Biological inventions  
(Supplementary reading)

**Definition**

Inventions relating to biotechnology are specifically addressed in Directive 98/44/EC (“Biotech Directive”), which was incorporated into the Implementing Regulations to the European Patent Convention (EPC) in 1999 in order to ensure uniformity in harmonised European patent law.

Article 3(1) Biotech Directive states that “inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”

“Biological material” is defined in Article 2(1)(a) as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system”.

**Scope of protection**

The scope of protection conferred by a European patent for a product containing or consisting of genetic information is referred to in Article 9 Biotech Directive and “shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.”

The Court of Justice of the European Union, (“CJEU”) held that the protection provided for in Article 9 was not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question was derived.

Accordingly, it seems that a claim to a DNA (or RNA) sequence will only be enforceable in the EU where the sequence is capable of performing its function.

**C-428 Monsanto Technology LLC v Cefetra BV [2010] EC1 1-0000**