

Patenting Genes: Canada, US and Europe

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A search of the Canadian Intellectual Property Office database reveals no issued patents for genes or nucleic acid sequences prior to 1980. As of January 2002, there were over 2200 issued patents and over 15,000 applications that made reference to genes or “nucleic acids” in their claims. This reflects the rate of development of the biotechnology industry over the last two decades. This development, along with completion of the human genome and sequence information available on public databases, has impacted on the requirements for patenting genes and novel nucleic acid sequences.

The Canadian Biotechnology Advisory Committee (CBAC), in November 2001, issued an interim report to the Government of Canada that raises issues pertaining to the patenting of genes, entitled, “Biotechnology and Intellectual Property: Patenting of Higher Life Forms and Related Issues”. Comments on this report are invited to be submitted by March 15, 2002.

The recommendations presented in the interim report make it clear that it would be helpful if Canada had patenting guidelines for biotechnology inventions. Such guidelines would assist the public in understanding what is or is not patentable and why. When developing these guidelines it is important to look at the treatment accorded these issues in other jurisdictions. Furthermore, the drafters must be cognizant of Canada's obligations under TRIPS and NAFTA.

However, there is very little case law in Canada. Canadian courts have frequently turned to other jurisdictions for guidance when domestic law is lacking. This approach was recently approved by the Federal Court of Appeal in *Monsanto Canada Inc. v. Schmeiser* (2001), 12 C.P.R. (4th) 204 (F.C.T.D.) and *Harvard Mouse v. Canada (Commissioner of Patents)* (2000), 7 C.P.R. (4th) 1, as well as by the Supreme Court of Canada in *Free World Trust v. Electro Sante Inc.* (2000), 9 C.P.R. (4th) 168. Both Courts espoused the value of referring to United States case law and practice to provide guidance in the development of Canadian patent law.

The United States and European patent offices have both adopted guidelines for patent grants of a gene or nucleic acid sequence. These guidelines are intended to assist patent examiners as well as the public. A commentary section compliments the United States guidelines. This commentary specifically addresses many of the issues raised in the CBAC's interim report.

What follows is a brief highlight of some of the approaches adopted in the United States and Europe in resolving certain issues of patenting genes and nucleic acid sequences.

Patentability

It is a virtually universal concept that in order to be patentable, an invention must be: novel, inventive (non-obvious) and have utility. Further, the patent must

provide a written description of the invention sufficient to enable a person skilled in the art to make and use the invention. There are some discrepancies on how these concepts are interpreted in the United States and Europe.

As Novelty (what was not done before is novel) is not usually difficult to determine, the patentability of genes or nucleic acid sequences primarily raises questions surrounding the inventiveness, utility and written description requirements.

The United States

The most recent "Utility Examination Guidelines" (Federal Register, Vol. 66, No. 4) issued by the United States Patent and Trademark Office, have been in effect since January 5, 2001. The Guidelines reflect pertinent U.S. case law.

The Guidelines state that the utility of an invention must be substantial, specific and credible. For instance, use of a DNA sequence as a probe to isolate the full-length sequence lacks specific utility. This is so because the probe target remains undefined and lacks substantial utility because the target sequences have no known mechanism. However, utility of a probe is established if used because it hybridizes near a disease-associated gene or has a gene-regulating activity.

It has become increasingly easy to mine sequence databases to identify potential new genes based on homology to previously identified sequences with known utility. Absent actual isolation and purification of the gene it is questionable whether a sequence identified in this manner would pass the hurdle of inventiveness.

Utility of an isolated and purified DNA sequence may be established based on homology to a sequence with known utility. The 2001 guidelines refrain from specifying a percent homology necessary to establish such utility. Instead the guidelines state that each application will be judged on its own merits.

The United States also has guidelines pertaining to the written description requirement (Federal Register, Vol. 66, No. 4). When claiming a DNA sequence the criteria of a written description requires the specification to describe the "relevant structural or physical characteristics" of the DNA.

To support a claim for a genus of cDNAs one must define "a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus". In *University of California v. Eli Lilly and Co.* (1997), 119 F.3d 1559 (Fed. Cir. C.A.) the patent at issue disclosed rat insulin cDNA and methods of making human insulin. The patent claimed all vertebrate insulin cDNA and human insulin cDNA. The Federal

Circuit found the written description supported the claim for rat insulin cDNA, however, insufficient for human insulin cDNA.

In a more recent case, *Carnegie Mellon University and Three Rivers Biological v. Hoffman-La Roche Inc. et. al.* (2001), 148 F. Supp. 2d 1004, a generic claim directed to *polA* from any bacterial source, was rejected in light of the fact that the application described a recombinant plasmid constructed from only one source, *E.coli*.

Europe

Biotechnology patent law in Europe is governed largely by the European Patent Convention and the recently adopted "Directive on the legal protection of biotechnological inventions" (Directive 98/44/EC).

The Directive clearly makes provision for the patenting of nucleic acid sequences. ESTs and partial sequences may be patentable if functional data is provided to satisfy the utility requirement. Essential features of the DNA sequence must be disclosed to be patentable. These features must be "express, or be directly and unambiguously implied by the text". (T479/97; para. 3; *Novartis Ag v. DSM gist Holding B.V.; pectin lyase*). In T479/97 the European Patent Appeal Board implicitly stated that disclosure of a 5Kb sequence may not forfeit a patent grant of an isolated and identified gene contained within the disclosed sequence.

The major hurdle in Europe for patent protection of DNA is the "inventive step requirement". Unlike Canada, where a "scintilla" of invention has traditionally been sufficient, the European Patent Appeal Board has strictly interpreted this requirement in relation to gene patents.

A DNA sequence encoding an unknown polypeptide is patentable. However, a DNA sequence may not be patentable if a partial or full-length cDNA is known. Purifying the DNA sequence lacks inventive step. This results because there is no inventive step in conducting standard cloning procedures. A person skilled in the art is expected to be able to isolate and characterize the DNA sequence with a reasonable expectation of success. (T386/94 *Re Unilever NV and Others; chymosin gene and precursors.*)

Inventive step is established should the person skilled in the art have difficulties cloning the DNA sequence for the known protein. These difficulties must be established, as opposed to theoretical. (T 207/94; *Biogen, Inc. v. Schering AG, Human beta-interferon*) An established obstacle resulting in a less than reasonable expectation of success in cloning the desired gene will render the gene patentable.

