UPDATES IN BIOTECH PRATICE AT THE PATENT OFFICE

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Following recent case law and legislative amendments relating to biotechnology in Canada, the Canadian Intellectual Property Office ("CIPO") has adapted its practice and modified Chapter 17 of its *Manual of Patent Office Practice* (the "Manual") on biotechnology. The Manual serves as a guide on the application of the *Patent Act* and its associated *Rules*.

Although Chapter 17 is related to biotechnology inventions, CIPO has specified that the current revision of this chapter presents an interest for specialists in all disciplines.

The summary provided below highlights issues of general interest that are raised in this new chapter which has been in effect since January 14, 2009

I. Matters that are Non-Specific to Biotechnology

Novelty and Non-Obviousness Criteria

The criteria of novelty and non-obviousness applicable to any patent application in Canada have been restated in the recent Supreme Court decision in *Apotex Inc.* v. *Sanofi-Synthelabo Canada Inc.*, rendered in November 2008. The Manual reflects these changes in case law. For more detailed analysis of the question, consult one of our recent publications on this subject.

Selection Patents

With respect to selection patents, the Manual mentions that when an invention is related to the selection of one or several species (that have not been previously developed) belonging to a given genus (the latter having been disclosed), the matter of the selection must be: (i) based on a substantial advantage, (ii) the whole of the selection must possess the advantage, and (iii) the advantage must be in respect of a special quality or character, to the whole of the selection.

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II. Matters that are Specific to Biotechnology

Subject-matter

The subject-matter of an invention must respect the definition found within Section 2 of the *Patent Act*. In Canada, while Courts have determined that our life forms such as animals and plants are not patentable, lower life forms such as animal or plant cells are patentable.

Following recent case law, the Manual states that non-patentable life forms include fertilized eggs and totipotent stem cells (except embryonic, multipotent and pluripotent stem cells) which have the inherentabiltiy to develop into an animal, as well as organs and tissues. However, certain artificial organ-like or tissue-like structures that are the result of technical intervention can be determined to be statutory subject-matter and therefore patentable.

The Manual also considers that processes that produce life forms which occur essentially according to nature, and biomolecules defined exclusively by their three-dimensional structure are not patentable.

Medical and surgical methods which are used in preventing, curing or improving an element or pathological condition (excluding natural conditions such as aging, pregnancy or baldness) are considered to be non-patentable. However, so-called use claims (for example: use of compound Y as an antiarrhythmic agent) can be patentable as long as they do not include a step corresponding to a medical or surgical act.

Utility

The Manual (always based on the Patent Act or case law) requires that the object of an invention in biotechnology must also be useful at the date of filing of the patent application. For example, if a claimed molecule is supposed to treat several diseases, the utility of the invention must be demonstrated for each of these diseases, particularly through demonstration of practical examples.

Sufficiency of the Description

If a patent application discloses a new nucleotide or amino-acid sequence, the sequence must be described through a sequence listing which complies with the International PCT sequence listing standard. Since June 2007 in Canada, for new applications, this sequence listing must be filed in electronic form.

Other Comments

In cases where statements in the chapter appear to contradict practice presented in (i) another chapter of the Manual having a previous publication date (and which has not been recently updated), (ii) a prior practice notice, or (iii) a prior published Commissioner of Patent's decision, the practice set out in the revised Chapter 17 applies.

This article is simply a summary of the subject-matter outlined herein. For more information please contact one of our professionals or visit the following website of the CIPO.

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