



CANADA TO CONSIDER GENE PATENT ELIGIBILITY:

Looking Abroad for Insight

New and inventive biological substances are generally patentable in Canada. These substances include, for example, genes, proteins, antibodies, hormones, vaccines, cell lines, bacteria and isolated genetic material as well as associated methods that make use of these products. In contrast, some of these types of inventions, primarily genes and methods of their use, have been under fire in other jurisdictions. Gene patent eligibility in Canada may soon be evaluated in light of a challenge brought by the Children's Hospital of Eastern Ontario ("CHEO").

The Canadian Intellectual Property Office's ("CIPO") practice manual, which is a guide for Examiners assessing applications for patents in Canada, confirms that "claims to nucleic acids, polypeptides, proteins and peptides are ... directed to statutory matter."¹ The CHEO case now challenges this practice. CHEO alleges that various patent claims, including isolated nucleic acid and method claims relating to assessing the risk of Long QT syndrome are invalid as being patent ineligible. Long QT syndrome is an inherited disorder affecting the heart's electrical activity that can result in arrhythmias. A hearing date has not yet been established. As such, it may prove useful to examine the status of biological patenting in other jurisdictions to deduce how Canada may resolve the issue.

In the United States, naturally occurring genetic sequences are not patent eligible following the Supreme Court decision of *Association for Molecular Pathology v Myriad Genetics Inc* [*Myriad*].² In *Myriad*, it was held that isolated nucleic acid claims relating to human breast and ovarian cancer related genes, *BRCA1* and *BRCA2*, were unpatentable "products of nature". However, claims to cDNA, synthetically created nucleic acid molecules that contain only part of the gene (the exons), were held to be patent eligible as cDNA is not naturally occurring. Presently, the US Patent and Trademark Office evaluates the patent eligibility of natural products such as genetic molecules or proteins by assessing whether the product has "markedly different characteristics" than its naturally occurring counterpart.³ If it does, it will be qualified for patent eligibility. If it does not, it is considered a "product of nature exception" and Examiners are to assess whether the claim as a whole recites "significantly more" than the exception.

Australia has recently considered the issue of whether isolated nucleic acid molecules constitute patentable subject matter.⁴ The High Court of Australia in *D'Arcy v Myriad Genetics Inc* followed a similar approach to the US in holding that claims directed to isolated *BRCA1* nucleic acids were not patentable subject matter as they were not directed to a "manner of manufacture."⁴ However, the Australian Patent Office ("IP Australia") has adopted a different approach towards natural products, noting that the majority of the High Court "did not deliberate about 'products of nature' versus 'artificially created products'."⁵ The guidance identifies isolated naturally occurring nucleic acid molecules as being "clearly excluded" subject matter.⁶ Claims to cDNA and synthetic nucleic acids, probes and primers, and isolated interfering/inhibitory nucleic acids are "excluded where they merely replicate the genetic information of a naturally occurring organism."⁷ However, where the utility of the invention lies in genetic information that has been "made" (e.g. created or modified by human action), these types of claims may be patentable.⁸ It remains to be seen how this guidance will apply in practice. Further, IP Australia has expressly confirmed that methods of treatment and recombinant or isolated proteins are technical subject matter that has been previously found by Australian courts to be patent eligible.

The European biological patent landscape is much more permissive than that of the US or Australia. Biological material, whether isolated or produced by means of a technical process, is patent eligible even if it previously occurred in nature provided its industrial application is disclosed in its patent application.⁹ However, mere discoveries, such as the discovery of a

sequence or partial sequence of a gene, are not patentable without more.¹⁰

It is notable that the Canadian CHEO applicants are alleging that the isolated nucleic acid claims are directed to unpatentable subject matter since they are "naturally-occurring genetic sequences that encode for naturally-occurring human genes."¹¹ Further, CHEO asserts that the "isolation of the claimed nucleic acids from their natural environment requires trivial effort and does not constitute a sufficiently marked departure from the naturally-occurring unpatentable nucleic acids to warrant patentability under section 2."¹² The language used is similar to that used by the US Supreme Court in *Myriad* and the subsequent USPTO guidelines, suggesting that CHEO hopes that foreign cases may be influential in Canada.

Canada may well maintain its current position since there is no statutory basis to exclude nucleic acids from patentability and there is no prior case law on point. Should Canada follow the Australian approach, the effect on patentees may be not be so detrimental since only isolated genetic molecules that merely replicate information found in nature is expressly excluded subject matter. Biological material including proteins remain patent-eligible. However, should the Canadian decision focus on the "naturally occurring" versus man-made with "markedly different characteristics" dichotomy that looms large in the US, the patentability of biological inventions may be impacted. If the Court takes its lead from the US, the biotechnology industry will need legislative reform, in order to make such inventions clearly patentable as has been done in Europe. In the meantime, Canadian applicants wishing to claim isolated biological material should prepare by including claims to biologics containing modifications or alterations compared to their naturally occurring counterparts and/or ensure that the patent application contains significantly more than the naturally occurring product itself.

References:

1. CIPO, *Manual of Patent Office Practice, December 2015 update* (Ottawa-Gatineau: Industry Canada, 1998) at ch 17.02.04.
2. 133 S.Ct. 2107 (2013).
3. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed Reg 74618 (2014) at 74623-74624; "July 2015 Update: Subject Matter Eligibility", United States Patent and Trademark Office (July 30, 2015) online: USPTO <<http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf>>.
4. [2015] HCA 35.
5. *Examination Practice following the High Court decision in D'Arcy v Myriad Genetics Inc*, Australian Patent Office.
6. *Ibid.*
7. *Ibid.*
8. *Ibid.*
9. *European Patent Convention Implementing Regulations, Rule 27(a) and 29 [EPC]*; see also EC, *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, [1998] OJ, L 213/13 at preamble (22) and Art 3 [EU Directive 98/44/EC].
10. *European Patent Convention at Art 52(2)(a)*; see also EU Directive 98/44/EC, *supra* note 9 at preamble (16) and Art 5.
11. *Children's Hospital of Eastern Ontario v Transgenomic, Inc* (14 May 2015), Toronto T-2249-14 (FCTD) (Amended Statement of Claim) at paragraph 54.
12. *Ibid* at paragraph 55.

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