Gene Patents Remain Valid in Canada

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The case involving a Children's Hospital of Eastern Ontario ("**CHEO**") challenge to an isolated gene patent has settled[1]. For background on the case and issues around isolated gene patenting, see our prior articles here and here. It is important to note that Canadian gene patents cover the chemical sequence of an *isolated* gene as it would exist, for example, in a test tube on a lab bench, but not the gene as it exists in a person's body. It is *not possible* to patent a gene in a human body.

CHEO has been granted a license by the patent owner, Transgenomic, Inc. ("**Transgenomic**"), to use the genes for *non-profit* diagnostic testing (click here for settlement agreement). The patent owners also agreed to grant licenses to other non-profit public sector users (click here for standard license agreement). Transgenomic has not issued a press release about the case, and is keeping its version of the diagnostic test using the genes available to Canadians.

The patents in question remain valid and enforceable against commercial use of the isolated genes in Canada, because the case settled without a determination of the subject matter patent-eligibility of genes ("subject-matter patent eligibility" refers to whether genes are a patentable category of invention - for example, abstract ideas, pure business methods and laws of nature are not patentable subject matter). Isolated gene patents remain available through the Canadian Intellectual Property Office, which considers isolated genes to be a patentable category of invention. As well, in a case involving isolated plant genes and methods of their use to make genetically modified plants, the Supreme Court of Canada held the patent valid and infringed by someone that produced the plants without permission[2]. The subject matter-eligibility of isolated genes and their methods of use was not in issue in that case. Since the CHEO case has petered out short of trial, there is no such subject-matter eligibility case on the horizon to revisit patenting of isolated genes. Those with patents on isolated genes and their methods of use should still expect to be able to fully enforce their patent rights in Canada, as in the prior Supreme Court case.

The settlement is being billed as a win for patients in CHEO's media release[3]. It is a short term win for the pockets of governments and any consumers that would have otherwise paid Transgenomic more money for the test. For those that would like to incentivize companies to do R&D to develop new, better diagnostics, trying to undermine patents on legitimate inventions is not a win in the long term. As noted above, the CHEO challenge was unsuccessful in the broader sense that Canadian gene patents are still generally valid and enforceable following this settlement. Due to recent actions by the Canadian Intellectual Property Office, there are potential issues on the horizon for our courts involving patentability of certain types of diagnostic methods discussed generally here. If the Canadian patent system is not effectively protecting gene and diagnostic-related inventions, multinational companies will still do their R&D - Canada is a small part of the global market - they may just not bother to promote and sell innovative diagnostics here. We all have an interest in getting the best diagnostic tests available in Canada *asap*. This should be the unifying goal, rather than than scoring short-term savings and short-sighted PR victories against gene-based diagnostics and those companies that spend millions to invent them.

1 *Children's Hospital of Eastern Ontario v Transgenomic, Inc et al.* (14 May 2015) T-2249-14 .

2 *Monsanto Canada Inc v Schmeiser*, [2004] 1 S.C.R. 902.