The immoral gene: Does it really exist?*

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ABSTRACT: Over the last years several European patents were opposed for protecting technology violating the morality requirement under Article 53(a) EPC. Attempts have been made by the Appeal Boards of the European Patent Office (EPO), as well as by amendments introduced into the Implementing Regulations of the European Patent Convention (EPC), to address this sensitive patentability requirement more precisely. The most recent hot topic coming up in this context is the patentability of stem cells. It is to be expected that this discussion will still go on in the field of biotechnological inventions for the next several years.

Legal Basis

The main criteria of patentability under the European Patent Convention (EPC) are set forth in Article 52 EPC:

Article 52 EPC – Patentable inventions
(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.
(…)

Article 52 EPC is complemented by a number of Rules laid down in the Implementing Regulations of the EPC. With respect to the patentability of biotechnological inventions, Rule 23(c) EPC is particularly relevant.

Rule 23(c) EPC
Biotechnological inventions shall also be patentable if they concern:

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(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature

Rule 23(e) EPC further elaborates for parts of the human body:

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

To answer the question of what is patentable under the EPC several exemptions in the law further have to be considered, such as Article 53 EPC. It reads:

Article 53 EPC – Exceptions to Patentability
European Patents shall not be granted in respect of:
(a) inventions the publication or exploitation of which would be contrary to “ordre public” or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

Article 53(a) EPC is consistent with Article 6(1) of the EU Biotechnology Directive. In the first clause of both articles, a violation of “ordre public” or “morality” is stated as a criterion which may bar the patenting of an invention. In decision T356/93 concerning the patentability of plants and plant genes, one of the Boards of Appeal of the European Patent Office (EPO) attempted to define the terms “public order” and “morality” and arrived at the following results.

**Ordre Public:**
It is generally accepted that the concept of “ordre public” covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (e.g. through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to the “ordre public”.

**Morality:**
The concept of morality is related to the belief that some behaviour is right and acceptable, whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For