

Resolution
Gene Patenting

Background:

- 1) For almost the past 40 years, isolated genes and genetic material have enjoyed general patentability worldwide. However, more recently, a series of legal decisions, most prominently the Myriad cases, has called into question the patentability of such material per se in several jurisdictions including the United States of America (**U.S.**) and Australia. The scope of this Resolution concerns the patenting of genetic materials, whether in a form isolated from nature by a technical process or artificially synthesized by man.
- 2) This Resolution does not address the requirements of patentability for genetic materials other than patent eligible subject matter, morality and utility.
- 3) There is a stark lack of harmonisation between jurisdictions as to the patentability of genetic materials. For example, even the EU Directive 98/44/EC is not implemented in a consistent manner across the EU Member States.
- 4) The Court of Justice of the European Union in Decision C428/08 has ruled that national patent legislation is precluded from offering “absolute protection” to patented DNA as such “regardless of whether it performs a function in the material containing it”.
- 5) TRIPS Article 27(1) provides that patents shall be available for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step and are capable of an industrial application.
- 6) TRIPS Article 27(2) and (3) allows members to exclude from patentability inventions the commercial exploitation of which would be contrary to *ordre public* or morality, diagnostic, therapeutic and surgical methods for the treatment of humans and animals, plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals, but does not require them to do so.
- 7) The patenting of genetic materials isolated from nature by a technical process or artificially synthesized is not something which appears inherently amenable to exclusion under TRIPS Article 27(2) and (3), for reasons including:
 - a) genes and other nucleic acids once isolated are not in the same form as in situ in nature;

- b) mere existence in nature does not equate to having an application in an applied setting; and
 - c) jurisdictions which permit patenting of genetic materials require that the patent specification cite at least a credible industrial application for the molecule, and in some cases, to be demonstrated.
- 8) Genes isolated from microorganisms, plants, insects and animals, as well as humans, including disease-associated variants, have been found to have industrial, agricultural, diagnostic and therapeutic applications. Patenting such molecules facilitates funding for further research by public bodies and academic institutions, and pharmaceutical and agricultural development more generally.
- 9) Exclusion from patentability deters such effort in genetic research preventing beneficial developments being available for the benefit of the public worldwide.

AIPPI resolves that:

- 1) As a matter of principle clearly reflected in TRIPS Agreement, patents should be granted for any inventions in all fields of technology including genes or parts thereof isolated from nature by a technical process or nucleic acid molecules artificially synthesized, provided an industrial, agricultural, diagnostic and/or therapeutic application is identified and other patentability criteria are met.
- 2) Genetic materials should not be regarded as subject matter excluded from patentability by virtue of TRIPS Article 27(2) and (3), and in particular, should not be regarded as inventions contrary to *ordre public* or morality.
- 3) Genetic material “isolated” from nature by a technical process, should not be treated as a mere “product of nature” and should not be treated as patent ineligible for this reason alone.
- 4) Isolated genetic material, whether or not identical to that which occurs in nature, should be treated for patent purposes as a chemical compound, its production and uses being “a manner of manufacture”.
- 5) EU Directive 98/44/EC should be implemented in each EU Member State in a consistent manner.
- 6) A patent claim to a nucleic acid molecule per se should provide a scope of protection no different to that afforded by any other claims defining a chemical compound.
- 7) AIPPI strongly urges governments to implement the necessary legislative measures to ensure that genetic materials, when isolated from nature or artificially synthesized, constitute patent eligible subject matter.
- 8) AIPPI also strongly urges governments to avoid any measures that would apply a different scope of protection for patent claims to genetic materials and nucleic acids solely by reason of the subject matter of those claims.

Links:

- <http://aippi.org/library/q114-resolutions/>
- <http://aippi.org/library/q150-resolutions/>
- http://ec.europa.eu/dgs/legal_service/arrets/08c428_en.pdf
- <http://aippi.org/wp-content/uploads/2017/08/Gene-Patenting-AIPPI-Position-Paper.pdf>