

Event

On November 3rd the Children's Hospital of Ontario (CHEO) launched a lawsuit challenging U.S. patent holders of genes related to a rare heart disorder, Long QT Syndrome (LQTS)¹. The goal of the public interest action brought by CHEO is to clarify the scope of Canadian law regarding gene patents and establish the freedom of healthcare providers to offer genetic testing to those who need it.

Significance

Patents are a tool to encourage innovation. Nevertheless, patenting and exclusive licensing of clinically-important human genes are highly controversial². In Canada, patents on LQTS-associated genes/tests are so broad that they prevent healthcare providers from offering clinical testing, and critically, from developing and improving next generation testing. Further, clinicians are obliged to purchase genetic testing services from foreign-patent holders or licensees at elevated prices. Significantly, patient genetic data is retained by foreign labs for their own commercial benefit, denying clinicians around the world a valuable clinical resource. As future innovation will increasingly rely on access to data, and comparisons between analytical methods and results, this will likely hamper the development and use of genetic tests that better predict disease susceptibility.

The implications for Canadian patients, taxpayers and the future provision of healthcare are serious. Healthcare costs and test turn-around times are increased. Clinicians are forced to rely on foreign test results, hampering optimal integration of patients' genetic findings and clinical decision-making. Innovation is chilled. The outsourcing of testing hinders growth of Canadian genetics expertise and capacity. The CHEO case offers a key opportunity to resolve gene patent policy in Canada.

Analysis

Despite gene patenting coming to public attention in the early 2000s when Myriad Genetics threatened provinces over unauthorized testing of its patented BRCA1/2 genes³, Canada has not yet addressed the issue. The [US](#), [Australia](#) and [Europe](#)⁴ have moved to settle gene patent policy variously through judicial or legislative means, respectively. There, litigation aimed to answer the more abstract question of whether DNA sequences/genes are patentable. Typically, patents are issued for new inventions. However, as naturally-occurring entities, genes are questionable in their status as 'inventions'. By contrast, the CHEO case seeks to invalidate LQTS gene patents with the practical goal of establishing certainty on the boundaries of permissible practice for Canadian clinicians, healthcare systems, researchers and innovators. In effect, broad patents on isolated genes are anachronistic, tantamount to historical artefacts from the 90s and early 2000s when gene isolation techniques were briefly novel and non-obvious. While patent law aims at maximizing public benefit, gene patents belie this principle in Canada.

Conclusion

Broad gene patents are impeding provision of timely and cost-effective genetic services in Canada. With molecular diagnostics becoming increasingly important components of healthcare, there is dire need for Canada to clarify its stance on gene patents. The CHEO case provides a sorely-needed opportunity to set effective policy that will clear the way for healthcare providers and innovators to deliver equitable, cutting-edge and cost-effective healthcare in Canada.

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1. The Genetics of Long QT Syndrome (2014). Tester BS, Ackerman MJ. *Methodist Debakey Cardiovasc J.* 10(1): 29–33.
 2. DNA patents and Diagnostics: Not a Pretty Picture (2010). Carbone J, Gold ER, Sampat B, Chandrasekharan S, Knowles L, Angrist M, Cook-Deegan R. *Nature Biotechnology.* 28(8) 784-791.
 3. Myriad Genetics: In the eye of the policy storm. Gold ER, Carbone J (2010). *Genet Med.* 12(4 Suppl): S39–S70.
 4. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. *Official J Eur Commun* 1998:L213/213–L213/221.