

Article 9 of the
Biotechnology Directive 98/44/EC:
The End of Absolute Product Protection?

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Daily IP Life In EPC Countries

- The EPO grants tens of thousands of patents per annum with claims to chemical products or compositions per se
- Article 69 EPC
- **All EPC countries have the concept of absolute product protection**
- Hundreds of court decisions in EU countries based on (non)-infringement of chemicals per se based on the doctrine of absolute product protection

Biotech Directive 98/44/EC

What is it?



- Guideline on (non)-patentable biotech subject matter in EU
- Guideline on scope of protection in EU
- Provision on disclosure/availability of biological matter
- Intention to harmonize EU IP law for biotech inventions
- Intention to provide legal certainty for biotech inventions

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History

What is it?



- Conceived by a European Commission in October 1988
- Born in the European Parliament in July 1998
- A difficult birth - NL/IT/NO brought suit in 1998 before the ECJ to annul Directive - rejected by ECJ in 2001
- Ratification was due by 30.7.2000 - actually ratified in EU States from 2000 to 2006 and 2007 in CH

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Subject matter of Directive



Regulates controversial subject matter such as: cloned humans, human and animal embryos, organs, stem cells, hereditary material, etc.

Biotech Directive 98/44/EC

Preamble

(1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;

(2) Whereas, in particular, in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

Biotech Directive 98/44/EC

Preamble

(3) Whereas effective and harmonized protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

(5) Whereas, differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;

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(8) Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;

