

Implementing Regulations, and is identical to Art. 6(2) of the Biotech Directive. The Biotech Directive was thereby transposed into European patent law.

Where an invention falls under one of the categories set out in R. 28 EPC, it is by its very nature non-patentable and there is no need additionally to consider Art. 53(a) EPC. However, if it does not fall under one of those categories, it must be examined more closely under Art. 53(a) EPC (T 315/03, OJ 2006, 15; see also G 2/06, OJ 2009, 306).

R. 29 EPC governs the patentability of the human body and its components. Under R. 29(2) EPC (R. 23e (2) EPC 1973), an element isolated from the human body or otherwise produced by a technical process, including the sequence or a partial sequence of a gene, may constitute a patentable invention, so that an invention falling under this category is not excluded from patentability pursuant to Art. 53(a) EPC (T 272/95 of 23 October 2002; see also T 1213/05).

2.1. Rule 28 EPC

R. 28 EPC, which sets out four non-patentable categories, entered into force on 1 September 1999 as R. 23d EPC 1973. It applies equally to applications pending on, i.e. filed before, the date of its entry into force (G 2/06, T 315/03).

2.1.1 Scope of exception under Rule 28(c) EPC

Under R. 28(c) EPC (R. 23d(c) EPC 1973), European patents may not be granted in respect of biotechnological inventions which concern "uses of human embryos for industrial or commercial purposes". The expression "uses for industrial or commercial purposes" in R. 28(c) EPC covers the making of the claimed product, even where it was intended to use that product for further research (G 2/06).

In G 2/06, the Enlarged Board considered an invention concerning, inter alia, human embryonic stem cell cultures which at the filing date could only be prepared by a method which necessarily involved the destruction of the human embryos from which they were derived, that method not being part of the claims.

When interpreting R. 28(c) EPC, the Enlarged Board also looked at Art. 6(2) Biotech Directive because the aim of introducing R. 26 to 29 EPC was to align the EPC to that directive. It observed that neither the EU legislator nor the EPC legislator, unlike their German and UK counterparts, had chosen to define the term "embryo". It assumed that they had been aware of the definitions in national laws on regulating embryos and deliberately refrained from defining the term. Given the aim of protecting human dignity and preventing the commercialisation of embryos, it could only presume that "**embryo**" was not to be construed restrictively and therefore rejected the appellant's argument that "embryo" was to be given a very specific interpretation as meaning embryos of 14 days or older, in accordance with usage in the medical field.

The appellant had argued that, for the R. 28(c) EPC prohibition to apply, the use of human embryos had to be claimed. The Enlarged Board disagreed, observing that R. 28(c) EPC