial product is information made available to Canadians remains to be seen.

Nonetheless, infringement of a Canadian patent does not turn on whether a "product" is imported. The *Patent Act* refers to "product" in various provisions,[16] but it does not define the rights conferred by a patent or infringement by reference to "product."[17] Thus, the thorny question faced by the Australian Federal Court whether pure information is in fact a product may not arise under Canadian law.

The Supreme Court of Canada has referred to the "guiding principle" that "patent law ought to provide the inventor with 'protection for that which he has actually in good faith invented'".

Thus, with respect to patent use, infringement turns on the question "whether the alleged infringer deprived the inventor in whole or in part, directly or in directly, of full enjoyment of the monopoly conferred by law".[18] The Federal Court has also held that while patent law has territorial limits, those limits should not prevent a court from reviewing all aspects of the extra-territorial processes and the products to determine whether the inventor has been deprived, even in part or even indirectly, of the full enjoyment of the invention.[19]

For these reasons, a Canadian court may well find a defendant liable for patent infringement on the facts of the Australian *Ariosa Diagnostics* case, especially if it saw the defendant's business model as calculated to deprive the plaintiff of the benefit of its invention, in a manner inconsistent with the scope of protection afforded by the *Patent Act*.

Takeaways

Diagnostic information that optimizes therapeutic decisions is no less valuable to patients than physical interventions that might bring about the same result. If so, patent law should provide innovators with the economic incentives to continue committing significant resources to developing diagnostic methods that are instrumental in achieving better, faster or safer therapeutic response, subject, of course, to countervailing policy objectives such as fostering patient access or preventing whole fields of scientific inquiries from being patented.

Canadian patent law seems well tuned to achieve these outcomes.

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[1] *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, [2021] FCAFC 101.

[2] *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, [2021] FCAFC 101, at para 166.

[3] *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, [2021] FCAFC 101, at para 155.

[4] *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, [2021] FCAFC 101 at para 247. In *Ariosa Diagnostics Inc. v Sequenom, Inc.*, 788 F.3d 1371 (Fed Cir 2015), Sequenom's corresponding U.S. patent was held to be directed to ineligible subject matter.

[5] *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, [2021] FCAFC 101, at para 247. In contrast, in *Ariosa Diagnostics Inc. v Sequenom, Inc.*, 788 F3d 1371 (Fed Cir 2015) (*Sequenom*), the United States Court of Appeals for the Federal Circuit held that the genetic based diagnostic test in the asserted claims of US 540 were not directed to patent eligible subject matter, in violation of 35 U.S.C. § 101. Therefore, the diagnostic method was not protected in the U.S.

[6] *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, [2021] FCAFC 101, at para 245.

[7] *Patents Act 1990*, No. 83, 1990. The Australian *Patents Act 1990* gives patentees the exclusive right to "exploit" the invention during the term of the patent. The definition of "exploit" reads in part: "(b) where the invention is a method or process–use the method or process or do any act mentioned in paragraph (a) in respect of a *product* resulting from such use" [emphasis added].

[8] *Ariosa Diagnostics, Inc v Sequenom, Inc.,* [2021] FCAFC 101, at para 269.

[9] *Ariosa Diagnostics, Inc v Sequenom, Inc.,* [2021] FCAFC 101, at para 270.

[10] *Choueifaty v Attorney General of Canada*, 2020 FC 837 (*Choueifaty*). See White et al., "Choueifaty patent application found to possess patentable subject-matter" (January 26, 2021), Osler Update. When determining subject-matter eligibility, the *Choueifaty* court instructed the Canadian Intellectual Property Office to first purposively construe the claims to identify the essential elements and then determine whether the patent application contains patentable subject-matter.

[11] Canadian Intellectual Property Office, "Patentable Subject-Matter under the *Patent Act*" (November 3, 2020).

[12] See, *e.g.*, *Ariosa Diagnostics Inc. v Sequenom, Inc.*, 788 F.3d 1371 (Fed Cir 2015).

[13] Canadian Patent No. CA 2,282,793 (related to WO 474) was issued October 12, 2010. It has not been judicially considered.

[14] *Canadian National Railway Company v. BNSF Railway Company*, 2018 FC 614, at para 46; *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30, at para 36.

[15] *Eli Lilly & Co v Apotex Inc*, 2010 FCA 240, aff'g 2009 FC 991. See *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, at paras 35 and 44.

[16] *Patent Act*, R.S.C., 1985, c. P-4, at ss. 21.02, 55.1 and 55.2.

[17] The *Patent Act*, R.S.C., 1985, c. P-4, s. 42, rather states that a Canadian patent grants "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction." The concept of "invention" may be more readily interpreted as comprising information than "product."

[18] *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, at para 35.

[19] *Pfizer Canada Inc. v. Canada (Health),* 2007 FC 898, at para 87.