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Genetically Modified Biological Materials

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Patenting isolated, naturally-occurring biological sequences still a green light in Canada

As U.S. patent practitioners can tell you, patent claims directed to naturally occurring genes cannot be patented in their country.[1] This was decided in the Supreme Court decision of *Association for Molecular Pathology et al. v. Myriad Genetics*[2] in 2013. In that case, the naturally occurring nucleic acid sequences for BRCA1 and BRCA2 genes were considered off-limits for patenting (i.e., non-statutory subject matter). The discovery of these genes was ground-breaking since mutations in their sequences were correlated with the development of breast cancer. This discovery in and of itself was not sufficient to bestow patentability on the genes themselves in isolated form, although the corresponding cDNA, which is a man-made copy of the gene devoid of extraneous sequences (non-coding introns), was considered eligible for patenting. The rationale underpinning the decision was that researchers had only discovered the location of the genes in the genome and elucidated their sequences. Simply isolating and characterizing the genes was not considered sufficient to make the subject matter patentable short of a more significant, man-made alteration. The cDNA sequences, however, were considered eligible subject matter for patenting since they were not considered "products of nature".

In a corresponding case in Australia, the courts reached a similar conclusion.[3] An analogous case came close to being decided in Canada, but then settled out of court.[4] If the case had been heard, it might have added clarity to the situation since some of the claims at issue were directed to human genes responsible for a genetic disorder (a genetic heart disorder referred to as "Long QT"). Since there continues to be no case law exactly on point, the Patent Office still allows claims for isolated, naturally-occurring biological sequences. Thus, patent applicants should take measures to ensure that such claims are included in their Canadian patent applications. This is particularly important to note since Canadian patent applications originating from the United States and Australia may not include claims to such sequences.[5] While recombinant sequences are the most interesting from an industrial perspective, it should not be ignored that the patenting of naturally occurring sequences is important in diagnostic applications since genetic tests typically require comparison of a defective gene with its natural counterpart.

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[1] Claims directed to an isolated gene itself having the same sequence as it exists in nature.

[2] *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.* 133 S. Ct. 2107 (June 13, 2013).

[3] *D'Arcy v. Myriad Genetics Inc* [2015] HCA 35.

[4] *Children's Hospital of Eastern Ontario v. University of Utah Research Foundation*, T-2249-14 [CHEO Statement of Claim]

[5] However, note that cDNA sequences, which typically have more relevance in industrial applications, are considered eligible for patenting in the United States.

Since isolated, naturally-occurring sequences are patentable in Canada, it will not be surprising that cDNA sequences and other recombinant biological sequences are likewise considered statutory subject matter, as they are in other jurisdictions. This also includes sequences to vectors, proteins or amino acid sequences with genetic modifications, including point mutations and nucleic acid sequences that are modified relative to their natural counterparts. Likewise, a biological sequence can be claimed that has a certain percentage sequence identity with respect to a reference sequence (but see challenges below).

That is not to say that everything is rosy at the Patent Office for patentees. The biggest challenge with patenting biological sequences is successfully arguing that the claimed subject matter is not overly broad. In Canada, a patent must, at a minimum, set out the invention in enough detail in the description to allow a person skilled in the art in possession of common general knowledge to reproduce it. This is often highly fact-dependent, and turns on the breadth of the claims, the amount of data contained in the patent disclosure and the knowledge possessed by a person of ordinary skill in the art. In the unpredictable arts, such a biotechnology, an examiner might reject the claims for failure to support a "sound prediction" of the utility of the invention. This means that if the claims cover subject matter not specifically demonstrated by working examples (or other forms of disclosure), then there must be a sound basis on which to predict that the subject matter has utility.

If a claim directed to a biological sequence does not recite the precise sequence of the biological material (i.e., each nucleotide or amino acid in the sequence), then the Patent Office will usually reject the claim for overbreadth in a first office action. However, if the scope of a claim is narrowed to this extent, the value of the resulting patent can be diminished since reciting the precise sequence of amino acids or nucleotides greatly increases the risk of non-infringement. Depending on how the claims are construed, potentially even changing a single amino acid or nucleotide could be enough to take an infringer outside the scope of the claim. In this case, thorough and persuasive argumentation, based on the facts, and properly supported by case law, can go a long way to help secure allowance of claims that have value to your business.

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