

## CANADA

---

### MISAPPROPRIATION OF GENETIC RESOURCES

There is no universally accepted definition for the concept of misappropriation of genetic resources (GR); this is also true in Canada. A patent application contains claims outlining the subject matter for which protection is being sought, a description which teaches the invention and optionally drawings and/or sequence listings, depending if they are required for the disclosure of the invention. Patent applications concerning an invention which includes biological material has additional requirements for the description. A deposit, as of the filing date, of a sample of biological material associated with the invention may, in some, but not all cases, be required for the description to sufficiently disclose the invention.

Patent applications can be submitted electronically or in hard copy. An applicant must request an examination within five years of filing a patent application. Once a request for examination is filed (and the associated fee is paid), the application is transferred to the examiner who is the expert in the field of the subject matter. Examiners review the claims, description and drawings to verify they conform to the Patent Act and Rules. A search is carried out to identify any relevant prior art (generally, written documentation that shows that what is being claimed is not novel or obvious). The application is examined in view of the criteria of novelty, obviousness, support, utility, patentable subject matter, and general compliance with the Canadian Patent Act and Rules and jurisprudence.

Canada has no specific, government-level rules for patents for inventions based on genetic resources and associated traditional knowledge (TK). There are, also, no specific patent practices for the processing of applications involving genetic resources and traditional knowledge. However, under section 34 of the *Patent Act* and as further provided for in chapter 18 of the Canadian Intellectual Property Office's (CIPO) *Manual of Patent Office Practice*, any person may file prior art with the Commissioner of Patents, and protest against the granting of a patent. Any prior art material so submitted becomes part of the file of the application.

Patent applications involving genetic resources are treated by the same process and assessed using the same criteria as any other patent application. In Canada, there are no distinct or specialized approaches for search and examination of inventions based on genetic resources and associated traditional knowledge. Furthermore, Canadian patent examiners do not necessarily concentrate or restrict their searches to particular areas of technology, but rather tailor their searches to suit the subject matter covered by the patent application. The success of these searches has more to do with the

availability of prior art sources and databases than with disclosure of the source country.

Of note, the focus on greater access for IP offices to digital libraries of genetic resources such as India's Traditional Knowledge Digital Library (TKDL) has proved to be a practical way of protecting GR and TK within the patent system. Having greater database access helps examiners in determining what is traditional knowledge, however, any references obtained from these sources must be able to be made available to the applicant in order for them to be citable under Canadian Patent Law (i.e., secret information can not be used as a bar to patentability). The selection of the database for a given search is the decision of the examiner. CIPO notifies the Council of Scientific & Industrial Research (CSIR), the TKDL provider, of the number of times documents from the database are cited by examiners as prior art. The Canadian Patent Act allows for third-party protests and submissions of prior art. Prior art submissions from TKDL, as with any other public database, are acceptable under these provisions.

The current system by which different types of patents are categorized and classified does not allow for patents to be identified according to whether they contain a claim to genetic or biological material. Furthermore, there are no means for an examiner to verify whether the source or origin of material, as identified by the applicant, is accurate.

Since genetic resources do not stop at national borders, limiting prior art searches to any given source country would be counterproductive and may overlook relevant prior sources located in other countries. Rather, Canadian patent examiners perform broader searches according to the subject matter; chapter 17 of the *Manual of Patent Office Practice* provides comprehensive guidelines on biotechnology, including as regards novelty.

---